IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al. *

Plaintiffs *

v. *

Case No. _____

KENNEDY KRIEGER INSTITUTE, INC., et al. *

Defendants *

****

NOTICE OF REMOVAL

TO: United States District Court for the District of Maryland:

Pursuant to 28 U.S.C. § 1442 (a)(1), Defendants Kennedy Krieger Institute, Inc. ("Kennedy Kreiger"), and Cecilia Davoli, M.D. (collectively referred to as the "Kennedy Krieger Defendants"), hereby remove this action, *Shayonna Featherstone, et al. v. Kennedy Krieger Institute, Inc., et al.*, case number 24-C-07-002027, from the Circuit Court for Baltimore City, Maryland (hereinafter "State Court Action"), to the United States District Court for the District of Maryland (Northern Division), and allege as follows:

1. In 1992, the federal government, through the National Institute of Environmental Health Sciences ("NIEHS")[1], issued a Request for Proposals ("RFP") seeking clinical centers for a study entitled "Toxicity of Lead in Children." The purpose of the study was to determine whether succimer, a drug approved by the United States Food and Drug Administration ("FDA") for use in treating individuals with blood lead levels greater than 45 micrograms per deciliter, could prevent cognitive delay in young children with blood lead levels less than 45 micrograms per deciliter. This action is brought by Shayonna Featherstone, a minor, and Keona Featherstone, a minor, by their mother and next

[1] NIEHS is a subsidiary of the National Institutes of Health ("NIH") itself a branch of the United States Department of Health and Human Services.

friend, Sharon Jackson (collectively "Plaintiffs"), and arises out of Plaintiff Keona Featherstone's participation in this NIEHS sponsored study conducted by Kennedy Krieger and others and is known as the Treatment of Lead-Exposed Children ("TLC") Study. Plaintiffs' Complaint asserts claims of negligence, negligent misrepresentation, civil conspiracy and breach of fiduciary duty against these Defendants and others and seeks damages in the amount of Four Million Dollars ($4,000,000). *See* Plaintiffs' Complaint, a copy of which is attached hereto as Exhibit A.

2. This Court has jurisdiction over this removal action under 28 U.S.C. § 1442(a)(1) because Plaintiffs filed a civil action in a State court against the Kennedy Krieger Defendants, who were acting under the control of an United States agency. Specifically, Plaintiffs' negligence claims directly call into question Kennedy Krieger's compliance with the contract it entered into with the NIEHS as well as Kennedy Krieger's compliance with the detailed and comprehensive framework of federal regulations that govern research on human subjects.

3. 28 U.S.C. § 1442(a)(1) governs removal for conduct performed under color of federal office. The Supreme Court has "held that the right of removal is absolute for conduct performed under color of federal office, and has insisted that the policy favoring removal 'should not be frustrated by a narrow, grudging interpretation of § 1442(a)(1).'" *See Arizona v. Manypenny*, 451 U.S. 232, 242, 101 S.Ct. 1657 (1981).

4. The purpose of the liberal removal policies underlying section 1442(a)(1) is to protect federal officers and their agents when they conduct business in the states. *See Durham v. Lockheed Martin Corp.*, 445 F.3d 1247, 1252-53 (9th Cir. 2006). "If the federal government can't guarantee its agents access to a federal forum if they are sued or prosecuted, it may have difficulty finding anyone willing to act on its behalf." *Id.* at 1253.

JURISDICTIONAL BASIS FOR REMOVAL

5. This Court has jurisdiction under 28 U.S.C. §1442(a)(1) because: (1) Kennedy Krieger and Dr. Davoli are considered "persons" within the meaning of the statute; (2) the Kennedy Krieger Defendants were acting at the direction of an officer of the United States; (3) a causal nexus exists between Plaintiffs' claims and the Kennedy Krieger Defendants actions under color of federal office; and (4) the Kennedy Krieger Defendants can assert a colorable federal defense. *See e.g., Mesa v. California,* 489 U.S. 121, 125-35 (1989); *Pack v. A.C. and S., Inc.*, 838 F.Supp. 1099, 1101 (D.Md. 1993), *reconsideration denied*, 857 F.Supp. 26 (D.Md. 1994) (holding that 28 U.S.C.§ 1442(a)(1) is satisfied when the moving party can demonstrate that (1) it acted under the direction of a federal officer; (2) it raises a federal defense to plaintiff's claims; and (3) demonstrates a causal nexus between plaintiff's claims and acts it performed under color of federal office). Pursuant to U.S.C. § 1442, a defendant acting under the direction of a federal officer of the United States can unilaterally remove a case to federal court. *See Durham v. Lockhead Martin Corp.*, 445 F.3rd at 1253. *See also Plourde v. Ferguson*, 519 F. Supp. 14, 16 (D.Md. 1980) (Single defendant can remove case from state court to federal court regardless of whether other defendants join in removal petition.)

A. Kennedy Krieger is a "person" under 28 U.S.C. § 1442 (a)(1)

6. Kennedy Krieger qualifies as a "person" as required by 28 U.S.C. § 1442 (a)(1). In *Pack*, this Court held that private corporations, like Kennedy Krieger, are "persons" for purposes of the statute. 838 F.Supp. at 1103.

B. The Kennedy Krieger Defendants were acting under the direction of the United States Government.

1. The Kennedy Krieger Defendants were acting under the direction and control of the National Institute of Environmental Health Sciences

7. The extent of control necessary to bring an individual within the person "acting under" clause of § 1442(a) has been broadly construed. *In re Methyl Tertiary Butyl Ether Products Liability*

Litigation, 342 F.Supp.2d 147, 154-155 (S.D.N.Y. 2004). Federal officer removal is appropriate when the removing party is subject to the direct and detailed control of the federal government. *Pack*, 838 F.Supp. at 1103. "Direct control is established by showing strong government intervention and the possibility that a defendant will be sued in state court as a result of the federal control." *Id.* (citing *Fung v. Abex Corp.*, 816 F. Supp. 569, 572 (N.D.Cal. 1992)); *see also McMahon v. Presidential Airways, Inc.*, 410 F.Supp.2d 1189, 1197 (M.D. Fla. 2006) (holding that private air transportation companies that contracted with the United States government were acting under the direction of a federal officer and met the federal officer removal standard, whereby "the government maintained control over the manner in which the contractor performed the contracted work or *monitored* the performance of the work")(citing *Watson v. Philip Morris Cos.*, 420 F.3d 852, 857 (8th Cir. 2005)) (emphasis added).

8. The federal government directed and controlled all of Kennedy Krieger's activity in the design, implementation and follow up of the TLC study. The federal government, through NIEHS, maintained detailed, hands-on control over all phases of this government sponsored and funded study. The following paragraphs provide a summary of the intimate and meticulous control the federal government maintained over the TLC study.

9. The genesis of the TLC study was an RFP issued by NIEHS. That document contains the government's rationale for embarking on this particular study:

> NIEHS has…supported clinical studies leading to the licensure of the drug succimer, an orally administered chelating drug now labeled for use in children with blood lead levels above 45 ug/dl, a level thought to indicate a high risk for symptomatic lead poisoning and above the levels that produce cognitive delay….The Centers for Disease Control and the American Academy of Pediatrics have revised downward the blood lead levels of concern in young children, and children with blood lead levels greater than 10 ug/dl are now thought to have unacceptable exposure to lead. **NIEHS believes that large numbers of children with blood lead levels below 45 ug/dl will be treated with succimer, and that a clinical trial of the use of succimer in the prevention of lead-associated cognitive delay in young children is both necessary and timely.**

NIEHS Request for Proposals, Section C.1 attached hereto as Exhibit B (emphasis added).

10. NIEHS unequivocally articulated in the RFP that control over the timing parameters for each and every aspect of the TLC study would rest with NIEHS. Furthermore, NIEHS directed the criteria for enrolling into this study. Finally, NIEHS mandated the areas of focus in analyzing the study's data:

> The trial **shall** proceed as follows: 9-12 months for planning; about 1 year for patient enrollment and treatment; the remaining 3 years for follow-up....The trial is of oral chelation therapy with the drug succimer in lead exposed children (blood leads of about 20 ug/dl to 45 ug/dl) of about 18 to 36 months of age. The endpoints are the scores on developmental tests; other endpoints of interest include evidence of drug efficiency and compliance, such as urine and blood lead levels; excretion of other ions like iron, zinc, and calcium; and nervous system, renal and hematopoietic function/toxicity.

Id. at C.2 (emphasis added.) Kennedy Krieger drafted its "proposal" within the specific criteria set forth by NIEHS.

11. In response to Kennedy Krieger's "proposal", NIEHS drafted a contract and forwarded it to Kennedy Krieger for signature.[2] No one from Kennedy Krieger participated in the preparation of that Contract. *See* Affidavit of Merrill Brophy attached hereto as Exhibit C, paragraph 3. This government contract served as the basis for the relationship between NIEHS and Kennedy Krieger in conducting the TLC study. *See* Contract attached hereto as Exhibit D.

12. After the signed contract was approved by NIEHS's contracting officer, the NIH Board of Contract Awards was required to review and provide final approval. *See* June 25, 1993 letter from Thomas M. Hardee, NIEHS Contracting Officer, to Karen Sorenson, Contract Administrator for Kennedy Krieger attached hereto as Exhibit E.

[2] This was a multi-center study and, accordingly, NIEHS contracted with three other Clinical Centers to conduct the TLC study in addition to Kennedy Krieger. Those other sites were Cincinnati, Philadelphia and New Jersey.

13. At the inception of the contractual relationship between NIEHS and Kennedy Krieger, the NIEHS Contracting Officer appointed Walter Rogan, M.D. as Project Officer and Beth Ragan as Alternate Project Officer to oversee the TLC study. *See* June 25, 1993 Department of Health and Human Services Memorandum attached hereto as Exhibit F. This memorandum provides a detailed outline of the Project Officer's duties which require, among other things, that the Project Officer:

> Maintain complete surveillance of the technical performance and contact with the contractor in order to give reasonable assurance that all specified contract deliverables are delivered on time and are in accordance with the specifications/requirements of the contract terms.

Id. (*See also*, Paragraph 14, *infra*).

14. The contract contained a detailed description of the estimated cost of the study including specific instructions regarding permissible expenditures such as salary rate limitations, restrictions on travel expenses, patient care costs, patient enrollment incentives, and permissible expenditures for house "clean-up." The Principal Investigator at Kennedy Krieger (and all clinical sites) was required to seek approval from NIEHS in order to allocate funds for *any* purpose that deviated *in any way* from the contract as drafted by NIEHS. *See* Affidavit of Cecilia Davoli, M.D., attached hereto as Exhibit I, paragraph 11; July 1995 letter from Kennedy Krieger to NIEHS regarding approval for funds attached hereto as Exhibit G.

15. The contract governing Kennedy Krieger's conduct in connection with the TLC study adopted *verbatim* the language contained in NIEHS's RFP expressing the rationale for why NIEHS believed this study was necessary. Further, the Statement of Work section of the contract, in describing the specific criteria to be used in protocol development, adopted *verbatim* the study criteria initially set forth by NIEHS in its RFP:

> The trial **shall** proceed as follows: 9-12 months for planning; about 1 year for patient enrollment and treatment; the remaining 3 years for follow-up....The trial is of oral chelation therapy with the drug succimer in lead exposed children (blood leads of about 20

> ug/dl to 45 ug/dl) of about 18 to 36 months of age. The endpoints are the scores on developmental tests; other endpoints of interest include evidence of drug efficiency and compliance, such as urine and blood lead levels; excretion of other ions like iron, zinc, and calcium; and nervous system, renal and hematopoietic function/toxicity.

Exhibit D at p. 10. NIEHS directed the Steering Committee, subject to federal government approval, to further develop the protocol and strategies for the TLC trial. This committee consisted of the NIEHS Project Officer, the Principal Investigators of the Central Lab (in this case the lab at the Centers for Disease Control, also a branch of the United States Department of Health and Human Services), as well as the Principal Investigators of each Clinical Center participating in the study (Kennedy Krieger was one of four Clinical Centers) and the Principal Investigator of the Coordinating Center (Harvard School of Public Health). *Id.* The NIEHS Project Officer and Alternate Project Officer participated in nearly every subcommittee created for the TLC study. *See* Protocol attached hereto as Exhibit H at 40-42. *Id.*

16. The NIEHS Project Officer supervised regular meetings and conference calls with Kennedy Krieger and the other centers regarding study design to ensure that the plans developed consistent with NIEHS objectives. *see* Affidavit of Cecilia Davoli, M.D. attached hereto as Exhibit I at ¶ 4; *see also*, Exhibit C at ¶ 4. Final authority over each and every aspect of this study rested with the NIEHS Project Officer. *Id.* at ¶ 5. *see also* Exhibit D at ¶ 21. Pursuant to the contract, Kennedy Krieger did not have the authority to deviate from the NIEHS approved study protocol. Indeed, NIEHS retained the ability to terminate the contract if Kennedy Krieger deviated from the study protocol. "Failure of the contractor to abide by the approved shared protocol may result in the termination in accordance with the termination clause." *See* Exhibit D at ¶19.

17. Pursuant to federal regulation (*see* ¶¶ 25-29, *infra*), Kennedy Krieger was required to obtain Institutional Review Board ("IRB") approval of the Informed Consent Form to be utilized in enrolling study participants. After the local IRB utilized by Kennedy Krieger approved a form, Kennedy Krieger was required to forward that form to the NIEHS' own IRB for further review. The

NIEHS IRB initially rejected the Kennedy Krieger Consent Form because the reading level required for comprehension of the Consent Form was too high. *See* Exhibit C at ¶ 10 and Exhibit I at ¶ 12. Only after Kennedy Krieger revamped its form, secured local IRB approval again and resubmitted the form to NIEHS was it approved such that the study could proceed. *Id.*

18. NIEHS imposed substantial reporting requirements on the Clinical Centers participating in the study. Kennedy Krieger was required to submit to NIEHS technical reports as well as racial/ethnic enrollment reports. Exhibit D at 15. During the first year of the study, Kennedy Krieger submitted semi-annual reports that described the progress in planning, recruitment, community activity and screening with particular emphasis on the material not covered in the Steering Committee meetings. *Id.* For all subsequent years, Kennedy Krieger submitted quarterly reports outlining the numbers of families contacted and screened, all activities planned and all activities executed during the reporting periods, again with particular emphasis on the materials not covered in the Steering Committee meetings. *Id.* NIEHS also required Kennedy Krieger to submit enrollment reports providing a summary of the planned study population and a summary of the actual number of participants enrolled according to designated racial/ethnic categories. *Id.*

19. NIEHS also maintained oversight of the study's implementation through periodic site visits. *See* Exhibit C at ¶ 6 and Exhibit I at ¶ 7. These visits were conducted to ensure that Kennedy Krieger was complying with the TLC study protocol. *Id.* During these visits, the NIEHS Project Officer reviewed study participant charts[3] to ensure compliance with federal regulations, observed the study facilities, and conducted visits to houses involved in the study. *Id.*

20. This study, as noted above, involved assessment of the drug succimer under certain clinical conditions. Because this drug was not approved by the FDA for use under those conditions, NIEHS submitted an Investigational New Drug ("IND") application to the FDA. *See* Exhibit D at p.13;

[3] The FDA imposes regulations regarding how researchers should document their use of investigational new drugs.

See also, Exhibit C at ¶ 8 and Exhibit I at ¶ 8. Because NIEHS held the IND for the use of Succimer in children with blood lead levels less than 45 micrograms per deciliter, NIEHS's Project Officer was actively engaged in ensuring that the Clinical Centers understood Succimer's biochemical behavior. *Id.*

21. The TLC study was fully funded by NIEHS with support from the Office of Research on Minority Health of the National Institutes of Health ("ORMH, NIH"). *See* Exhibit H at ¶ 2.2.

22. In addition to NIEHS, the United States Centers for Disease Control ("CDC") was actively involved in the TLC study. The CDC laboratory in Atlanta, Georgia, served as the central laboratory and performed blood lead analysis on all study participants. *Id.* at p. 28. Managers of the CDC participated on several TLC study committees. *Id.* at pp. 40-42.

23. The CDC had responsibility for all activities related to drawing study participants' blood. *See* Exhibit C at ¶ 9 and Exhibit I at ¶ 9. Prior to the implementation of the Study, the CDC held a training session for all Clinical Centers to ensure that all centers were drawing blood consistent with CDC protocol. *Id.* In addition to training, the CDC provided the Clinical Centers with the supplies needed to draw study participants' blood as well as the supplies needed to send the blood samples to the CDC lab in Atlanta. *Id.*

24. The intimate control exercised by NIEHS over the TLC study extended through to the study's conclusion. NIEHS prohibited Kennedy Krieger from writing-up and summarizing the results of the study absent NIEHS approval. Exhibit D at pp.11, 13.

2. Kennedy Krieger was acting under the authority of the United States Congress and the Department of Health and Human Services

25. In addition to the federal government's active involvement in the creation, design, and implementation of the TLC study pursuant to its contract with Kennedy Krieger, the actions of Kennedy Krieger were at all times subject to exceedingly complex regulations and guidelines in the conduct of this research study. *See* 42 U.S.C. § 289; 45 CFR § 46.101, et seq. For example, when conducting research on human subjects, the federal government requires an Institutional Review Board ("IRB") to

approve the study. 42 U.S.C. § 289. The IRB is essentially an oversight committee that "shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy." 45 C.F.R. § 46.109(a). Federal regulations further govern, among other things, the membership of the IRB (45 C.F.R. § 46.107); IRB functions and operations (45 C.F.R. § 46.108); the review procedures that the IRB may use in certain types of research (45 C.F.R. § 46.109); additional protections for children involved as subjects in research (45 C.F.R. § 406); and criteria for IRB approved research (45 C.F.R. § 46.111).

26. Exercising removal jurisdiction will also promote uniformity in the application and interpretation of the federal laws at issue. According to a Guidebook published by the DHHS, the regulations cited in Plaintiffs' Complaint and relied upon by the Plaintiffs were promulgated by sixteen federal agencies that conduct, support, or regulate human research. *See* Exhibit J, Department of Health and Human Services Institutional Review Board Guidebook Introduction. The DHHS Guidebook chronicles the detailed and deliberative process the federal government employed in arriving at the regulations at issue here. *Id.*

The Introduction states:

> The DHHS regulations are codified at Title 45 Part 46 of the Code of Federal Regulations. Those "basic" regulations became final on January 16, 1981, and were revised effective March 4, 1983, and June 18, 1991. The June 18, 1991, revision involved the adoption of the Federal Policy for the Protection of Human Subjects. **The Federal Policy (or "Common Rule," as it is sometimes called) was promulgated by the sixteen federal agencies that conduct, support, or otherwise regulate human subjects research**; the FDA also adopted certain of its provisions. **As is implied by its title, the Federal Policy is designed to make uniform the human subjects protection system in all relevant federal agencies and departments.** The Federal Policy is discussed in depth in Chapter 2, Section A(i).

Id. (emphasis added).

27. A substantial federal interest exists in the uniformity of interpretation and application of federal laws governing scientific research involving children.

28. Because the TLC study involved use of an Investigational New Drug Exemption, Kennedy Krieger was also required to comply with extensive FDA regulations controlling the use of IND's.

29. These regulations expressly and in great detail governed Kennedy Krieger's handling of all aspects of the TLC study including enrolling study participants, obtaining informed consent and ensuring study participant safety.

C. A causal nexus exists between Plaintiffs' claims and Kennedy Krieger's actions pursuant to its contract with the National Institute of Environmental Health Sciences

30. The causal nexus prong requires that Plaintiffs' suit arise out of acts by Kennedy Krieger taken pursuant to the direction of a federal officer. *See Pack*, 857 F.Supp. at 28. A direct causal relationship exists between Plaintiffs' claims and Kennedy Krieger's actions under color of federal office. The allegations made against the Kennedy Krieger Defendants in Plaintiffs' Complaint and their relationship to action taken by the Kennedy Krieger Defendants pursuant to formal authority are summarized in the following chart:[4]

Plaintiffs' Allegations	**Conduct of Kennedy Krieger Taken Pursuant to Federal Authority**
"The parents of TLC research subjects, including the Plaintiffs, were not informed by KKI or Davoli that drugs like succimer should not be used as a substitute for the complete abatement of lead hazards to which a child is exposed nor were they informed that succimer should not be used on a child who continues to be exposed to lead hazards." *See* Complaint, Exhibit A at ¶ 8.	The process for enrolling Study participants and the information provided to Study participants was directly controlled by NIEHS in the Contract. *See* Contract, Exhibit D at 11 and the Steering Committee, *Id.* at 10. The Informed Consent provided to Study participants was governed by NIEHS. and through the Contract. *See* Contract, Exhibit D at § H; Exhibit C at ¶ 10; Exhibit I at ¶ 12.

[4] To the extent that this Court finds that Plaintiffs have asserted non-federal claims, it is appropriate for the Court to exercise its supplemental jurisdiction. *Rosmer v. Pfizer Incorporated*, 263 F.3d 110 (4th Cir. 2001); *Shanaghan v. Cahill*, 58 F.3d 106, 109 (4th Cir. 1995); *Parker, PPA v. Della Rocco, Jr.*, 252 F.3d 663, 665 (2nd Cir. 2001) (holding that the exercise of supplemental jurisdiction was appropriate after an agent of the federal government properly removed an action to federal court pursuant to 28 U.S.C. § 1442 (a)(1)).

"Via the Informed Consent Form ("IC") Parents and guardians of the children used in the TLC Study were promised that during the "treatment phase another doctor would know the results of blood-lead tests (in case their [was] a problem" and that the childrens' blood-lead levels would also be reported to the Baltimore City Health Department." *See* Complaint, Exhibit A at ¶ 9.	Measures taken to insure the safety of the Study participants was covered by the protocol created under the direct supervision of the NIEHS Project Officer (*See* Protocol, Exhibit H) and is further governed by Federal Regulation. ***See* ¶¶ *23-25.*** Obtaining of informed consent in the Study was governed by the NIEHS by the Contract and by Federal Regulation. Furthermore, the researcher/subject relationship Kennedy Krieger entered into was based solely on the NIEHS Contract, NIEHS approved trial protocol, and the NIEHS approved Informed Consent form; Exhibit C at ¶ 10, Exhibit I at ¶ 12.
"Via the IC Parents and the guardians of the children used in the TLC Study were promised that KKI and Davoli and/or their agents such as Lady "H" would clean up the lead in the homes of the study subjects." *See* Complaint, Exhibit A, ¶ 12.	Kennedy Krieger monitored and "cleaned" Plaintiffs' residences to the extent that it was required to pursuant to its Contract with NIEHS and the NIEHS approved trial protocol. *See* Contract, Exhibit D at 10, 13; Protocol, Exhibit H at 18-20; Exhibit C at ¶ 10, Exhibit I at ¶ 12.
"Pursuant to 45 C.F.R. § 46.101 (2005) approval and oversight by an Institutional Review Board (IRB) is required whenever research on human beings is conducted, supported, or is subject to federal regulation." Md. Code Health Gen. Art. § 13-201, *et seq.* (2005) requires that all research conducted in Maryland on human subjects to be conducted in compliance with federal regulations, regardless of the source of funding and/or support for the research." *See* Complaint, Exhibit A at ¶ 16.	The measures taken to insure the safety of Study participants was covered by the protocol created under the direct supervision of the NIEHS Project Officer. *See* Protocol, Exhibit H. It is further governed by federal regulation. *See* ¶¶ 23-25, *infra.;* Exhibit C at ¶ 10, Exhibit I at ¶ 12.
"There was no direct benefit to the child research subjects from participating in the TLC Study and the monitoring procedure employed in the TLC Study, including but not limited to "blinding" the results of Plaintiffs' blood-lead tests, was less beneficial to the child research subjects' well-being than the monitoring regime already in place." *See* Complaint, Exhibit A at ¶ 21.	The use of "blinding" blood-lead tests results was approved and required by the NIEHS Protocol. *See* Protocol, Exhibit H at 2.
"The IRB assisted the TLC study investigators in concealing the fact that the child research subjects would be placed in serious risk of permanent harm as a result of participating in the study, and concealing that recognize and approved therapies already existed for children with similar lead levels, to wit, the removal from the leaded environment." *See* Complaint,	Information provided to the TLC participants and their guardians were governed by the trial protocol. *See* Protocol, Exhibit H; Exhibit C at ¶ 10, Exhibit I at ¶ 12.

Exhibit A at ¶ 23.	
"The Defendants knew, or should have known, that the properties identified in paragraphs 4 (a) and 4 (b), contained numerous surfaces covered in lead-based paint. However, KKI, Davoli and/or their agents nonetheless represented to the Plaintiffs' family, the Plaintiffs' treating physician, and to the Baltimore City Health Department, hereinafter BCHD, that the homes were free of lead hazards." *See* Complaint, Exhibit A at ¶ 30.	Provision of information and obtaining of informed consent in the Study, was governed by the NIEHS and. and through the Contract and by Federal Regulation. *See* Exhibit C at ¶ 10, Exhibit I at ¶ 12.
"Prior to the lease of the premises to the property set forth in paragraphs 4 (a) and 4 (b), Baltimore, Maryland, the Defendants herein negligently made, and/or negligently permitted to be made misrepresentations to the Plaintiffs and their families regarding the condition of the premises." *See* Complaint, Exhibit A at ¶ 43.	The process of enrolling Study participants was directly controlled by the NIEHS Contract (*See* Contract, Exhibit D at 11) and by the Steering Committee (*See Id.* at 10). Moreover, the informed consent provided to the study participants was governed by NIEHS in and through the Contract as well as by federal regulation. *See* Contract, Exhibit D at Attachment 8; Exhibit C at ¶ 10 and Exhibit I at ¶ 12.
"The Defendants, KKI, JHU, the IRB and Davoli, by virtue of the IC form, entered into an agreement with the Plaintiffs, that in exchange of the Plaintiffs' participation in the TLC Study, the Defendants herein assumed a duty to: ensure that all children in the TLC Study, including the Plaintiffs, had their homes repaired and/or cleaned to get rid of lead dust and chipped paint, to carefully inspect the properties identified in paragraphs 4(a) and 4(b) to see if they could be repaired and/or cleaned to eliminate lead hazards, if the home did not qualify, the Defendants would assist with relocation to housing that was known to be free from lead-hazards, the Defendants would eliminate any lead hazards in the home, ensure that a doctor would monitor the blood-lead levels of the Plaintiffs and promptly and accurately report those test results to the family of the minor Plaintiffs and to the Baltimore City Health Department, and the Defendants also assumed a duty to provide ongoing medical care of the Plaintiffs' lead paint poisoning and lead toxicity." *See* Complaint, Exhibit A at ¶ 61.	The process for enrolling Study participants was directly controlled by NIEHS and the Contract. *See* Contract, Exhibit D at 11, and by the Steering Committee, *See Id.* at 10. Moreover, the informed consent provided to study participants was governed by NIEHS in and through the Contract as well as by federal regulation. *See* Contract, Exhibit D at Attachment 8; Exhibit C at ¶ 10 and Exhibit I at ¶ 12.
"The Defendants KKI and JHU warranted and agreed to the United States Department of	The TLC Study was conducted pursuant to the Contract with NIEHS (*See* Contract, Exhibit D)

Health and Human Services, hereinafter referred to as DHHS, prior to the constitution of, and during the administration of the TLC Study, that all human research at KKI would be conducted in accordance with the terms of the Belmont Report. *See* Ethical Principles and Guidelines for the Protection of Human Subjects of Research, promulgated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979. The Defendants agreed to abide by the ethical duties and obligations set forth within the Belmont Report in furtherance of the Defendants' KKI and JHU Agreement with DHHS under a Multiple Project Assurance Agreement, hereinunder MPAA. This agreement existed prior to the tortuous acts alleged herein." *See* Complaint, Exhibit A at ¶ 67.	and by the Steering Committee (*See Id.*).
"The minor Plaintiffs allege that the Defendants herein, and each of them, by agreement or understanding agreed to materially breach their duties set forth within the IC to the child research subjects used in the TLC Study, including the minor Plaintiffs. *See* Complaint, Exhibit A at ¶ 78."	KKI's actions and relationship with the study participants was governed by the trial protocol and the Contract with the NIEHS. *See* Contract, Exhibit D; see trial protocol, Exhibit H.

31. In sum, the rationale for and purpose of the TLC study is contained in the RFP and Contract, both of which were prepared and promulgated by the federal government. This research study was conducted and implemented pursuant to protocol developed and approved by NIEHS, an agency of the federal government. Kennedy Krieger's recruiting and enrollment of study participants was regulated in great detail by not only the contract approved by NIEHS, but also through an elaborate regulatory scheme enacted pursuant to federal law. *See* B.2. *infra*. Further, Kennedy Krieger was prohibited from deviating from the directives of the contract and/or the research protocol or in taking any action whatsoever unless directly approved by NIEHS. *See* Exhibits D at 19, C at paragraph 13, and I at paragraph 12.

32. Because Plaintiffs' allegations of wrongdoing against Kennedy Krieger implicate conduct and action taken pursuant to federal regulation and mandated by its contract with an agency of the federal government, a direct causal nexus exists between Plaintiffs' claims and the actions Kennedy Krieger took under color of federal office.

D. The "colorable federal defense" requirement of 28 U.S.C. § 1442 (a)(1) is met because Kennedy Krieger is entitled to assert the government contractor defense.

33. The final element required for removal under 28 U.S.C. § 1442(a)(1) – that the defendant must assert a colorable federal defense – is satisfied by Kennedy Krieger's entitlement to the government contractor defense.[5]

34. The government contractor defense shields a contractor from liability when acting under the direction and authority of the United States. *Tozer v. LTV Corp.*, 792 F.2d 403, 405 (4th Cir. 1986)(citing *Yearsley v. W.A. Ross Construction Company*, 309 U.S. 18, 20 (1940)). In *Yearsley*, the United States Supreme Court stated that "it is clear that if this authority to carry out the project was validly conferred, that is, if what was done was within the constitutional power of Congress, there is no liability on the part of the contractor for executing its will." 309 U.S. at 20-21, 60 S. Ct. at 414-15.

35. *Boyle v. United Technologies Corp.*, 487 U.S. 500 (1988) sets forth the elements required to satisfy the government contractor defense: (1) the United States approved reasonably precise specifications; (2) the contractor's performance conformed to those specifications; and (3) the contractor warned the United States about the dangers associated with the contract that were known to the contractor but not to the United States. *Id.* at 512, 108 S. Ct. at 2518. It is well established that the defense is viable in the context of non-military performance contracts such as the one Kennedy Krieger entered into with NIEHS. *See Boyle,* 487 U.S. at 506, 108 S. Ct. at 2515 (stating that "[t]he federal

[5] For purposes of satisfying 28 U.S.C. § 1442 (a)(1), Kennedy Krieger need not definitively **prove** the asserted defense. It need only articulate it's "colorable applicability to plaintiff's claims." *Jamison v. Wiley*, 14 F.3d 222, 238 (4th Cir. 1994) (citing *Mesa*, 489 U.S. at 133).

interest justifying this holding surely exists as much in procurement contracts as in performance contracts; we see no basis for distinction."); *Richland-Lexington Airport District v. Atlas Properties, Inc.*, 854 F.Supp. 400, 422 (D.SC. 1994)(in holding that the defense applies to performance contracts, the court stated that "the dispositive issue is not one of performance versus procurement, but whether there is a uniquely federal interest in the subject matter of the contract"); *Yeroshefsky v. Unisys Corp.*, 962 F.Supp. 710, 717 (D.Md. 1997)(holding that the government contractor defense is applicable in the civilian as well as military context).[6]

36. Consistent with the first prong of the *Boyle* test, the United States, through NIEHS, approved precise specifications for developing, implementing, and reporting on the TLC study. *See* ¶¶ 5-23. The RFP, Award/Contract, and supervision and participation in the TLC study clearly demonstrate that NIEHS provided reasonably precise specifications. *Id.*

37. As required by the second prong of the *Boyle* test, Kennedy Krieger fully complied with the federal government's detailed specifications. As required by contract, Kennedy Krieger followed the NIEHS approved study protocol throughout its implementation of the TLC study. *See* Exhibit D at p.19. Kennedy Krieger was obligated to follow, and did comply with, the strict and comprehensive requirements imposed by the federal government when conducting research on human study participants. *Id.* at 26; *See also* Exhibit C at ¶ 13 and Exhibit I at ¶ 13.

38. Finally, the third prong of the *Boyle* test is satisfied. Kennedy Krieger did not withhold from NIEHS any information regarding potential dangers associated with the TLC study. As set forth in

[6] Arguably, *Richland* recognized an additional element to the defense. The *Richland* Court suggested that the party claiming the defense must first demonstrate that the conduct at issue constituted a "discretionary function" of the federal government. 854 F.Supp. at 423. Pursuant to this "discretionary function", Kennedy Krieger will not be liable to Plaintiffs if the challenged government action involved an element of judgment or choice and if the challenged government action is based on considerations of public policy. *Id.* Without question, as described herein, the genesis for this study, as expressly articulated in the RFP, was NIEHS's concern regarding (1) the large numbers of children with blood lead levels below 45 micrograms per deciliter will be treated with Succimer and (2) NIEHS's belief that a clinical trial of the use of Succimer in the prevention of lead-associated cognitive delay in young children was both necessary and timely. Exhibit B. This is precisely the type of conduct contemplated in the *Richland* "discretionary function" analysis.

¶¶ 5-28 *supra*, NIEHS was intimately involved in all aspects of the study and therefore was fully aware of all risks and benefits associated with the TLC study.

39. The foregoing facts and analysis establish, at a minimum, that the Kennedy Krieger Defendants are entitled to assert the government contractor defense in this matter.

PROCEDURAL REQUIREMENTS FOR REMOVAL

40. On April 3, 2007, the Kennedy Krieger Defendants became aware of Plaintiffs' Complaint after Defendant Thomas R. Hendrix was served with a copy of the Complaint. On April 16, 2007, counsel for the Kennedy Krieger Defendants sent a letter to Plaintiffs' counsel agreeing to accept service of the Plaintiffs' Complaint. *See* Exhibit K. Because this Notice of Removal is filed within 30 days of the service of the Complaint, it is timely filed under 28 U.S.C. § 1446(b). Copies of all process and pleadings filed in state court are attached to this Notice of Removal as Exhibit L.

41. Kennedy Krieger files and presents herewith the sum of $350.00 as required by Title 28, U.S.C. § 1446.

42. The United States District Court for the District of Maryland (Northern Division) embraces the City of Baltimore in which the state court action is now pending, and thus, this Court is a proper venue for this action pursuant to 28 U.S.C. § 100(1).

43. There is no consent requirement for removal under 28 U.S.C. § 1442 (a)(1).

44. The Kennedy Krieger Defendants are filing written notice of this removal, in substantially the form attached hereto as Exhibit M with the Clerk of the State Court in which the action is currently pending pursuant to 28 U.S.C. § 1446(d). A copy of the Kennedy Krieger Defendants' Notice to the Circuit Court for Baltimore City of Filing of Notice of Removal to the United States District Court, together with this Notice of Removal, are being served upon Plaintiffs' counsel and all other parties in this action pursuant to 28 U.S.C. § 1446(d).

WHEREFORE, Defendant Kennedy Krieger Institute, Inc. and Cecilia Davoli, M.D., respectfully remove this action from the Circuit Court for Baltimore City, bearing case number 24-C-07-00202, to this Court, pursuant to 28 U.S.C. § 1442 (a)(1).

Respectfully submitted,

Barry C. Goldstein
(Federal Bar No. 24796)
Nicole A. McCarus
(Federal Bar No. 27971)
Waranch & Brown, LLC
1301 York Road, Suite 300
Lutherville, Maryland 21093
(410) 821-3511
ATTORNEYS FOR DEFENDANTS KENNEDY KRIEGER INSTITUTE, INC. and CECILIA DAVOLI, M.D.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 1st day of May, 2007, a copy of the foregoing Notice of Removal was mailed first-class, postage prepaid, to:

Evan K. Thalenberg, Esquire
Evan K. Thalenberg, P.A.
11 E. Chase Street, Suite 7F
Baltimore, Maryland 21202

Attorney for Plaintiffs

Timothy P. Knepp, Esquire
P. O. Box 21221
Baltimore, Maryland 21221

Attorney for Pythagoras Passas and Anne L. Passas

Michael D. Vogelstein, Esquire
201 N. Charles Street
Suite 801
Baltimore, Maryland 21201

Attorney for Marc Medin, Nancy Medin and Shenan Management, Inc., and N.A.C.I. Corporation

Natalie Magdeburger, Esquire
Raymond Marshall, Esquire
Whiteford, Taylor & Preston, L.L.P.
210 W. Pennsylvania Avenue
Towson, MD 21204-4514

Attorneys for The Johns Hopkins University, The Institutional Review Board of The Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman, Hayden G. Braine and Peter Lees.

Barry C. Goldstein

INDEX OF EXHIBITS

Exhibit A	Plaintiffs' Complaint
Exhibit B	NIEHS's Request for Proposals
Exhibit C	Affidavit of Merrill Brophy in Support of Notice of Removal
Exhibit D	Contract between NIEHS and Kennedy Krieger Institute, Inc.
Exhibit E	June 25, 1993 letter from NIEHS to Karen Sorenson
Exhibit F	June 25, 1993 Department of Health and Human Services Memorandum
Exhibit G	July 1995 letter from Kennedy Krieger Institute, Inc. to NIEHS
Exhibit H	TLC Trial Protocol
Exhibit I	Affidavit of Cecilia Davoli, M.D. in Support of Notice of Removal
Exhibit J	Department of Health and Human Services Institutional Review Board Guidebood Introduction
Exhibit K	Letter from Kennedy Krieger Defendants' counsel to Plaintiffs' counsel agreeing to accept service of the Complaint
Exhibit L	Copies of all process and pleadings
Exhibit M	Kennedy Krieger Institute Defendants' Notice to the Circuit Court for Baltimore City of Filing of Notice of Removal to the United States District Court

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al.	*	
Plaintiffs	*	
v.	*	**Case No. _____**
KENNEDY KRIEGER INSTITUTE, INC.	*	
Defendant.	*	

****

AFFIDAVIT OF MERRILL BROPHY IN SUPPORT OF NOTICE OF REMOVAL

I, the undersigned, am over the age of eighteen, am competent to testify and have personal knowledge of the following:

1. I, Merrill Brophy, was employed by the Kennedy Krieger Institute ("Kennedy Krieger") until 2002, when I retired.

2. In the fall of 1993 I became involved with the National Institute of Environmental Health Sciences ("NIEHS") study - Treatment of Lead-Exposed Children ("TLC"). My involvement at Kennedy Krieger was with J. Julian Chisolm, M.D. I served as project manager for the portion of the TLC study conducted at Kennedy Krieger.

3. In my role as project manager I have obtained first-hand knowledge regarding activities of the NIEHS and its officers as well as the CDC, related to the design and implementation of the TLC study. The contract for the TLC study was drafted and prepared by NIEHS without any involvement from Kennedy Krieger.

4. A group consisting of, among others, the NIEHS Project Officer and the Principal Investigators from the Clinical Centers, was charged with responsibility for virtually all aspects of the TLC study, including, the design and implementation of the protocol, enrollment of study

participants, and follow up. This group held regular meetings and/or conference calls in fulfillment of that responsibility. Also participating in those meetings and calls were various other individuals from NIEHS and the clinical centers who were involved with this study. I was one such participant. Those meetings were supervised by the NIEHS Project Officer, Dr. Walter Rogan. Dr. Rogan actively participated in the discussions, and guided the direction of the Steering Committee meetings to ensure that the TLC study plans developed consistent with NIEHS objectives.

5. During the Steering Committee meetings, there was active discussion from all interested participants. However, the only way for a substantive TLC study decision to be implemented and become part of the study, was following review by NIEHS. Each and every decision of the Steering Committee was reviewed by Dr. Rogan prior to or during the process of its implementation. No decision was final without review by Dr. Rogan and the NIEHS.

6. The NIEHS Project Officer and staff conducted periodic site visits at Kennedy Krieger. These visits were intended to: (1) ensure that Kennedy Krieger was conducting its portion of the study consistent with the trial protocol; (2) review study participant charts to ensure compliance with the United States Food and Drug Administration ("FDA") regulations for investigational new drugs ("IND"); (3) observe Kennedy Krieger's facilities; and (4) survey the residential houses involved in the study.

7. If NIEHS determined during one of these site visits or otherwise, that study matters needed revision or modification, compliance with such a determination was required immediately. For example, I recall during one of the site visits, an observation by Dr. Rogan that it was too noisy in the room where the psychometric testing was being administered. Kennedy

Krieger was required and did immediately move the psychometric testing room to a quieter area of the facility.

8. NIEHS was the owner of the IND exemption for the study drug, Succimer. Dr. Rogan conducted quizzes to make certain that Kennedy Krieger staff involved in the TLC study understood the nature of the drug, including its side effects, in order to ensure compliance with NIEHS and FDA reporting requirements.

9. In the TLC study, the United States Centers for Disease Control and Prevention ("CDC") conducted the laboratory analysis of all blood lead samples from study participants. Accordingly, it maintained oversight responsibility for all issues related to drawing blood at the Clinical Centers. The CDC established the protocol used by all Clinical Centers for drawing blood as well as for packaging the blood samples for shipment to the CDC laboratory in Atlanta, Georgia. Prior to the implementation of the TLC study, the project manager for each clinical site was required to attend CDC training and was then expected to train personnel responsible for obtaining blood samples. This training provided instruction for compliance with the CDC protocol. The CDC conducted site visits to ensure that the Clinical Centers were complying with its blood drawing protocol. The CDC also provided certain of the equipment utilized in drawing the blood samples as well as all of the packaging materials.

10. Kennedy Krieger was required to obtain IRB approval of the Informed Consent Form to be utilized in enrolling study participants. After the local IRB utilized by Kennedy Krieger approved a form, Kennedy Krieger was required to submit that form to the NIEHS IRB for further review. The NIEHS IRB initially rejected the Kennedy Krieger form because it felt that the reading level required for comprehension was too high. Only after Kennedy Krieger

revamped its form, secured local IRB approval again, and resubmitted the revised form to NIEHS was it approved such that the study could proceed.

11. In order to ensure uniform implementation of the TLC study protocol, NIEHS required all Clinical Centers to participate in central training sessions to learn NIEHS approved techniques for measuring the height, weight, head circumference and blood pressure of study participants. These were all values required to be obtained as part of the study. Further, instruction was provided as to NIEHS approved methods for administering relevant psychometric testing, the results of which would be crucial to analyzing the outcome of the study.

12. Kennedy Kreiger's ability to enlist the participation of other institutions in the TLC study was limited by NIEHS. For example, Kennedy Krieger had secured the assistance of the University of Maryland and the Johns Hopkins University School of Medicine as co-clinical centers for the study. In order to enter into a contract with those institutions, however, Kennedy Krieger was required to obtain approval from NIEHS for each and every term contained in the subcontract.

13. When conducting the TLC Study, Kennedy Krieger was obligated to follow, and did comply with, the strict and comprehensive requirements issued by the federal government regarding research involving human beings.

14. Based on my personal involvement and observation of virtually all aspects of the design and implementation of the TLC study at Kennedy Krieger, there is no question that the federal government, through the NIEHS and CDC, retained and exercised a very detailed level of control over every aspect of this study.

I DECLARE UNDER THE PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Executed on: April 19, 2007

Merrill C Brophy

Merrill Brophy

Exh I
Affidavit of Cecilia Davoli

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al. *

Plaintiffs *

v. *

Case No. _____

KENNEDY KRIEGER INSTITUTE, INC., et al. *

Defendant. *

* * * * * * * * * * *

AFFIDAVIT OF CECILIA DAVOLI, M.D.
IN SUPPORT OF NOTICE OF REMOVAL

I, the undersigned, am over the age of eighteen, am competent to testify and have personal knowledge of the following:

1. I, Cecilia Davoli, M.D. am a physician currently licensed to practice medicine in the State of Maryland. My area of expertise is developmental pediatrics and I am Board Certified in pediatrics and neurodevelopmental disabilities. I am employed by the Kennedy Krieger Institute ("Kennedy Krieger") and am an Assistant Professor of Pediatrics at the Johns Hopkins University School of Medicine.

2. In the spring of 1993 I became involved with the National Institute of Environmental Health Sciences ("NIEHS") Study – Treatment of Lead-Exposed Children ("TLC"). My involvement was at Kennedy Krieger with J. Julian Chisolm, M.D. I served as a co-investigator for the portion of the TLC Study conducted at Kennedy Krieger.

3. In my role as co-investigator I have obtained first-hand knowledge regarding activities of the NIEHS and its officers as well as the CDC, related to the design and implementation of the TLC Study.

4. A group consisting of, among others, the NIEHS Project Officer and the Principal Investigators from the Clinical Centers, was charged with responsibility for virtually all aspects of the TLC Study, including, the design and implementation of the protocol, enrollment of Study participants, and follow-up. This group held regular meetings and/or conference calls in fulfillment of that responsibility. Also participating in those meetings and calls were various other individuals from NIEHS and the clinical centers who were involved with this Study. I was one such participant. Those meetings and calls were supervised by the NIEHS Project Officer, Dr. Walter Rogan. Dr. Rogan actively participated in the discussions, and guided the direction of the Steering Committee meetings to ensure that the TLC Study plans developed consistent with NIEHS objectives.

5. During the Steering Committee meetings, there was active discussion from all interested participants. However, the only way for a substantive TLC Study decision to be implemented and become part of the Study, was following review by NIEHS. Each and every decision of the Steering Committee was reviewed by Dr. Rogan prior to or during the process of its implementation. No decision could be final without review by Dr. Rogan and the NIEHS.

6. The NIEHS directly controlled and approved the information provided to the Study participants and their families as well as the information contained in the Informed Consent forms.

7. The NIEHS Project Officer and staff conducted periodic site visits at Kennedy Krieger. These visits were intended to: (1) ensure that Kennedy Krieger was conducting its portion of the Study consistent with the trial protocol; (2) review Study participant charts to ensure compliance with the United States Food and Drug Administration ("FDA") regulations for investigational new drugs ("IND"); (3) observe Kennedy Krieger's facilities; and (4) survey the residential houses involved in the Study.

8. NIEHS (Dr. Walter Rogan) held the IND exemption for the Study drug, Succimer. During one of the site visits, Dr. Rogan conducted a quiz to make certain that Kennedy Krieger staff involved in the TLC Study understood the nature of the drug, including its side effects, in order to ensure compliance with NIEHS and FDA reporting requirements.

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11. The Principal Investigator at Kennedy Krieger was required to seek approval form NIEHS in order to allocate funds for any purpose that deviated in any way from the contract drafted by NIEHS.

12. Kennedy Krieger was required to obtain IRB approval of the Informed Consent Form to be used in enrolling Study participants. After the local IRB utilized by Kennedy Krieger approved the form, Kennedy Krieger was required to submit that form to the NIEHS IRB for further review. The NIEHS IRB ultimately approved the Informed Consent Form used in the TLC Study.

13. Kennedy Krieger was obligated to follow, and did comply with, strict and comprehensive requirements pursuant to research involving human subjects, imposed by the federal government.

14. Based on my personal involvement and observation of virtually all aspects of the design and implementation of the TLC Study at Kennedy Krieger, there is no question that the federal government, through the NIEHS, FDA and CDC, retained and exercised a very detailed level of control over every aspect of the Study.

Exh I
Affidavit of Cecilia Davoli

I HEREBY DECLARE UNDER THE PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Executed on: 19 April 2007

Cecilia Davoli MD

Cecilia Davoli, M.D.

EXHIBIT A

EXHIBIT I

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al.	*	
Plaintiffs	*	
v.	*	
		Case No. _____
KENNEDY KRIEGER INSTITUTE, INC., et al.	*	
Defendant.	*	

* * * * * * * * * * *

AFFIDAVIT OF CECILIA DAVOLI, M.D.
IN SUPPORT OF NOTICE OF REMOVAL

I, the undersigned, am over the age of eighteen, am competent to testify and have personal knowledge of the following:

1. I, Cecilia Davoli, M.D. am a physician currently licensed to practice medicine in the State of Maryland. My area of expertise is developmental pediatrics and I am Board Certified in pediatrics and neurodevelopmental disabilities. I am employed by the Kennedy Krieger Institute ("Kennedy Krieger") and am an Assistant Professor of Pediatrics at the Johns Hopkins University School of Medicine.

2. In the spring of 1993 I became involved with the National Institute of Environmental Health Sciences ("NIEHS") Study – Treatment of Lead-Exposed Children ("TLC"). My involvement was at Kennedy Krieger with J. Julian Chisolm, M.D. I served as a co-investigator for the portion of the TLC Study conducted at Kennedy Krieger.

3. In my role as co-investigator I have obtained first-hand knowledge regarding activities of the NIEHS and its officers as well as the CDC, related to the design and implementation of the TLC Study.

4. A group consisting of, among others, the NIEHS Project Officer and the Principal Investigators from the Clinical Centers, was charged with responsibility for virtually all aspects of the TLC Study, including, the design and implementation of the protocol, enrollment of Study participants, and follow-up. This group held regular meetings and/or conference calls in fulfillment of that responsibility. Also participating in those meetings and calls were various other individuals from NIEHS and the clinical centers who were involved with this Study. I was one such participant. Those meetings and calls were supervised by the NIEHS Project Officer, Dr. Walter Rogan. Dr. Rogan actively participated in the discussions, and guided the direction of the Steering Committee meetings to ensure that the TLC Study plans developed consistent with NIEHS objectives.

5. During the Steering Committee meetings, there was active discussion from all interested participants. However, the only way for a substantive TLC Study decision to be implemented and become part of the Study, was following review by NIEHS. Each and every decision of the Steering Committee was reviewed by Dr. Rogan prior to or during the process of its implementation. No decision could be final without review by Dr. Rogan and the NIEHS.

6. The NIEHS directly controlled and approved the information provided to the Study participants and their families as well as the information contained in the Informed Consent forms.

7. The NIEHS Project Officer and staff conducted periodic site visits at Kennedy Krieger. These visits were intended to: (1) ensure that Kennedy Krieger was conducting its portion of the Study consistent with the trial protocol; (2) review Study participant charts to ensure compliance with the United States Food and Drug Administration ("FDA") regulations for investigational new drugs ("IND"); (3) observe Kennedy Krieger's facilities; and (4) survey the residential houses involved in the Study.

8. NIEHS (Dr. Walter Rogan) held the IND exemption for the Study drug, Succimer. During one of the site visits, Dr. Rogan conducted a quiz to make certain that Kennedy Krieger staff involved in the TLC Study understood the nature of the drug, including its side effects, in order to ensure compliance with NIEHS and FDA reporting requirements.

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11. The Principal Investigator at Kennedy Krieger was required to seek approval form NIEHS in order to allocate funds for any purpose that deviated in any way from the contract drafted by NIEHS.

12. Kennedy Krieger was required to obtain IRB approval of the Informed Consent Form to be used in enrolling Study participants. After the local IRB utilized by Kennedy Krieger approved the form, Kennedy Krieger was required to submit that form to the NIEHS IRB for further review. The NIEHS IRB ultimately approved the Informed Consent Form used in the TLC Study.

13. Kennedy Krieger was obligated to follow, and did comply with, strict and comprehensive requirements pursuant to research involving human subjects, imposed by the federal government.

14. Based on my personal involvement and observation of virtually all aspects of the design and implementation of the TLC Study at Kennedy Krieger, there is no question that the federal government, through the NIEHS, FDA and CDC, retained and exercised a very detailed level of control over every aspect of the Study.

I HEREBY DECLARE UNDER THE PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Executed on: 19 April 2007

Cecilia Davoli, MD

Cecilia Davoli, M.D.

RECEIVED
CIRCUIT COURT FOR
BALTIMORE CITY
2007 MAR 22 PM 3:06
CIVIL DIVISION

SHAYONNA FEATHERSTONE, Minor,
by Her Mother and Next Friend
SHARON JACKSON
1636 Ashland Avenue
Baltimore, Maryland 21205

and

KEONA FEATHERSTONE, Minor,
by Her Mother and Next Friend
SHARON JACKSON
1636 Ashland Avenue
Baltimore, Maryland 21205

Plaintiffs,

v.

KENNEDY KRIEGER INSTITUTE, INC.
(A Maryland Corporation)
707 North Broadway
Baltimore, Maryland 21205
SERVE ON: James M. Anders
707 North Broadway
Baltimore, Maryland 21205

and

CECILIA DAVOLI
707 North Broadway
Baltimore, Maryland 21205

and

JOHNS HOPKINS UNIVERSITY
(A Maryland Corporation)
3400 Charles Street
Baltimore, Maryland 21218
SERVE ON: Stephen S. Dunbam
Johns Hopkins University
3400 Charles Street
113 Garland Hall
Baltimore, Maryland 21218

and

IN THE

CIRCUIT COURT

FOR

BALTIMORE CITY

CASE NO.: 24-C-07-002027 LP

JURY TRIAL PRAYED

THE INSTITUTIONAL REVIEW BOARD
OF THE JOHNS HOPKINS UNIVERSITY SCHOOL
OF MEDICINE'S JOINT COMMITTEE ON
CLINICAL INVESTIGATION
Administration 129
720 Rutland Avenue
Baltimore, Maryland 21205-2196
SERVE ON: Thomas R. Hendrix, M.D.
Chairman JCCI
Administration 129
720 Rutland Avenue,
Baltimore, Maryland 21205-2196

and

THOMAS R. HENDRIX
Administration 129
720 Rutland Avenue
Baltimore, Maryland 21205-2196

and

LEWIS C. BECKER
1208 Poplar Hill Road
Baltimore, Maryland 21210

and

DAVID R. CORNBLATH
10 Melissa Court
Owings Mills, Maryland 21117

and

PAUL LIETMAN
1750 Circle Road
Towson, Maryland 21204

and

HAYDEN G. BRAINE
2132 Corbett Road
Monkton, Maryland 21111

and

JOHN/JANE DOE
Unknown Member of the JCCIRB

and

N.A.C.L. CORPORATION
A Maryland Corporation
416 East 25th Street
Baltimore, Maryland 21218
SERVE ON: Marc Medin
7955 Starburst Drive
Pikesville, Maryland 21208

and

SHENAN MANAGEMENT, INC.
(A Maryland Corporation)
1900 Lexington Street
Baltimore, Maryland 21228
SERVE ON: Elizabeth Harding
1900 Lexington Street
Baltimore, Maryland 21228

and

MARC MEDIN
7955 Starburst Drive
Pikesville, Maryland 21208

and

NANCY MEDIN
7955 Starburst Drive
Pikesville, Maryland 21208

and

PYTHAGORAS PASSAS
601 Dembytown Road
Joppa, Maryland 21085

and

ANNE L. PASSAS
601 Dembytown Road
Joppa, Maryland 21085

and

HELEN HEATH, Individually and Trading As
Lady "H" Enterprises
5317 West North Avenue
Gwynn Oak, Maryland 21207

Defendants

* * * * * * * * * * * * * * *

COMPLAINT AND ELECTION FOR JURY TRIAL

COME NOW the Plaintiffs, Shayonna Featherstone and Keona Featherstone, Minors, by and through their mother and next friend, Sharon Jackson, and by and through their attorneys, Evan K. Thalenberg, Nicholas A. Szokoly, and Evan K. Thalenberg, P.A., and sue the Kennedy Krieger Institute, Incorporated, Cecilia Davoli, the Johns Hopkins University, the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman, Hayden G. Braine, John/Jane Doe unknown member of the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, NACI Corporation, Shenan Management, Incorporated, Marc Medin, Nancy Medin, Pythagoras Passas, Anne Passas, and Helen Heath, individually and trading as Lady "H" and as grounds therefore respectfully submits the following:

FACTS COMMON TO EACH COUNT

1. The Plaintiffs herein are Shayonna Featherstone, born October 22, 1992, and

Keona Featherstone, born September 11, 1993. The minor Plaintiffs are proceeding through their mother and next friend Sharon Jackson.

2. The Plaintiffs were child research subjects in a non-therapeutic clinical research study known as Treatment of Lead-exposed Children, (TLC), from approximately 1994 through 2001.

3. The TLC study was administered by the Defendants Kennedy Krieger Institute (KKI) and Cecilia Davoli (Davoli) and at all times relevant hereto was to have been reviewed and overseen by the Defendants the Johns Hopkins University, (JHU), the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman, Hayden G. Braine, John/Jane Doe unknown member of the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, (collectively, the IRB).

4. During their participation in the TLC study, the Plaintiffs resided at and/or spent significant periods of time at the below indicated properties for the below indicated time periods:

a. The Plaintiffs resided at and/or spent significant periods of time at 2418 East Jefferson Street, Baltimore, Maryland from approximately 1994 through 1996. The Defendants NACI Corporation, Marc Medin and/or Nancy Medin owned and/or operated the property during the Plaintiffs' tenancy.

b. The Plaintiffs resided at and/or spent significant periods of time at 739 North Milton Avenue, Baltimore, Maryland, from 1996 through 1997. The Defendants Pythagoras Passas and Anne L. Passas owned and/or operated the property during the Plaintiffs'

tenancy.

5. The Defendant Helen Heath, individually, and trading as Lady "H" Enterprises, (hereinafter Lady "H") was an agent of KKI and Davoli throughout the TLC study. Lady "H" was to perform interventions, pursuant to the TLC study, to lead-contaminated homes where child-research subjects, such as the minor Plaintiffs, were to reside. At the direction of KKI and Davoli, Lady "H" performed interventions at the properties set forth in paragraphs 4(a) and 4(b). The interventions were intended by KKI and Davoli to be less than full lead-based paint abatements.

6. The TLC study was conducted by Defendants KKI and Davoli, and approved and reviewed by the IRB, from approximately 1994 to approximately 1998 and was extended as "TLC Plus" through as late as 2001. The TLC study was a double-blind placebo study. The purpose of the study was to evaluate the effect of administering succimer, a chelating agent, to one half of the study participants and a placebo to the remaining participants. The research subjects in the TLC study were children and each child had been previously referred to KKI in order to obtain treatment for lead-poisoning. However, despite the name of the study and the misrepresentations of the Defendants to the parents of research subjects, the child research subjects would not be receiving treatment for lead-poisoning. KKI and Davoli used the subjects as controls in an effort to determine if children receiving succimer would suffer less brain damage and cognitive impairments than children who did not. Succimer was not indicated for prophylaxis of lead poisoning in an environment containing lead hazards and the use of succimer should have been accompanied by identification and removal of the source of the child's lead exposure.

7. Because the study was conducted in a double-blind fashion, neither the child research subjects, their parents, nor the childrens' doctors would know the blood-lead levels of the children in the study during the "treatment phase." Likewise, none of the above could know if their child was actually receiving succimer or simply a sugar pill.

8. The parents of TLC research subjects, including the plaintiffs, were not informed by KKI or Davoli that drugs like succimer should not be used as a substitute for the complete abatement of lead hazards to which the child is exposed nor were they informed that succimer should not be used on a child who continues to be exposed to lead hazards.

9. Via the "informed consent form" (IC) Parents and guardians of the children used in the TLC study were promised that during the "treatment phase" another doctor would know the results of the blood-lead test "in case there [was] a problem," and that the childrens' blood-lead levels would also be reported to the Baltimore City Health Department.

10. Via the IC, Parents and guardians of the children used in the TLC study were promised that the TLC administrators would look carefully at the childrens' homes to identify lead hazards and that information would be communicated to the parents.

11. The Parents and guardians of the children used in the TLC study were promised that if their house did not "qualify" that KKI and Davoli would relocate them to housing free of lead hazards.

12. Via the IC, Parents and guardians of the children used in the TLC study were promised that KKI and Davoli, and/or their agents such as Lady "H" would "clean up the lead" in the homes of study subjects.

13. Via the IC, Parents and guardians of the children used in the TLC study were

promised that KKI and Davoli would "check the amount of lead in [the] child's body carefully."

14. In order to facilitate the recruitment of child research subjects, the parents and guardians of the children were offered cash, gift certificates, and other financial rewards for allowing their children to remain in the study.

15. KKI and Davoli were required, but failed, to obtain valid and fully informed consent, not simply a signed form, of the guardians of the child research subjects in the TLC study and to ensure that the guardians of the child research subject were fully informed of the foreseeable risk of serious harm to the study participants.

16. Pursuant to 45 C.F.R. § 46.101 (2005) approval and oversight by an Institutional Review Board (IRB) is required whenever research on human beings is conducted, supported, or otherwise subject to federal regulation. Maryland Code Health Gen. Art. § 13-2001, *et seq*, (2005) requires that all research conducted in Maryland on human subjects be conducted in compliance with federal regulations, regardless of the source of funding and/or support for the research.

17. In approving research proposals the IRB's duties include, but are not limited to, ensuring that subjects are protected from risks of harm, ensuring that the risks of harm are reasonable in relation to the anticipated benefits to the subjects, ensuring that the methods employed to select the subjects are equitable, ensuring that the principle investigator and/or the institution sponsoring the research obtains and documents the informed consent of the subject or the subjects' guardian, ensuring that the research plan provides for monitoring the collected data to ensure that safety of the subjects, and including additional safeguards to protect the rights and welfare of vulnerable subjects, such as children.

18. Because the TLC study involved research on children, the IRB had a duty to ensure that additional protections were made of the rights and welfare of the subjects. The IRB had a duty to ensure that the risk of harm to the child research subjects, the potential for direct benefit to the subjects, and the relation between the risk and the benefit were accurately determined. As the risk of harm to the child research subjects in the TLC study was lead poisoning and permanent brain damage. The IRB was responsible for ensuring the safety of the child research subjects in the TLC stud and failed to do so..

19. The homes of study subjects would receive "interventions" performed by Lady "H" and others at the direction of KKI and Davoli. KKI, Davoli, and the IRB knew, or should have known, that the "interventions" performed by Lady "H" and others on the homes of the research subjects were not sufficient to remove the lead hazards contained therein.

20. In order to secure homes for the TLC study, KKI and/or their agents recruited the participation of landlords, including those as set forth in paragraphs 4(a) and 4(b), who operated low-income residential rental properties. In return for permitting the properties to be used in the TLC study and for an agreement that the dwellings would only be rented to tenants with young children and/or that priority would be given to such families in renting the vacant units, KKI assisted the landlords, including those as set forth in paragraphs 4(a) and 4(b), in applying for and receiving grants, forgivable loans, and/or loans of money to be used to perform the requisite interventions.

21. The administration of the TLC study required that small children who had come to KKI seeking treatment for lead poisoning would instead have a 50/50 chance of receiving an unproven therapy for children with similar levels of blood-lead or a sugar pill. At all times

relevant thereto, the children would reside in homes which KKI and/or its agents, Davoli, the IRB, Lady "H" and the landlords as set forth in paragraphs 4(a) and 4(b), knew or should have known contained lead-based paint hazards. There was no direct benefit to the child research subjects from participating in the TLC study and the monitoring procedure employed in the TLC study, including but not limited to "blinding" the results of the Plaintiffs' blood-lead tests, was less beneficial to the child research subjects' well being than the monitoring regime already in place.

22. The Defendants knew or should have known that the lead-poisoning of the instant Plaintiffs, which resulted from their use as child research subjects in the TLC study, was both foreseeable and preventable.

23. The IRB assisted the TLC study investigators in concealing the fact that the child research subjects would be placed at serious risk of permanent harm as a result of participating in the study, and concealing that recognized and approved therapies already existed for children with similar lead levels, to wit, **removal from the leaded environment.**

24. Absent from the IC forms used in the TLC study was a clear explanation regarding the various levels of interventions or any explanation of the risk that the child participants could become lead-poisoned as a result of their participation in the study. Further, there was no explanation in the IC of the already accepted and recognized treatment for children with similar blood-lead levels.

25. JHU knew, or should have known, that the IRB members lacked the professional expertise and resources to adequately ensure the safety of the child research participants within the TLC Study.

26. The Defendants knew, or should have known, that partial abatement of lead-based paint hazards used in the TLC study were not sufficient to remove lead-based paint hazards, inasmuch as KKI's own doctors had already discovered as much in two prior studies. The results of the previous studies indicated that lead-based paint dust remained in and/or returned to homes which received only partial abatements over a period of time.

27. The Defendants knew, or should have known, that exposure to lead-bearing dust was particularly hazardous for children because hand-to-mouth activity was a recognized route of entry of lead-based paint dust into a child's body and because, as discovered by KKI's own doctors in prior lead-based paint studies, the absorption of lead is inversely related to particle size.

28. The Defendants knew, or should have known that the ingestion of lead-based paint chips and lead-based paint dust by children causes permanent and irreversible brain damage, diminished intellectual abilities, learning disabilities, behavioral problems, and in sufficient doses, even death.

29. The minor Plaintiff Shayonna Featherstone was diagnosed with an elevated blood-lead level of 32 µg/dL on or about July 22, 1994. She was subsequently referred by her treating physician to the lead poisoning clinic of Defendant KKI. The Plaintiff's family was recruited into the TLC study soon thereafter by KKI and both minor Plaintiffs became research subjects.

30. The Defendants knew, or should have known, that the properties identified in paragraphs 4(a) and 4(b), contained numerous surfaces covered in lead-based paint. However, KKI, Davoli, and/or their agents nonetheless represented to the Plaintiffs' family, the Plaintiffs'

treating physician, and to the Baltimore City Health Department, hereinafter BCHD, that the homes were free of lead hazards.

31. The Defendants knew, or should have known, that the homes as identified in paragraphs 4(a) and 4(b) were not free of lead hazards, that the dwellings contained numerous lead-based paint hazards, and that it was foreseeable that the minor Plaintiffs would be exposed to those lead-based paint hazards and that they would ingest lead-based paint chips and lead-based paint dust therein.

32. The Defendants did not inform the minor Plaintiffs' mother that the homes identified in paragraphs 4(a) and 4(b) contained numerous areas of lead-based paint, lead-based paint hazards, or that the homes presented an ongoing lead-based paint exposure hazard to the minor Plaintiffs. This information was suppressed by the Defendants in order to secure a signed consent form to allow the minor Plaintiffs' to participate in the TLC study.

33. The Defendants knew, or should have known, that both minor Plaintiffs were placing non-food items into their mouths, including paint chips, on an almost daily basis at the onset of their use a research subjects.

34. The Defendants knew, or should have known, that the homes identified in paragraphs 4(a) and 4(b) contained chipping, peeling, and flaking lead-based paint in windows throughout the home which were accessible to the minor Plaintiffs during their tenancy.

35. The Defendants knew, or should have known, that the lead-based paint covered surfaces within the homes identified in paragraphs 4(a) and 4(b) began to rapidly deteriorate after the "interventions" and during the Plaintiffs' tenancy causing the presence of lead-based paint dust during the tenancy of the minor Plaintiffs, thus constituting a lead-based paint hazard to the

minor Plaintiffs.

COUNT ONE
NEGLIGENCE
Violations of the Baltimore City Housing Code

36. The Plaintiffs, incorporate by reference in this Count those facts and allegations set forth in paragraphs one through thirty-five as if fully stated herein.

37. The Defendants, as required by the study: determined which homes would receive partial lead-abatements (interventions), the degree of those interventions, specified the work to be done by those conducting the interventions, the cost of the intervention, the time and manner in which the interventions were to be conducted, and inspected the completed interventions prior to approving payment to the contractor. By controlling the decisions about the scope of repairs, the manner and means of repairs and the level of interventions to be performed, the Defendants exercised charge, care, and/or control over the dwellings set forth in paragraph 4(a) and 4(b) during the tenancy of the minor Plaintiffs. Pursuant to Article 13, Section 105(bb) of the Baltimore City Housing Code, (the Housing Code), those who exercise charge, care, and/or control of residential rental dwellings are operators.

38. Pursuant to Article 13, Section 310(a) of the Housing Code, the Defendants were responsible for ensuring that the properties set forth in paragraph 4(a) and 4(b) was maintained in compliance with all provisions of the Housing Code during the tenancy of the minor Plaintiffs.

39. The Defendants, as well as their agents, servants and/or employees, caused and allowed the continued existence of peeling, flaking and chipping paint and paint containing lead pigment to be present on the walls, woodwork, doors, door frames, window sills, common areas and other areas of the premises thereby rendering the building and premises unsafe and dangerous as well

as unfit for human habitation, especially for infants such as the Plaintiffs.

40. During the years that the Plaintiffs resided in the premises they ingested and consumed paint, and paint dust which was known to the Defendants to contain lead pigment and lead, thereby causing the Plaintiffs to suffer severe and unremitting illness, injury and infirmities hereinafter set forth. The Plaintiffs assert that all of the injuries, damages and infirmities and permanent disabilities sustained by the Plaintiffs are due to the following:

(a) The violation by the Defendants of statutes, rules and regulations, including, but not limited to, Article 13, Sections 702 and 706, of the Housing Code, requiring every dwelling and every part thereof to be maintained by the owner, manager(s) and operator so as to be fit for human habitation and prohibiting the use of paint for interior painting at any dwelling or dwellings, unless such paint is free from any lead pigment. Defendants are liable for said violations under sections of the Housing Code including, but not limited to 105 (jj) and 310.

(b) The violation by the Defendants of statutes, rules and regulations, including, but not limited to, Article 13, Section 703 (c), of the Housing Code, requiring that all walls, ceilings, woodwork, doors, and windows be kept clean and free of any loose or peeling paint and paper. Defendants are liable for said violations under sections of the Housing Code including, but not limited to 105 (jj) and 310.

(c) The fact that notice was provided to the Defendants and their duly authorized agents, servants and/or employees of the flaking condition of the paint at the leased premises. Further, the Defendants had actual notice of the hazardous condition and nevertheless permitted this dangerous condition to go unrepaired and failed in their duty to warn the Plaintiffs and their family of the dangerous and defective condition of the properties and the lead-based paint therein. It is alleged

that the Plaintiffs accumulated dangerous levels of lead in their bodies as a direct and proximate result of the failure on the part of the Defendants to maintain the premises in a safe condition, avoiding the presence of toxic materials which were accessible to the Plaintiffs.

(d) The ongoing negligence of the Defendants in causing, permitting and allowing the premises to become and remain in an unsafe condition despite having the duty both by agreement and by statute to inspect and conduct repairs pursuant to the Housing Code including, but not limited to section 909.

(e) The failure of the Defendants to exercise, on an ongoing basis, reasonable care in the proper maintenance of the premises including, but not limited to, the walls, woodwork, doors, door frames, windows and window sills as well as other areas, and in a continuous failure to undertake suitable and adequate means to eradicate the aforesaid danger caused by ongoing and unremitting flaking, peeling, cracking and the deterioration of the lead-based paint referred to herein above.

(f) The permitting of the lead-based paint to remain within the premises, making same unsafe and dangerous as a place for human residence, especially unsafe for the residence of infant children such as the Plaintiffs herein.

(g) The ongoing failure on the part of the Defendants herein to use reasonable and prudent care to inspect, test and maintain the premises as well as remove and eradicate said lead-based paint which the Defendants knew or by the exercise of due care, should have known had been used and applied in the premises. The Defendants possessed actual notice of the presence of lead-based paint and lead-based paint dust within the premises and the ongoing condition of the premises including, specifically, the presence of flaking, peeling, and cracking lead-based paint, and walls and surfaces coated with lead pigment and lead. The Defendants knew that the continued use and

existence of the premises as it was maintained, rendered it an inherently dangerous place of residence.

41. The Plaintiffs assert that all of the injuries, damages and severe permanent disability inflicted upon the Plaintiffs set forth herein are due solely to the wrongful and negligent acts and conduct as well as omissions to act on the part of the Defendants herein, the minor Plaintiffs being in no way contributorily negligent.

WHEREFORE the minor Plaintiffs, Shayonna Featherstone and Keona Featherstone, by their Mother and Next Friend, Sharon Jackson, bring this action against the Defendants, the Kennedy Krieger Institute, Incorporated, Cecilia Davoli, the Johns Hopkins University, the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman, Hayden G. Braine, John/Jane Doe unknown member of the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, NACI Corporation, Shenan Management, Incorporated, Marc Medin, Nancy Medin, Pythagoras Passas, Anne Passas, and Helen Heath, individually and trading as Lady "H", jointly and severally and each Plaintiff claims Two Million Dollars ($2,000,000.00) damages.

COUNT TWO
NEGLIGENT MISREPRESENTATION
Lead-Based Paint Hazards Within the Properties Set Forth in Paragraphs 4(a) and 4(b)

42. The Plaintiffs incorporate by reference in this Count those facts and allegations set forth in paragraphs one through forty-one as if fully stated herein.

43. Prior to the lease of the premises of the properties set forth in paragraph 4(a) and 4(b), Baltimore, Maryland, the Defendants herein negligently made, and/or negligently permitted to be

made, misrepresentations to the Plaintiffs and their family regarding the condition of the premises. Those explicit and implicit negligent misrepresentations included, but were not limited to, (a) that the premises was free of lead-based paint, (b) that the premises was in habitable condition, (c) that the premises would be maintained in a habitable condition throughout the tenancy and/or time spent there, (d) that the premises was in compliance with all applicable statutes, code, and regulations pertaining to rental properties at the inception of Plaintiffs' tenancy, (e) that the premises would be maintained in compliance with all applicable statutes, code, and regulations pertaining to rental properties throughout the Plaintiffs' tenancy, and (f) that the premises was safe for the Plaintiffs to reside in. The Plaintiffs assert that the Defendants made and/or permitted to be made these misrepresentations to the Plaintiffs and their family intending that the Plaintiffs and their family would rely upon the representations, enter into a lease for the premises, and allow the minor Plaintiffs to be used in the TLC Study. Furthermore, the Defendants knew or should have known that the Plaintiffs would rely upon the misrepresentation which, if false, would cause injuries to the Plaintiffs.

44. The Plaintiffs assert that they and their family reasonably and justifiably relied on the misrepresentations of the Defendants herein that the properties set forth in paragraph 4(a) and 4(b) was and would be free of lead hazards and suffered injuries including but not limited to brain injury due to lead-paint poisoning.

45. The Plaintiffs assert that all of the injuries, damages and severe permanent disability inflicted upon the Plaintiffs set forth herein are due solely to the wrongful and negligent acts and conduct as well as omissions to act on the part of the Defendants herein, the minor Plaintiffs being in no way contributorily negligent.

WHEREFORE the minor Plaintiffs, Shayonna Featherstone and Keona Featherstone, by their Mother and Next Friend, Sharon Jackson, bring this action against the Kennedy Krieger Institute, Incorporated, Cecilia Davoli, the Johns Hopkins University, the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman Hayden G. Braine, John/Jane Doe, individually as members of the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, NACI Corporation, Shenan Management, Incorporated, Marc Medin, Nancy Medin, Pythagoras Passas, and Anne Passas, jointly and severally, and each Plaintiff claims Two Million Dollars ($2,000,000.00) damages.

COUNT THREE
NEGLIGENT MISREPRESENTATION
Risk Of Harm to Plaintiffs

46. The Plaintiffs, incorporate by reference in this Count those facts and allegations set forth in paragraphs one through forty-five as if fully stated herein.

47. The Defendants herein negligently made and/or negligently permitted to be made false representations to the Plaintiffs and their family regarding the risk of harm to the Plaintiffs if they were enrolled in the TLC Study. Despite the knowledge that the properties set forth in paragraph 4(a) and 4(b) contained numerous lead-based paint hazards and the childrens' PICA would almost certainly result in their becoming lead-poisoned, the Defendants herein negligently made and/or negligently permitted to be made false representations to the Plaintiffs' family that the TLC Study posed no more than a minimal risk of harm to the Plaintiffs. The Plaintiffs assert that the Defendants made and/or permitted to be made these false representations to the Plaintiffs and their

family intending that the Plaintiffs and their family would rely upon these representations and allow the minor Plaintiffs to be used in the TLC Study. Furthermore, the Defendants knew or should have known that the Plaintiffs would rely upon the misrepresentation which, if false, would cause injuries to the Plaintiffs.

48. The Plaintiffs assert that they and their family reasonably and justifiably relied on the misrepresentations of the Defendants that their participation in the TLC Study posed no more than a minimal risk and suffered injuries including but not limited to brain injury due to lead-paint poisoning.

49. The Plaintiffs assert that all of the injuries, damages and severe permanent disability inflicted upon the Plaintiffs set forth herein are due solely to the wrongful and negligent acts and conduct as well as omissions to act on the part of the Defendants herein, the minor Plaintiffs being in no way contributorily negligent.

WHEREFORE the minor Plaintiffs, Shayonna Featherstone and Keona Featherstone, by their Mother and Next Friend, Sharon Jackson, bring this action against the Defendants, the Kennedy Krieger Institute, Incorporated, Cecilia Davoli, the Johns Hopkins University, the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman, Hayden G. Braine, John/Jane Doe, individually as members of the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, jointly and severally, and each Plaintiff claims Two Million Dollars ($2,000,000.00) damages.

COUNT FOUR
NEGLIGENCE

Failure to Properly Review and Oversee the TLC Study

50. The Plaintiffs, incorporate by reference in this Count those facts and allegations set forth in paragraphs one through forty-nine as if fully stated herein.

Duty to Ensure Safety Based Upon Regulations

51. JHU and the members of the IRB, each owed a duty to the child research subjects in the TLC study by virtue of regulations including, but not limited to, 45 C.F.R. § 46.101, *et seq.* (2005), 45 C.F.R. § 46.401, *et seq.* (2005), and Md. Code Health Gen. Art. § 13-2001, *et seq*, (2005) to exercise reasonable care to ensure the safety of child research subjects, such as the minor Plaintiffs, in the approval and administration of the TLC study.

52. The Defendants herein each knew or should have known that TLC Study posed an unreasonably high risk of serious and irreversible harm to the child research subjects who participated in the study and that the TLC Study protocols deviated from the standard of care for children with levels of lead in their bodies similar to plaintiffs. It was foreseeable that participation in the study would cause subjects such as the minor Plaintiffs to suffer severe and irreversible brain damage and other injuries as set forth herein.

53. The Defendants herein each knew or should have known that the participation of child research subjects, including the Plaintiffs, in the TLC Study would pose no benefit to the children being used in the experiment.

54. The Defendants herein knew or should have known that KKI and Davoli were conducting the TLC experimentation upon child subjects, including the Plaintiffs, without

the valid informed consent of the child research subjects or their guardians.

Duty to Ensure Safety Based Upon Special Relationship

55. JHU and the members of the IRB, each owed a duty to the child research subjects in the TLC Study by virtue of the special relationship created between child research subjects, such as the minor Plaintiffs, and researchers, that was separate and apart from the duties owed by the Defendants KKI and Davoli. JHU and the IRB owed a duty to the Plaintiffs to exercise reasonable care to ensure that the statements and representations made by KKI and Davoli in the administration of the TLC Study were accurate and that the parents and guardians of the child research subjects in the TLC Study, such as the Plaintiffs, were provided with truthful and reliable information concerning the serious risk of harm to the subjects of the experiment and the lack of any discernable benefit.

56. By virtue of that special relationship, JHU and the members of the IRB each owed a duty to ensure that low-income families were not inappropriately and unethically enticed by KKI and Davoli with monetary remuneration and other enticements to enroll their children in a non-therapeutic research study which posed substantially more than a minimal risk of harm.

57. The Defendants herein each knew or should have known that TLC Study posed an unreasonably high risk to the child research subjects which foreseeably would cause subjects such as the minor Plaintiffs to suffer severe and irreversible brain damage and other injuries as set forth herein.

58. The Plaintiffs allege that JHU and the IRB each negligently breached the above duties and permitted KKI, Davoli to mislead the parents and guardians of the minor Plaintiffs as to the actual risks and benefits of the participation of the minor Plaintiffs in the TLC Study, to

improperly and unethically lure and entice low income families with monetary remuneration and other enticements in order to obtain consent to expose the child research subjects, such as the minor Plaintiffs, to unreasonable and serious risks of harm during their participation in the TLC Study, to enroll the minor Plaintiffs in the TLC Study without valid informed consent, and to expose the minor Plaintiffs to an unreasonable risk of harm.

59. The Plaintiffs assert that all of the injuries, damages and severe permanent disability inflicted upon the Plaintiffs set forth herein are due solely to the wrongful and negligent acts and conduct as well as omissions to act on the part of the Defendants herein, the minor Plaintiffs being in no way contributorily negligent.

WHEREFORE the minor Plaintiffs, Shayonna Featherstone and Keona Featherstone, by their Mother and Next Friend, Sharon Jackson, bring this action against the Defendants the Johns Hopkins University, the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman, Hayden G. Braine, John/Jane Doe, individually as members of the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, jointly and severally, and each Plaintiff claims Two Million Dollars ($2,000,000.00) damages.

COUNT FIVE
NEGLIGENCE
The IC Form

60. The Plaintiffs, incorporate by reference in this Count those facts and allegations set forth in paragraphs one through fifty-nine as if fully stated herein.

61. The Defendants, KKI, JHU, the IRB, and Davoli, by virtue of the IC

form, entered into an agreement with the Plaintiffs, that in exchange for the Plaintiffs' participation in the TLC study, the Defendants herein assumed a duty to: ensure that all children in the TLC study, including the Plaintiffs, had their homes repaired and/or cleaned to get rid of lead dust and chipped paint, to carefully inspect the properties identified in paragraphs 4(a) and 4(b) to see if they could be repaired and/or cleaned to eliminate lead hazards, if the home did not qualify, the Defendants would assist with relocation to housing that was known to be free from lead-hazards, the Defendants would eliminate any lead hazards in the home, ensure that a doctor would monitor the blood-lead levels of the Plaintiffs and promptly and accurately report those test results to the family of the minor Plaintiffs and to the Baltimore City Health Department, and the Defendants also assumed a duty to provide ongoing medical care of the Plaintiffs' lead-paint poisoning and lead toxicity.

62. The Defendants' actions and omissions including, but not limited to, the failure to promptly and accurately report the existence of lead-based paint hazards to the Plaintiffs at the properties set forth in paragraph 4(a) and 4(b), failure to promptly and accurately report the results of the minor Plaintiffs' blood-lead test results during their participation as child research subjects in the TLC Study, failure to make the properties set forth in paragraph 4(a) and 4(b) free of lead hazards, and the Defendants' failure to provide ongoing medical care of Plaintiffs' lead-paint poisoning and lead toxicity constituted a breach of the Defendants' duties to the Plaintiffs that the Defendants agreed to assume. The Defendants breach of these and other duties was inextricably intertwined with the tortious conduct alleged herein.

63. The minor Plaintiffs allege that the damages suffered by them, as stated herein, were the foreseeable result of the Defendants' breach of their duties to the minor Plaintiffs.

64. In the alternative, the Plaintiffs allege that they were clearly intended to be third-party beneficiaries of the agreement between the Defendants and the parents or guardians of the Plaintiffs and that the damages suffered by them, as stated herein, were reasonably foreseeable by the Defendants as the probable result of the Defendants' material breach of their obligations to the Plaintiffs.

65. The Plaintiffs assert that all of the injuries, damages and severe permanent disability inflicted upon the Plaintiffs set forth herein are due solely to the wrongful acts and conduct as well as omissions to act on the part of the Defendants herein.

WHEREFORE the Plaintiffs, Shayonna Featherstone and Keona Featherstone, by their Mother and Next Friend, Sharon Jackson, bring this action against the Defendants the Kennedy Krieger Institute, Incorporated, Cecilia Davoli, the Johns Hopkins University, the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman, Hayden G. Braine, John/Jane Doe, individually as members of the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, jointly and severally, and each Plaintiff claims Two Million Dollars ($2,000,000.00) damages.

COUNT SIX
NEGLIGENCE
ON BEHALF OF PLAINTIFFS AS THIRD PARTY BENEFICIARIES
The MPAA/The Belmont Report

66. The Plaintiffs, incorporate by reference in this Count those facts and allegations set forth in paragraphs one through sixty-five as if fully stated herein.

67. The Defendants KKI and JHU warranted and agreed to the United States

Department of Health and Human Services, hereinafter referred to as DHHS, prior to the constitution of, and during the administration of the TLC Study, that all human research at KKI would be conducted in accordance with the terms of the Belmont Report. *See*, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, promulgated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979. The Defendants agreed to abide by the ethical duties and obligations set forth within the Belmont Report in furtherance of the Defendants' KKI and JHU agreement with DHHS under a Multiple Project Assurance Agreement, hereinafter MPAA. This agreement existed prior to the tortious acts alleged herein.

68. The Belmont Report provides that researches must ensure that subjects of human research enter into the research **voluntarily** and with **sufficient information**. The authors of the Belmont Report likewise recognize that children are not capable of self-determination and their inclusion into a research program requires, in effect strict scrutiny.

69. The Belmont Report also provides that researchers should exercise beneficence towards their human research subjects. Beneficence, within the Belmont Report, incorporates two general rules: first, do no harm, and second, maximize the possible benefits to the human research subject.

70. The minor Plaintiffs allege that the Defendants actions and omissions, as stated herein, were a material breach of their agreement to accept the ethical duties and obligations set forth within the Belmont report, as embodied within the MPAA; and that said breach is inextricably intertwined with the tortious conduct alleged herein.

71. The minor Plaintiffs allege that the Defendants agreed to follow the terms of the

Belmont report in an agreement with DHHS, and that the minor Plaintiffs herein, as child research subjects, were clearly amongst the intended beneficiaries of that agreement. By virtue of the MPAA, KKI and JHU had a duty to ensure that they obtained the informed consent of the child research subjects in the R&M study, to protect the child research subjects from harm, and to maximize the benefit to the research subjects.

72. The minor Plaintiffs allege that the Defendants' failure to ensure that the Plaintiffs were voluntarily enrolled into the study and the failure of the Defendants to ensure that the parents of the Plaintiffs were adequately informed of the risk of harm were material breaches of the MPAA, and thus, of the duty owed by the Defendants to the Plaintiffs.

73. The minor Plaintiffs allege that the Defendants' actions and omissions in placing the success of the study above the health and well being of the child research subjects were material breaches of the MPAA, and thus, of the duty owed by the Defendants to the Plaintiffs.

74. The minor Plaintiffs allege that the damages suffered by them, as stated herein, were reasonably foreseeable by the Defendants and the probable result of the Defendants' material breach of their agreement with DHHS, and thus, of the duty owed by the Defendants to the Plaintiffs.

75. The Plaintiffs assert that all of the injuries, damages and severe permanent disability inflicted upon the Plaintiffs set forth herein are due solely to the wrongful acts and conduct as well as omissions to act on the part of the Defendants herein.

WHEREFORE the minor Plaintiffs, Shayonna Featherstone and Keona Featherstone, by their Mother and Next Friend, Sharon Jackson, bring this action against the Defendants the

Kennedy Krieger Institute, Incorporated and the Johns Hopkins University, jointly and severally, and each Plaintiff claims Two Million Dollars ($2,000,000.00) damages.

COUNT SEVEN
CIVIL CONSPIRACY
KKI, Davoll, JHU, and the IRB

76. The Plaintiffs, incorporate by reference in this Count those facts and allegations set forth in paragraphs one through seventy-five as if fully stated herein.

77. The minor Plaintiffs allege that the Defendants herein, and each of them, by agreement or understanding agreed to tortiously mislead and/or negligently misrepresent to the parents and/or guardians of the child research subjects used in the TLC Study, including the minor Plaintiffs, as to the serious risk of irreversible harm posed by the TLC Study to the child participants.

78. The minor Plaintiffs allege that the Defendants herein, and each of them, by agreement or understanding agreed to materially breach their duties set forth within the IC to the child research subjects used in the TLC Study, including the minor Plaintiffs.

79. The minor Plaintiffs allege that the Defendants herein, and each of them, by agreement or understanding agreed to materially breach their obligations as set forth within the MPAA and the Belmont Report to the child research subjects used in the TLC Study, including the minor Plaintiffs.

80. The minor Plaintiffs allege that the Defendants herein, and each of them, by agreement or understanding agreed to tortiously fail to perform their duties to the child research subjects used in the TLC Study, including the minor plaintiffs, which arose from the "special relationship" between the minor Plaintiffs as child research subjects in the TLC Study and the

researchers and IRB charged with ensuring their safety.

81. The Plaintiffs allege that the Defendants herein, and each of them, by agreement or understanding agreed to violate regulations designed to protect the safety of the child research subjects used in the TLC Study, including the Plaintiffs, to promote the success of the study over the health and well being of the children the Defendants had a duty to protect from harm.

82. The Plaintiffs assert that all of the injuries, damages and severe permanent disability inflicted upon the Plaintiffs set forth herein are due solely to the wrongful acts and conduct on the part of the Defendants herein.

WHEREFORE the minor Plaintiffs, Shayonna Featherstone and Keona Featherstone, by their Mother and Next Friend, Sharon Jackson, bring this action against the Defendants the Kennedy Krieger Institute, Incorporated, Cecilia Davoli, the Johns Hopkins University, the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman, Hayden G. Braine, John/Jane Doe, individually as members of the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, jointly and severally, and each Plaintiff claims Two Million Dollars ($2,000,000.00) damages.

COUNT EIGHT
BREACH OF FIDUCIARY DUTY

83. The Plaintiffs, incorporate by reference in this Count those facts and allegations set forth in paragraphs one through eighty-two as if fully stated herein.

84. The Plaintiffs allege that the Defendants herein, and each of them, owed the child

research subjects used in the TLC Study, including the minor Plaintiffs, a fiduciary duty by virtue of the agreements, representations, and the position of the parties as stated herein.

85. The Defendants, through their acts and omissions breached their fiduciary duty to the child research subjects used in the TLC Study, including the minor Plaintiffs.

86. The Defendants gained the confidence of the parents and/or guardians of the child research subjects used in the TLC Study, including the minor Plaintiffs, by virtue of Defendant KKI's prestigious reputation for the treatment of children suffering from lead poisoning and coupled with the Defendants' targeted recruitment of children from low-income families for use as research subjects in the TLC Study, including the minor Plaintiffs. It was anticipated by the Defendants that the parents of children used in the TLC Study would reasonably rely upon the Defendants to provide care and aid to the child research subjects and to act in the subject's best interests.

87. The Defendants, and each of them, breached their fiduciary duty to act in the best interests of the children used as research subjects in the TLC Study. Instead, the Defendants, and each of them, placed their own interests in prestige and monetary reward over the interests of the children they used as research subjects.

88. The injuries suffered by the minor Plaintiffs as a result of the Defendants' breach were the foreseeable and probable results of the Defendants' actions and/or omissions.

89. The Plaintiffs assert that all of the injuries, damages and severe permanent disability inflicted upon the Plaintiffs set forth herein are due solely to the wrongful and negligent acts and conduct as well as omissions to act on the part of the Defendants herein.

WHEREFORE the minor Plaintiffs, Shayonna Featherstone and Keona Featherstone, by

their Mother and Next Friend, Sharon Jackson, bring this action against the Defendants the Kennedy Krieger Institute, Incorporated, Cecilia Davoli, the Johns Hopkins University, the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, Lewis C. Becker, David R. Coimblath, Paul Lietman, Hayden G. Braine, John/Jane Doe, individually as members of the Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, jointly and severally, and each Plaintiff claims Two Million Dollars ($2,000,000.00) damages.

Respectfully submitted,

Evan K. Thalenberg

Nicholas A. Szokoly
Law Offices of Evan K. Thalenberg, P.A.
216 East Lexington Street
Baltimore, Maryland 21202
(410) 625-9100

ELECTION FOR JURY TRIAL

The Plaintiff elects to have this case tried before a jury.

Evan K. Thalenberg

Circuit Court for Baltimore City
City or County

CIVIL—NON-DOMESTIC CASE INFORMATION REPORT

Directions:

Plaintiff: This Information Report must be completed and attached to the complaint filed with the Clerk of Court unless your case is exempted from the requirement by the Chief Judge of the Court of Appeals pursuant to Rule 2-111. A copy must be included for each defendant to be served.

Defendant: You must file an Information Report as required by Rule 2-323(h).

THIS INFORMATION REPORT CANNOT BE ACCEPTED AS AN ANSWER OR RESPONSE.

FORM FILED BY: ☒ PLAINTIFF ☐ DEFENDANT CASE NUMBER: (Clerk to insert)

CASE NAME: Shayonna Featherstone, et al (Plaintiff) v. Kennedy Kriger Institute, et al (Defendant)

JURY DEMAND: ☒ Yes ☐ No Anticipated length of trial: ____ hours or 5 days

RELATED CASE PENDING? ☐ Yes ☒ No If yes, Case #(s), if known: ____

HAS ALTERNATIVE DISPUTE RESOLUTION (ADR): Been Tried? ☐ Yes ☒ No Requested? ☐ Yes ☒ No

If yes, specify: ____

Special Requirements? ☐ Interpreter/communication impairment ☐ Other ADA accommodation: ____

NATURE OF ACTION (Check one box)

TORTS
- ☐ Motor Tort
- ☐ Premises Liability
- ☐ Assault & Battery
- ☐ Product Liability
- ☐ Professional Malpractice
- ☐ Wrongful Death
- ☐ Business & Commercial
- ☐ Libel & Slander
- ☐ False Arrest/Imprisonment
- ☐ Nuisance
- ☐ Toxic Torts
- ☐ Fraud
- ☐ Malicious Prosecution
- ☒ Lead Paint
- ☐ Asbestos
- ☐ Other ____

LABOR
- ☐ Workers' Comp.
- ☐ Wrongful Discharge
- ☐ EEO
- ☐ Other ____

CONTRACTS
- ☐ Insurance
- ☐ Confessed Judgment
- ☐ Other ____

REAL PROPERTY
- ☐ Judicial Sale
- ☐ Condemnation
- ☐ Landlord Tenant
- ☐ Other ____

OTHER
- ☐ Civil Rights
- ☐ Environmental
- ☐ ADA
- ☐ Other ____

DAMAGES / RELIEF

A. TORTS

Actual Damages
- ☐ Under $7,500
- ☐ $7,500 - $50,000
- ☐ $50,000 - $100,000
- ☒ Over $100,000

- ☐ Medical Bills $ ____
- ☐ Property Damages $ ____
- ☐ Wage Loss $ ____

B. CONTRACTS
- ☐ Under $10,000
- ☐ $10,000 - $20,000
- ☐ Over $20,000

C. NONMONETARY
- ☐ Declaratory Judgment
- ☐ Injunction
- ☐ Other ____

TRACK REQUEST

With the exception of Baltimore County and Baltimore City, please fill in the estimated LENGTH OF TRIAL. THIS CASE WILL THEN BE TRACKED ACCORDINGLY.

- ☐ 1/2 day of trial or less
- ☐ 1 day of trial time
- ☐ 2 days of trial time
- ☐ 3 days of trial time
- ☐ More than 3 days of trial time

IF YOU ARE FILING YOUR COMPLAINT IN BALTIMORE COUNTY, BALTIMORE CITY, OR PRINCE GEORGE'S COUNTY, PLEASE SEE REVERSE SIDE OF FORM FOR INSTRUCTIONS.

IF YOU ARE FILING YOUR COMPLAINT IN BALTIMORE COUNTY, BALTIMORE CITY, OR PRINCE GEORG COUNTY, PLEASE FILL OUT THE APPROPRIATE BOX BELOW.

CIRCUIT COURT FOR BALTIMORE CITY (check only one)

☐ Expedited	Trial 60 to 120 days from notice. Non-jury matters.
☐ Standard-Short	Trial seven months from Defendant's response. Includes torts with actual damages up to $7,500; contract claims up to $20,000; condemnations; injunctions and declaratory judgme
☐ Standard-Medium	Trial 12 months from Defendant's response. Includes torts with actual damages over $7,50 and under $50,000, and contract claims over $20,000.
☐ Standard-Complex	Trial 18 months from Defendant's response. Includes complex cases requiring prolonged discovery with actual damages in excess of $50,000.
☒ Lead Paint	Fill in: Birthdate of youngest plaintiff 9-11-93
☐ Asbestos	Events and deadlines set by individual judge.
☐ Protracted Cases	Complex cases designated by the Administrative Judge.

CIRCUIT COURT FOR PRINCE GEORGE'S COUNTY

To assist the Court in determining the appropriate Track for this case, check one of the boxes below. This information is not an admission and may not be used for any purpose other than Track Assignment.

☐ Liability is conceded.
☐ Liability is not conceded, but is not seriously in dispute.
☐ Liability is seriously in dispute.

CIRCUIT COURT FOR BALTIMORE COUNTY

☐ Expedited (Trial Date-90 days)	Attachment Before Judgment, Declaratory Judgment (Simple), Administrative Appeals, District Court Appeals and Jury Trial Prayers, Guardianship, Injunction, Mandamus.
☐ Standard (Trial Date-240 days)	Condemnation, Confessed Judgments (Vacated), Contract, Employment Related Cases, Fraud and Misrepresentation, Intentional Tort, Motor Tort, Other Personal Injury, Workers' Compensation Cases.
☐ Extended Standard (Trial Date-345 days)	Asbestos, Lender Liability, Professional Malpractice, Serious Motor Tort or Personal Injury Cases (medical expenses and wage loss of $100,000, expert and out-of-state witnesses (parties), and trial of five or more days), State Insolvency.
☐ Complex (Trial Date-450 days)	Class Actions, Designated Toxic Tort, Major Construction Contracts, Major Product Liabilities, Other Complex Cases.

EXHIBIT D

AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)

CONTRACT (Proc. Inst. Ident.) NO.: 01-ES-35362

3. EFFECTIVE DATE: SEE BLOCK 20C

4. REQUISITION/PURCHASE REQUEST/PROJECT NO.: 59528

ISSUED BY: CODE
ional Institute of
vironmental Health Sciences
ontracts & Procurement Management Branch, OM
.O. Box 12874 (79 Alexander Dr., 4401 Bldg.)
esearch Triangle Park, NC 27709

6. ADMINISTERED BY (If other than Item 5): CODE
OMB No. 0990-0115
ATTN: Thomas M. Hardee

NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, State and ZIP Code)

Kennedy Krieger Research Institute, Inc.
707 North Broadway
Baltimore, MD 21205

8. DELIVERY
☐ FOB ORIGIN ☒ OTHER (See below)

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: ITEM

DE FACILITY CODE

SHIP TO/MARK FOR: CODE
SEE ARTICLE C.3.c., ARTICLE G.2.

12. PAYMENT WILL BE MADE BY: CODE
SEE ARTICLE G.3.

. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:
☐ 10 U.S.C. 2304(c)( ) ☐ 41 U.S.C. 253(c)( )

14. ACCOUNTING AND APPROPRIATION DATA
DOC: N1ES35362A SOCC: 25.3T CAN: 3-8420886
EIN: 1-521524967-A1 PIN: A451

5A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	TITLE: "TOXICITY OF LEAD IN CHILDREN TRIAL -- CLINICAL CENTER"				
	NTRACT PERIOD OF PERFORMANCE: June 30, 1993 - June 29, 1998 (Sixty Months)				
	CONTRACT TYPE: Cost-Reimbursement, Completion Form				
	HUMAN SUBJECTS MULTIPLE PROJECT ASSURANCE NO.: M1011				
	CURRENT OBLIGATION:				$ 445,410

5G. TOTAL AMOUNT OF CONTRACT: BASIC: $5,765,029 INCLUDING OPTIONS: $5,951,305

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I — THE SCHEDULE	
X	A	SOLICITATION/CONTRACT FORM	
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	
X	D	PACKAGING AND MARKING	
X	E	INSPECTION AND ACCEPTANCE	
X	F	DELIVERIES OR PERFORMANCE	
X	G	CONTRACT ADMINISTRATION DATA	
X	H	SPECIAL CONTRACT REQUIREMENTS	
		PART II — CONTRACT CLAUSES	
X	I	CONTRACT CLAUSES	
		PART III — LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	J	LIST OF ATTACHMENTS	
		PART IV — REPRESENTATIONS AND INSTRUCTIONS	
X	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
	M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 2 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18. ☐ AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number ____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

19A. NAME AND TITLE OF SIGNER (Type or print)
Karen R. Cox
Research Administrator

20A. NAME OF CONTRACTING OFFICER

19B. NAME OF CONTRACTOR
BY Karen R. Cox (Signature of person authorized to sign)

19C. DATE SIGNED: 6/29/93

20B. UNITED STATES OF AMERICA
BY (Signature of Contracting Officer)

20C. DATE SIGNED

NSN 7540-01-152-8069
PREVIOUS EDITION UNUSABLE

26-107

STANDARD FORM 26 (REV. 4-85)
Prescribed by GSA
FAR (48 CFR) 53.214(a)

SECTION B

SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

"Toxicity of Lead in Children Trial -- Clinical Center"

ARTICLE B.2.a. ESTIMATED COST - BASIC CONTRACT (CLIN 0001)

a. The estimated cost of the work under this contract is $5,765,029.

b. Total funds currently available for payment and allotted to this contract are $445,410. For further provisions on funding, see the LIMITATION OF FUNDS clause incorporated herein.

c. It is estimated that the amount currently allotted will cover performance of the contract through June 29, 1994.

d. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

e. For general information only, the following schedule of incremental funding is provided:

Year 1	$ 445,410
Year 2	$1,864,556
Year 3	$1,157,636
Year 4	$1,123,879
Year 5	$1,173,548

f. Costs contributed/shared by the contractor shall not be charged to the Government under any other contract, grant, or cooperative agreement (including allocation to other grants, contracts, or cooperative agreements as part of an independent research and development program). The contractor shall report the organizations' share of the costs expended by category, on the Financial Report of Individual Project/ Contract NIH Form 2706, as referenced in SECTION G, ARTICLE G.4, Contract Financial Report. Costs applicable to this condition are salary rates in excess of $125,000 as precluded in accordance with Public Law (P.L.) 102-394 and as addressed in ARTICLE B.4.b. and ARTICLE H.12., and costs shared for the maintenance contracts as addressed in ARTICLE B.4.b.

ARTICLE B.2.b. ESTIMATED COST - OPTION No. 1, XRF (CLIN 0002)

a. The estimated cost of the work under this contract is $39,400.

b. Total funds currently available for payment and allotted to this contract are $_____. For further provisions on funding, see the LIMITATION OF FUNDS clause incorporated herein.

c. It is estimated that the amount currently allotted will cover performance of the contract through _____.

d. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.2.c. ESTIMATED COST - OPTION No. 2, Caldwell Testers (CLIN 0003)

a. The estimated cost of the work under this contract is $146,876.

b. Total funds currently available for payment and allotted to this contract are $_____. For further provisions on funding, see the LIMITATION OF FUNDS clause incorporated herein.

c. It is estimated that the amount currently allotted will cover performance of the contract through _____.

d. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the Clauses, ALLOWABLE COST AND PAYMENT, [and FIXED FEE (if applicable),] incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

(1) Acquisition, by purchase or lease, of any interest in real property;

(2) Special rearrangement or alteration of facilities;

(3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.); (See ARTICLE B.4)

(4) Travel to attend general scientific meetings; (See ARTICLE B.4)

(5) Foreign Travel;

(6) Patient Care Costs; (See ARTICLE B.4)

(7) Property classified as sensitive equipment, regardless of acquisition value (as defined in Appendix C of the 1990 HHS publication entitled Contractor's Guide for Control of Government Property);

(8) Capitalized non-expendable equipment (defined as both real and personal property having an acquisition cost of $1,000 or more with a life expectancy of more than two years). (See ARTICLE B.4)

b. Travel Costs

(1) Domestic Travel

(a) Total expenditures for domestic travel incurred in direct performance during the entire period of performance of this contract shall not exceed $30,765 including registration fees. Domestic travel expenditures incurred for any one year shall not exceed $10,000. The Contractor shall not incur costs in excess of the foregoing amounts without prior written approval of the Contracting Officer.

(b) The cost of travel by privately-owned automobile shall be reimbursed at the mileage rate prescribed by the contractor's established, generally applicable travel policy in lieu of actual cost, provided, however, that such reimbursement shall not exceed the otherwise allowable comparative cost of travel by common carrier. The initial rate applicable to this contract is $0.25/mile.

Reasonable actual costs of lodging and subsistence, or per diem in lieu of actual costs, shall be allowable to the extent that such actual costs or per diem amounts do not exceed the amounts or per diem rates prescribed by the contractor's established, generally applicable travel policy.

Any revision to the contractor's established, generally applicable travel policy submitted to the cognizant audit agency during the period of performance of this contract shall be effective, without formal modification to this contract, upon delivery to the contracting officer of notice describing such revised policy together with evidence of submission thereof to the cognizant audit agency.

(c) Government Contract Discounts for Air Fares, Hotel/Motel Accommodations, and Automobile Rentals

The Contractor may take advantage of Government contract discounts when performing travel authorized under this contract. The Contractor will be responsible for obtaining a copy of the Federal Travel Directory which lists the (GSA)

contractors offering discounts for air fares and automobile rentals, and the Federal Hotel/Motel Discount Directory which lists lodging accommodations. Information regarding yearly subscriptions for the Federal Travel Directory and the Federal Hotel/Motel Discount Directory may be obtained by contacting the Government Printing Office order desk at area code (202) 783-3238. Requests for subscriptions should be mailed to:

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

When using the Directories the Contractor should insure that the airlines, hotels/motels, or automobile rental firms listed in the appropriate directory offer Government rates. Next, if the Contractor elects to utilize Government contract discounts, the Contractor must write the Contracting Officer in advance, and request permission to use the GSA contractor. The Contracting Officer shall provide a specific authorization to use the Government fare which must be presented by the Contractor to the carrier with the payment for the flight.

Contract fare air carriers accepting payment only by Government Travel Order (GTR) may not be used since NIEHS does not issue GTRs to contractors.

Any savings achieved through the Contractor's use of Government travel discount programs shall accrue to the Government.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, authorization of the following items within the limits set forth is hereby granted.

a. Salary Rate Limitations

Pursuant to the conditions set forth in Public Law (P.L.) 102-394, ARTICLE H.12, the cost for reimbursement of salary rates currently in excess of the established limitation for the individuals named below shall be shared at a rate of 100% of the excess amount by Kennedy Research Institute or its subcontractors:

NAME	TITLE
J. Julian Chisolm, M.D.	Principle Investigator
Gary W. Goldstein, M.D.	Co-Principle Investigator
Martha B. Denckla, M.D.	Co-Principle Investigator

b. Subcontracts

(1) University of Maryland

A cost-reimbursable type subcontract with the University of Baltimore at Maryland to serve as a "mini-subcenter" in the recruitment of patients in the estimated cost of $599,499 is hereby authorized in accordance with FAR 44.201-2. The subcontract will provide for blood lead screening for lead toxicity of potential patients, identifying eligible recruits, and conducting follow-up blood monitoring throughout the course of the contract. Contracting Officer approval of the subcontract in accordance with FAR 44.203 will be granted upon receipt of a fully executed copy of the subcontract. The subcontract will contain the general clauses applicable to a non-profit educational institution.

(2) Johns Hopkins University School of Medicine

A cost-reimbursable type subcontract with the Johns Hopkins University School of Medicine to serve as a "mini-subcenter" in the recruitment of patients in the estimated cost of $593,962 is hereby authorized in accordance with FAR 44.201-2. The subcontract will provide for blood lead screening for lead toxicity of potential patients, identifying eligible recruits, and conducting follow-up blood monitoring throughout the course of the contract. Contracting Officer approval of the subcontract in accordance with FAR 44.203 will be granted upon receipt of a fully executed copy of the subcontract. The subcontract will contain the general clauses applicable to a non-profit educational institution.

c. Travel

Travel by the following individuals in the total amount of $30,761 for attendance at steering committee sessions, general scientific meetings, and project related training:

Principle Investigator
Co-Principle Investigators
Nurse Study Coordinator
Data Coordinator

d. Patient Care Costs

Patient care costs are provided through the subcontracts authorized under this contract. In accordance with the clause entitled "Research Patient Care Costs", NIH (RC)-11, the Contractor shall, through its subcontractors, make every reasonable effort to obtain third party payment where third party payors (including Government agencies) are authorized or under a legal obligation to pay all or a portion of the charges incurred under this contract for the appropriate types of procedures/tests. Only those charges not recoverable from third party

payors and which are consistent with the Terms and Conditions of the contract are chargeable to this contract.

e. Patient Travel

The contractor shall be responsible for all local travel associated with recruitment and retention of patients. The amount authorized to support this travel shall not exceed $228,500.

f. Patient Incentives

In order to recruit and retain sufficient numbers of children for participation in the study trial, the Contractor is authorized up to $48,700 for incentives approved by the IRB and protocol.

g. Clean-up

To ensure a safe environment of study patients, a maximum of $436,923 is authorized for lead dust clean-up. The Contractor shall not expend contract funds for lead abatement. (See ARTICLE H.14. for conditions applying to recovery of costs.)

h. Relocation

Relocation costs are authorized at a rate of $550 per relocation in cases where a patient must vacate the original primary residence. The total maximum allowable for relocation expenses is $13,750.

i. Cost Sharing

The following costs for equipment maintenance contracts shall be shared in the ratios indicated, with the Government's ratio being indicated first and the Contractor's ratio indicated second (Government/Contractor). The Contractor shall account for the charges by reporting the total costs incurred and the amount billed to the Government on NIH Form 2706, Financial Report of Individual Project/Contract.

Provider	Equipment Maintained	Estimated Cost	Share Ratio
Perkin Elmer Maintenance Plan	GFAA[1] model 2510OPC and peripherals	$7,190/yr	10%/90%
ESA, Inc.	ASV[2] model 3010A	$1,000/yr	50%/50%

[1] GFAA (Graphite Furnace Atomic Absorption Spectrophotometer)
[2] ASV (Anodic Stripping Voltammeter)

j. Lease Arrangements

Authorization is hereby granted for lease of one (1) compact vehicle at the rate of $159 per month.

SECTION C

DESCRIPTION/SPECIFICATION/WORK STATEMENT

ARTICLE C.1. BACKGROUND

Precedents: Since 1980, NIEHS has supported a series of longitudinal studies of childhood lead poisoning. These studies have shown small deficits in the cognitive development of young children in association with levels of blood lead commonly found in the US. NIEHS has also supported clinical studies leading to the licensure of the drug succimer, an orally administered chelating drug now labelled for use in children with blood lead levels above 45 µg/dl, a level thought to indicate a high risk for symptomatic lead poisoning and above the levels that produce cognitive delay.

General Background: Cognitive delay in toddlers has been associated with maternal lead levels in the 10-20 µg/dl range, and delays in four year olds with similar lead concentrations when they themselves were 2 years old. The Centers for Disease Control and the American Academy of Pediatrics have revised downward the blood lead levels of concern in young children, and children with blood lead levels greater than 10 µg/dl are now thought to have unacceptable exposure to lead. There are, however, no data on whether treatment of children with chelating agents prevents the cognitive delay associated with these levels. There are about four million children who fulfill the new criteria for unacceptable exposure to lead. NIEHS believes that large numbers of children with blood lead levels below 45 µg/dl will be treated with succimer, and that a clinical trial of the use of succimer in the prevention of lead-associated cognitive delay in young children is both necessary and timely. The objective of this Contract is to conduct, analyze, and issue a report of a randomized, multi-center, placebo controlled trial of succimer in the prevention of lead-associated cognitive delay in young children. This Contract is for one (1) of three (3) or possibly four (4) Clinical Centers. A separate, companion contract, N01-ES-35360 has been awarded for the support of the Coordinating Center.

ARTICLE C.2. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the work set forth below, including recruitment, treatment, retention, and follow-up of children in a clinical trial. In doing so, the Contractor shall comply with all local, state, and Federal laws and regulations pertinent to the various aspects of the trial. The Contractor shall conduct performance predicated on the agreements and understandings reached through discussions and negotiations leading to award based on the following documents which are incorporated by reference:

(1) Original Proposal dated November 24, 1992
(2) Revised Proposal dated May 10, 1993

(3) Best and Final Offer dated June 4, 1993
(4) Clarifying Information dated June 13, 1993

If there is any inconsistency between the referenced documents and the work described in Paragraph a. of this ARTICLE, the terms and conditions of Paragraph a. of this ARTICLE shall control.

(BASIC CONTRACT)

The protocol and strategies for the trial will result from the deliberations of the Steering Committee during the planning phase. The Steering Committee, as initially constituted, shall consist of the PIs of the Clinical Centers, the PI of the Coordinating Center, and the NIEHS Project Officer. The PI of the central lab will be a member of the Steering Committee ex officio. The Manual of Operations and Final Protocol shall be incorporated by reference into this Statement of Work when they are completed by the Steering Committee and approved by the Data and Safety Monitoring Committee. The clean up protocol at each site will be incorporated by reference into this Statement of Work when completed by the Clinical Center PI and approved by the Project Officer. The Steering Committee may elect to alter its composition at any time after it has been constituted; it must notify the PO of plans to do so. The trial shall proceed as follows: 9-12 months for planning; about 1 year for patient enrollment and treatment; the remaining 3 years for follow-up. Each child will be followed to age 4 at a minimum; longer follow-up is desirable for those children randomized early. Most close out activities should be completed by the final (5th) year of the contract. The activities, none of which are currently anticipated, of any center beyond five years from the initial award except for work specified herein will depend on the issuance of a continuation RFP by the Institute and successful re-competition. The trial is of oral chelation therapy with the drug succimer in lead exposed children (blood leads of about 20 μg/dl to 45 μg/dl) of about 18 to 36 months of age. The endpoints are the scores on developmental tests; other endpoints of interest include evidence of drug efficacy and compliance, such as urine and blood lead levels; excretion of other ions like iron, zinc, and calcium; and nervous system, renal and hematopoietic function/toxicity.

The Clinical Center shall evaluate the children prior to randomization for iron, vitamin, or other nutrient deficiency, and treat such deficiencies. Clinical Center staff, as may be augmented by local/state health officials, shall evaluate children's homes, and, if necessary, their day care or other sites where they spend time, and provide clean-up according to trial protocol. The criteria by which homes will be evaluated and the clean-up protocol shall be decided during the planning phase, but clean-up will not be identical at each site, and will consist of means suited to the catchment area of each Clinical Center. The Steering Committee shall, among their other functions, appoint a Clean-Up subcommittee, whose function will be to coordinate the various clean-up activities. However, the ultimate decision about clean-up methods at each site rests with the PI of the site and the PO. Chelation challenge and XRF studies are separately budgeted options, which may be included at some of the Clinical Centers (see "Options"below.

In cooperation with the Coordinating Center, the other Clinical Centers, and NIEHS staff, the Clinical Center shall participate in the design of the trial protocol, and then recruit, evaluate, treat and follow-up patients according to trial protocol. The Clinical Center shall provide data to the Coordinating Center, and monitor for efficacy and adverse effects. The Clinical Center shall participate in the randomization according to trial protocol and document that randomization has occurred according to assignment; and collect, monitor and edit data. The Clinical Center principal investigator (PI) shall participate, along with the other Clinical Center PIs, the Coordinating Center PI, and NIEHS program staff, in the final analyses and write-up of the studies.

Patient population: For purposes of planning the study, the Clinical Center shall provide to the Steering Committee the source population from which the Clinical Center will draw patients eligible for the trial, including numbers, ages, racial composition, and regular sources of health care. For all Centers combined, NIEHS estimates that evaluating the drug treatment for an effect of 3 developmental quotient points will require that the trial have 786 evaluable children with complete data at an absolute minimum; each Clinical Center shall recruit enough children so that on the order of 333 children per center are randomized. Stratified or blocked sampling may be desirable.

Recruitment: For purposes of planning the study, the Clinical Center shall provide to the Steering Committee a description of any previous efforts at recruiting patients into clinical studies at the institution, and plans for recruitment into this one. If referred patients are to be the source, then the referral sources shall be discussed and the rates of referral estimated.

If the Clinical Center must screen their population (or otherwise deal with children who have no information on recent blood lead levels) then it the Clinical Center shall provide blood lead analyses in support of the screening program; however, the blood lead level determination that actually determines eligibility will be performed centrally for the study (see Laboratory section below.)

Eligibility: Children eligible for the trial should be about two years old and have blood lead levels between about 20 and 45 µg/dl at the time of randomization, i.e., on at least two occasions and after iron deficiency is treated. (See women and minority recruitment below.)

Data collection schedules: The Clinical Center shall schedule and see the children according to trial protocol.

Source identification and clean-up: The Clinical Center will evaluate and clean-up the children's homes and other sites as necessary according to trial protocol. The Clinical Center shall identify lead sources in the child's environment and decrease the exposure in those who need it. If clean-up efforts involve other institutions, such as health departments, then the Clinical Center shall coordinate plans for working with them. Each Clinical Center shall be responsible for preparing its own clean up efforts, in consultation with the Clean-up Subcommittee.

Each Clinical Center shall provide short term housing as it considers necessary.

Nutritional management: The Clinical Center shall evaluate the children for iron deficiency and treat it, and insure that all children meet RDAs for relevant micronutrients, such as zinc and calcium, according to trial protocol. It is possible that there may be a high prevalence of iron deficiency, deficiency of micronutrients such as zinc, and diets deficient in calcium or other nutrients. The Clinical Center shall be responsible for monitoring compliance with such supplementation according to trial protocol.

Laboratory Support: Laboratory activities in support of this project are in three parts: blood lead levels used to determine the possible eligibility of the children for the trial (screening); clinical testing of the children, for iron status, hematocrit, etc., and monitoring of blood lead or urine lead levels immediately prior to randomization and during and after therapy. Each Clinical Center shall be responsible for those blood lead level determinations necessary to go from their catchment population to about 350-400 children who are iron-replete and who meet the trial's blood lead level criteria.

Each Clinical Center shall perform clinical monitoring of children, and including any laboratory procedures necessary for safety monitoring because the children are being treated under an IND.

Drug therapy: The Clinical Centers shall treat the children according to trial protocol. The treatment regimen will be decided upon by the Steering Committee during the planning phase.

Safety and efficacy monitoring: The Clinical Centers have the primary responsibility for the monitoring of the safety of the children and monitoring the efficacy of the drug. The Clinical Center shall be responsible for safety monitoring, and shall implement a means of following compliance, blood lead and urine lead according to trial protocol. The Clinical Center shall schedule the follow-up and evaluation of children.

Developmental testing: The Clinical Centers shall perform developmental testing of the children according to trial protocol.

Retention: The Clinical Center is primarily responsible for the retention of the children in the trial. A high percentage is absolutely necessary for the trial to succeed. The Clinical Center shall implement plans for keeping families active in the study, including contact with other than immediate family members, newsletters, etc. according to trial protocol and as appropriate for their catchment areas.

Clinical Center involvement with the Coordinating Center: The initial activity of the selected Coordinating Center and Clinical Centers shall be the development of a common protocol and study manual of operations. The Clinical Center PI shall cooperate with both the other Clinical Centers and with the Coordinating Center in carrying out the trial.

NIEHS will serve in a coordination, advisory, and assistance role at this stage, will approve final study design, and arbitrate disagreements between centers. The Clinical Center shall work with the Coordinating Center, any other Clinical Centers, NIEHS, and outside experts as appropriate.

Records: The Clinical Center shall generate quality data on the events in all phases of the trial. The Clinical Center shall document data that it provides to the Coordinating Center, and handle all study forms or their electronic equivalent appropriately. The Clinical Center shall insure confidentiality and security of records. In general, clinical records dealing directly with the care of the children are the property of the Clinical Center and subject to whatever safeguards the Institution has. To the degree possible, the government will not have access to individually identifiable records, which will reside with the Clinical Centers. In the event that the government must take possession of individually identifiable records, then the provisions of the Privacy Act apply. In such case, the NIEHS System of Records (Federal Register, Vol. 58, No. 8, Jan. 11, 1991) will apply for routine uses.

Monitoring: Monitoring shall be done according to trial protocol. The Clinical Center shall monitor the children and provide data to the Coordinating Center. The Clinical Center shall respond promptly to all queries raised by the Coordinating Center, and provide accurate, high quality data.

Interim reporting: Primary responsibility for interim reports on the progress of the trial in general rests with the Coordinating Center; however, the Clinical Center shall provide all data necessary for the construction of interim reports at site visits, meetings of the Data and Safety Monitoring Committee, etc., as they pertain to the individual Clinical Centers.

Publication: Reports for publication are the primary responsibility of the publications subcommittee; the Clinical Center's PI or a designee must be prepared to serve on that Committee. The initial design and main results papers of the study will be prepared by the subcommittee and appear under the name of the study, depending on the journal selected and journal policy. During the main analyses of the study, any publications proposed by a single Clinical Center from its own data must be seen and approved by the Steering Committee.

IND: NIEHS plans to sponsor the IND applications, but substantial cooperation will be needed from the Clinical Centers. The Clinical Center(s) shall provide all necessary support to NIEHS for the IND application.

Women and minority enrollment: Both boys and girls will be eligible. Encouragement of minority participation shall be part of the Clinical Centers' responsibilities.

Pilot: The decision as to whether to have a pilot study , and which institution will function as the pilot if there is one, will be made by the Steering Committee.

Treatment allocation: The Clinical Center shall randomize children into drug and placebo arms according to trial protocol.

Data handling: The Clinical Center shall be responsible for obtaining and transmitting data to the Coordinating Center under the trial protocol, including such aspects as programming, editing, and data transfer. Training in data entry shall be provided by the Coordinating Center.

Training: In addition to the general training provided by the Coordinating Center, the Clinical Center shall provide necessary training to and/or certification of study personnel at their site in home inspection, home clean up, nutritional evaluation and supplementation of children, developmental testing, and the other activities of the trial.

Study manual: The construction of the overall study manual will primarily be a responsibility of the Coordinating Center, but the Clinical Centers' staff will be the primary source for material on home evaluation, clean up, nutritional supplementation, management, and testing of the children.

Close out: The respective Clinical Centers shall be responsible for the orderly close-out of the trial at their sites, including active follow-up of patients, return of extra drugs or other materials to the Coordinating Center, and the establishment of a registry to enable later follow-up of the children. The Clinical Center shall deal with any questions arising about the conduct of the trial after publications have appeared.

(OPTION)

The following elements are not a requirement of the basic contract, but included as options which may be exercised in accordance with ARTICLE H.7., Options.

OPTIONAL - XRF and Chelation Challenge

NIEHS has not determined, at the time of the award of the basic contracts, whether or not to support XRF studies or chelation challenge studies. Clinical Centers taking this option have provided proposals and accompanying budgets. Before NIEHS decides to fund these options, it will request that the Steering Committee propose a coordinated protocol for XRF and/or chelation challenge studies. The cost of these studies shall not exceed, at each site, the amount budgeted for such studies in the Best and Final offer. If NIEHS approves an XRF or chelation challenge protocol and opts to fund it, the protocol will be included by reference in this requirement.

ARTICLE C.3. REPORTING REQUIREMENTS

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below:

a. Technical Reports

Type of Report	Description
Semi-annual Report* (1st year only)	Report describing progress in planning, recruitment, community activity, screening, etc. Emphasis on material not covered in Steering committee meetings.
Quarterly Progress Report* (subsequent years)	(1) Tabular material with numbers of families contacted and screened, or referrals; eligibles, numbers randomized, treated, and followed. Activities planned and executed during reporting period. Activities planned for next reporting period. Report of difficulties encountered which may affect further progress (2) Narrative describing study activities, with emphasis on those activities not covered in the Steering committee meetings.

b. Racial/Ethnic Enrollment Reports

Planned Enrollment Report	Summary of study population in terms of planned sample size and inclusion of participants by ethnic minorities (use table that follows).
Actual Enrollment Report	Summary of the number of participants actually enrolled according to designated racial/ethnic categories (use table that follows).

American Indian or Aleskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total

During the last portion of the planning phase (year 1), the programmer and study manager (2 people) will also be required to make three (3) trips for training. Three (3) trips for programmer and study manager for training will be required in the second year, and one (1) trip per year each for programmer and study manager for continued training in the third and fourth years of the contract. The destination for all training trips will be Research Triangle Park, North Carolina.

Two (2) trips per year in years 1-5 of the contract shall be made to scientific meetings of direct pertinence to the project.

Contractor shall support local travel for project staff.

The contractor shall be responsible for all local travel associated with recruitment and retention of patients.

SECTION D

PACKAGING, MARKING, AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

ARTICLE D.1. PACKAGING

The Contractor shall comply with special packaging requirements which may be identified in the protocol.

ARTICLE D.2. MARKING

All reports and other documents and materials to be delivered under this contract shall be submitted with a letter of transmittal identifying the contract number, project title, type of report or document, etc.

ARTICLE D.3. SHIPPING

All reports, documents, and other materials to be delivered under this contract shall be submitted to the addressee(s) in ARTICLE C.3.c.

SECTION E

INSPECTION AND ACCEPTANCE

ARTICLE E.1. INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this ARTICLE, Dr. Walter J. Rogan is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at the National Institute of Environmental Health Sciences, Division of Intramural Research, Research Triangle Park, NC. Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer, or the duly authorized representative.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

Number	Title
52.246-8	Inspection of Research and Development -- Cost-Reimbursement (APR 1984)

ARTICLE E.2. PROTOCOL ACCEPTANCE

Notification of the formal acceptance of the protocol shall be provided in writing by the Project Officer and endorsed by the Contracting Officer.

Failure of the contractor to recognize fully the cooperative nature of this project during any time of performance and failure of the contractor to abide by the approved shared protocol may result in Termination (either for convenience or default) in accordance with the Termination Clause (FAR 52.249-5).

SECTION F

DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The Period of Performance of this Contract shall be for a period of sixty (60) months, beginning June 30, 1993 and continuing through June 29, 1998. The Period of Performance encompasses the completion of all technical effort as described in Section C., ARTICLE C.2. and submission of all reports as specified in Section C., ARTICLE C.3.

ARTICLE F.2. DELIVERIES

a. Satisfactory performance of this contract shall be deemed to occur upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

(1) The items specified below as described in SECTION C, ARTICLE C.3. shall be delivered f.o.b. destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APR 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING, AND SHIPPING, if included, of this contract]:

Item	Description	Quantity	Delivery Schedule
(a)	Biannual Report		
(b)	Quarterly Progress Report		
(c)	Planned Enrollment Report		(See ARTICLE C.3.c.)
(d)	Actual Enrollment Report		
(e)	Final Report		

The above items shall be addressed and delivered to:

Addressee	Deliverable Item No.	Quantity
	(See ARTICLE 3.d)	

ARTICLE F.3. STOP WORK ORDER

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER I) CLAUSE:

52.212-13, STOP WORK ORDER (AUG 1989) - ALTERNATE I (APR 1984)

SECTION G

CONTRACT ADMINISTRATION DATA

ARTICLE G.1, REFERENCES TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

All references to the Secretary, Department of Health, Education and Welfare, HEW, HEWPR, HEW forms, etc., shall be changed to Secretary, Department of Health and Human Services, HHS, HHSAR, etc., as appropriate.

ARTICLE G.2, PROJECT OFFICER/ALTERNATE PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

Project Officer

Dr. Walter J. Rogan
Acting Clinical Director
National Institute of Environmental Health Sciences
Division of Intramural Research
P.O. Box 12233, Mail Drop A3-05
Research Triangle Park, NC 27709
Telephone No.: (919) 541-4578

Alternate Project Officer

Ms. Beth Ragan
National Institute of Environmental Health Sciences
Division of Intramural Research
P.O. Box 12233, Mail Drop A3-05
Research Triangle Park, NC 27709
Telephone No.: (919) 541-2767

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Alternate Project Officer is responsible for conducting the actions of the Project Officer as set forth in the above paragraph in the absence or other unavailability of the Project Officer. The authority of the Alternate Project Officer will not extend beyond those circumstances where the Project Officer is unable or unavailable to conduct the express limited responsibilities as set forth in this Contract and in the Project Officer's Appointment Letter.

**** For all other costs specifically approved under ARTICLE B.4., Advance Understandings, include separate cost information as an attachment.

ARTICLE G.5. FINAL PROTOCOL AND MANUAL OF OPERATIONS

The final Protocol and final Manual of Operations and all Project Officer approved revisions to those documents shall be automatically incorporated into this contract's Statement of Work.

The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor of any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.3. INVOICE SUBMISSION -- LETTER OF CREDIT (Payee Identification Number [PIN])

Advance payments will be provided pursuant to HHSAR Clause No. 352.232-73, entitled METHOD OF PAYMENT--LETTER OF CREDIT (APR 1984), which is incorporated in this contract by reference. The PIN is A451. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, are attached and made a part of this contract for the submission of completion and/or final invoices. The invoice instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper" invoice, pursuant to FAR 32.9. The completion and/or final invoice shall be submitted concurrently as follows:

(1) An original and two copies to the following office:

National Institutes of Health
Division of Financial Management
Contracts Section, FAAB
Building 31, Room B1B05A
9000 Rockville Pike
Bethesda, Maryland 20892

(2) Three copies to the following approving officer:

National Institute of Environmental Health Sciences
Attn: Contracting Officer
Contracts & Procurement Management Branch, OM
79 T.W. Alexander Drive, 4401 Building
P.O. Box 12874
Research Triangle Park, North Carolina 27709

(3) Inquiries regarding letter of credit payments should be directed to the office administering advance payments designated in HHSAR Clause No. 352.232-73 entitled, METHOD OF PAYMENT--LETTER OF CREDIT (APR 1984) at the following address:

Department of Health and Human Services/OASH/OM/ORM
Division of Payment Management
P.O. Box 6021
Rockville, Maryland 20852

Telephone: (301) 443-1350

ARTICLE G.4, CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Form NIH 2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the NIH Instructions, Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the thirtieth (30th) working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph d. below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. The first financial report shall cover the period consisting of the first full calendar month/first full calendar three months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a monthly/quarterly basis.

c. If the final payment of this contract is to be made on the basis of a desk audit, the Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This article does not supersede the record retention requirements in FAR Part 4.7.

d. The following expenditure categories shall be reported:

Direct Labor
Fringe Benefits
Project Management
Travel
Clinical Management
Lead Dust Management
QA/QC
Lab Analysis
Data Collection
Psychometrics
Indirect Costs
Subcontracts
Univ. of Maryland @ Baltimore
Johns Hopkins Univ. School of Medicine
Total Estimated Cost

* For Direct Labor, itemize the effort contributed by each individual on an attachment to Form 2706.

** For Costs recovered through 3rd party payers such as insurance carriers, landlords, et.al., indicate the costs recovered and subsequently credited to the contract

*** For costs shared for maintenance contracts, include the total amount charged by the service organization and the amount billed as the Government's portion.

ARTICLE G.5. FINAL PROTOCOL AND MANUAL OF OPERATIONS

The final Protocol and final Manual of Operations and all Project Officer approved revisions to those documents shall be automatically incorporated into this contract's Statement of Work.

SECTION H

SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. KEY PERSONNEL

a. Pursuant to the Key Personnel clause incorporated in this contract, by reference in Part II, Section I, the following individual(s) [is/are] considered to be essential to the work being performed hereunder:

NAME	TITLE
J. Julian Chisolm, M.D.	Principle Investigator
Gary W. Goldstein, M.D.	Co-Principle Investigator

b. When "key personnel" have been identified in this contract, it has been determined that such named personnel are necessary for the successful performance of this contract; and the Contractor agrees to assign such persons to the performance of the work under this contract, and shall not reassign or remove any of them without the consent of the Contracting Officer in accordance with the procedure outlined in d. below.

c. In addition, during the first ninety (90) days of performance, the Contractor shall make no substitutions of key personnel unless the substitution is necessitated by illness, death, or termination of employment. The Contractor shall notify the Contracting Officer within 15 calendar days after the occurrence of any of these events and provide the information required by Paragraph d. below. After the initial ninety (90) day period, the Contractor shall submit the information required by paragraph d. to the Contracting Officer at least 15 days prior to making any permanent substitutions.

d. The Contractor shall provide a detailed explanation of the circumstances necessitating the proposed substitutions, complete resumes for the proposed substitutes and any additional information requested by the Contracting Officer. Proposed substitutes shall have substantially equal abilities and qualifications to those of the persons being replaced. The Contracting Officer will notify the Contractor within 15 calendar days after receipt of all required information of the decision on substitutions. This article will be modified to reflect any approved changes of key personnel.

ARTICLE H.2. CRITICAL PERSONNEL

Positions designated as critical to the performance of this contract are set forth below. Whenever the Contractor anticipates changes to any personnel in these critical positions, the Contractor shall notify the Contracting Officer, providing detailed explanation of the circumstances necessitating the change(s), proposed substitution(s), resumes for the proposed substitute(s),

and any additional information requested by the Contracting Officer for review.

There are no critical personnel designated under this Contract

ARTICLE H.3. HUMAN SUBJECTS

The research involving human subjects required under this Contract shall not be conducted without the prior written joint approval of the Project Officer and Contracting Officer (See SECTION E. ARTICLE E.3.). As a condition for receiving such approval, the Contractor shall have provided to the Contracting Officer a properly completed Optional Form 310,"Protection of Human Subject Assurance Identification/Certification/Declaration", certifying Institutional Review Board (IRB) review and approval of the protocol. The appropriate human subjects multiple project assurance number applicable to this Contract is M1011.

ARTICLE H.4. HUMAN MATERIALS

No material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans. The acquisition and supply of all human specimen material (including fetal material) used under this contract will be obtained by the Contractor in full compliance with applicable State and local laws and the provisions of the Uniform Anatomical Gift Act in the United States and that no inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.5. PRIVACY ACT

This Contract requires the Contractor to do one or more of the following: design, develop or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violations of the Act may involve the imposition of criminal penalties. In compliance with the requirements of this Act, the Contractor shall utilize the NIEHS existing system of records, identified in the Federal Register, Volume 56, Number 8, January 11, 1991 under System of Records Number 09-25-0134.

ARTICLE H.6. GOVERNMENT PROPERTY

a. In addition to the requirements of the Clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor shall comply with the provisions of the DHHS Publication Contractor's Guide for Control of Government Property, dated 1990, which is incorporated by reference. Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations,

inventory, and reporting requirements under the contract. A copy of this publication is available from the Contract Property Administrator. This contract's Contract Property Administrator is:

Mike Zindell
Research Contracts Property Administrator
Research Contracts Property Administration
National Institutes of Health
Building 13, Room 2E-65
9000 Rockville Pike
Bethesda, MD 20892

Telephone: (301) 496-6466

ARTICLE H.7. CONTRACTOR-ACQUIRED GOVERNMENT PROPERTY - SCHEDULE I-A

Pursuant to the Clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor is hereby authorized to acquire the property listed in the attached Schedule I-A for use in direct performance of the contract. This contract is for scientific research and is with a nonprofit institution whose primary purpose is the conduct of scientific research. Therefore, pursuant to subparagraph (c)(2) of the Clause, GOVERNMENT PROPERTY, title to equipment having an acquisition cost of less than $5,000 shall vest in the Contractor and title to equipment having an acquisition cost of $5,000 or more purchased with funds made available under the contract shall vest in the Contractor subject to the provisions of the Clause, GOVERNMENT PROPERTY; provided that the Government may direct transfer of the title to the Government or to a third party within twelve months after completion or termination of the contract. The transfer of title to such equipment to the Government or to a third party shall not be the basis for any claim against the Government by the Contractor.

Schedule I-A

There is currently no property identified for this Contract

ARTICLE H.8. GOVERNMENT FURNISHED PROPERTY - SCHEDULE II-B

Pursuant to the Clause, GOVERNMENT PROPERTY, incorporated in this contract, the Government [agrees to furnish/has furnished] to the Contractor for use in direct performance of the contract, the items listed in Schedule II-B below:

Schedule II-B

1. Drugs to be administered during trial
2. Placebo to be administered during trial
3. Laboratory determinations of blood lead levels

ARTICLE H.9. OPTIONS

a. Unless the Government exercises its option(s) pursuant to paragraph b. and/or c. of this article, the contract consists only of the statement of work as defined in Sections C and F of this contract.

b. The Government may, by unilateral modification, exercise an option within six (6) months after contract award for XRF Studies. Preliminary written notice of its intent to exercise the options will be provided at least sixty (60) days in advance. The preliminary notice does not commit the Government to exercise the option.

c. The Government may, by unilateral modification, exercise an option within twelve (12) months after contract award for Caldwell Testing. Preliminary written notice of its intent to exercise the options will be provided at least sixty (60) days in advance. The preliminary notice does not commit the Government to exercise the option.

ARTICLE H.10. SAFETY AND/OR HEALTH STANDARDS

The Government is not legally responsible for accidents, illnesses, or claims arising out of any work undertaken as a result of this Contract. The Contractor shall take the steps necessary to ensure compliance with all pertinent local, state, and Federal statues relating to occupational health, safety, and environmental protection associated with this Contract. In accordance with PHSAR 352.223-70 incorporated by reference under PART II, all work under this contract shall be conducted in accordance with the following general standards, as appropriate:

1. Standards issued pursuant to the National Occupation Safety and Health Act of 1970 (Title 29, Code of Federal Regulations [CFR])

2. Standards issued pursuant to the Atomic Energy Act of 1954 (42 USC 2021)

3. Standards issued pursuant to the U.S. Environmental Protection Agency, Title 40 CFR, as amended

4. Standards issued pursuant to the Department of Transportation Hazardous Materials regulations (Title 49 CFR parts 72, 171-180)

The Clinical Center shall report by telephone or FAX services adverse reactions, serious unanticipated side effects, etc. to the Coordinating Center, to the NIEHS Project Officer and Contracting Officer, and to the Chairman of the Data Safety Monitoring Board, within one (1) work day. The notification shall be confirmed by the Contractor in writing.

ARTICLE H.11. CONFIDENTIALITY OF INFORMATION

Approval of the Project Officer will be required prior to publishing any data arising from contract studies. Information which will be derived from this project may require special consideration with regard to the timing of its disclosure in order to protect the interests of the Government and the public.

In consideration of this the clause HHSAR 352.224-70, CONFIDENTIALITY OF INFORMATION (APR 1984) is incorporated in this contract under PART II, SECTION I, ARTICLE I.3.b. Department of Health and Human Services Acquisition Regulations (HHSAR) (48 CFR Chapter 3) Clauses.

It is understood that this is a multi-center study and that a single center may not publish its own data until after multi-center publication or two (2) years following termination of the project, whichever comes first. Then a single Clinical Center may publish scientific papers from its own data. During the main analysis of the study, copies of any such papers shall be provided to the Steering Committee for review and comment forty-five (45) days prior to submission for publication or presentation.

ARTICLE H.12. SUBCONTRACTING PROVISIONS

a. Small Business and Small Disadvantaged Business Subcontracting Plan

(1) The Small Business and Small Disadvantaged Business Subcontracting Plan, undated, is attached hereto and made a part of this contract.

(2) The failure of any Contractor or Subcontractor to comply in good faith with the Clause entitled "Utilization of Small Business Concerns and Small Disadvantaged Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages - Small Business Subcontracting Plan."

b. Subcontracting Reports

(1) The Contractor shall submit the original and 2 copies of Subcontracting Report for Individual Contracts, SF-294 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30
October 30

The Report shall be sent to the following address:

National Institute of Environmental Health Sciences
Attn: Contracting Officer
Contracts & Procurement Management Branch, OM
79 T.W. Alexander Drive, 4401 Building
P.O. Box 12874
Research Triangle Park, North Carolina 27709

If difficulties are encountered in attaining established subcontracting goals, the Contractor or Subcontractor shall explain why and include their "good faith" efforts in Item 18, Remarks, in the SF-294.

(2) The Contractor shall submit 1 copy of Summary Subcontract Report, SF-295 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. The Summary Subcontract Report shall be submitted annually on October 30.

The first report shall be submitted after the first full year of this contract in addition to any fractional part of the year in which this contract became effective. This Report shall be mailed to the following address:

Office of Small and Disadvantaged Business Utilization
Department of Health and Human Services
Room 517-D
200 Independence Avenue, S.W.
Washington, D.C. 20201

ARTICLE H.13. SALARY RATE LIMITATION IN FISCAL YEAR 1993

Pursuant to Public Law (P.L.) 102-394, no NIH Fiscal Year 1993 (October 1, 1992 - September 30, 1993) funds may be used to pay the direct salary of an individual through this contract at a rate in excess of $125,000 per year (direct salary is exclusive of overhead, fringe benefits and general and administrative expenses). The $125,000 per year salary limit also applies to individuals proposed under subcontracts. If this is a multi-year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate exceeds any salary rate ceiling established in future HHS appropriations acts. P.L. 102-394 states in pertinent part:

"None of the funds appropriated in this title for the National Institutes of Health and the Substance and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of $125,000 per year."

ARTICLE H.14. RECOVERY OF COSTS

During performance of this Contract, where contract funds are expended to discharge performance of certain functions such as residential lead hazard clean-up, temporary housing, patient care, etc. which may in turn be reimbursed by parties bearing a legal obligation to have borne such costs originally, such costs shall be recovered from the appropriate sources and applied as a credit to the Contract.

The Contractor shall keep an accurate account of all payments received from recipients of third party payments or other payors when such charges have been previously billed to the Government, or for other costs recovered in

PART II - CONTRACT CLAUSES

SECTION I

CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSABLE TYPE CONTRACT WITH NON-PROFIT INSTITUTIONS OTHER THAN EDUCATIONAL INSTITUTIONS

FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (JUN 1988)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

FAR Clause No.	Title and Date
52.203-1	Officials Not to Benefit (APR 1984)
52.203-3	Gratuities (APR 1984)
52.203-5	Covenant Against Contingent Fees (APR 1984)
52.203-7	Anti-Kickback Procedures (OCT 1988)
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (SEP 1990)
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (JAN 1990) (Over $100,000)
52.209-6	Protecting the Government's Interests when Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (NOV 1992)
52.215-1	Examination of Records by Comptroller General (FEB 1993)
52.215-2	Audit-Negotiation (FEB 1993)
52.215-22	Price Reduction for Defective Cost or Pricing Data (JAN 1991) (over $100,000)
52.215-24	Subcontractor Cost or Pricing Data (DEC 1991) (over $100,000)
52.215-26	Integrity of Unit Prices (APR 1991)

52.215-31	Waiver of Facilities Capital Cost of Money (SEP 1987)
52.215-33	Order of Precedence (JAN 1986)
52.215-39	Reversion or Adjustment of Plans for Postretirement Benefits Other Than Pensions (PRB) (JUL 1991)
52.216-7	Allowable Cost and Payment (JUL 1991) NOTE: For contracts with hospitals, in paragraph (a) the words "Subpart 31.2 of the Federal Acquisition Regulation (FAR)" are deleted and the words "45 CFR part 74 appendix E" are substituted in lieu thereof. For contracts with nonprofit organizations exempted from OMB Circular A-122, in paragraph (a), the words "Subpart 31.2" are deleted and the words "Subpart 31.7" are substituted in lieu thereof.
52.216-11	Cost Contract - No Fee (APR 1984)
52.217-5	Evaluation of Options (JUL 1990)
52.219-8	Utilization of Small Business Concerns and Small Disadvantaged Business Concerns (FEB 1990)
52.219-9	Small Business and Small Disadvantaged Business Subcontracting Plan (over $500,000) (JAN 1991)
52.219-13	Utilization of Women-Owned Small Businesses (AUG 1986)
52.219-16	Liquidated Damages - Small Business Subcontracting Plan (over $500,000) (AUG 1989)
52.220-1	Preference for Labor Surplus Area Concerns (APR 1984)
52.220-3	Utilization of Labor Surplus Area Concerns (APR 1984)
52.222-2	Payment for Overtime Premium (JUL 1990) (over $100,000) NOTE: The amount to be inserted in paragraph (a) is "zero" unless specified otherwise elsewhere in this contract.
52.222-3	Convict Labor (APR 1984)

52.222-26	Equal Opportunity (APR 1984)
52.222-28	Equal Opportunity Preaward Clearance of Subcontracts ($1,000,000 or more) (APR 1984)
52.222-35	Affirmative Action for Special Disabled and Vietnam Era Veterans (APR 1984)
52.222-36	Affirmative Action for Handicapped Workers (APR 1984)
52.222-37	Employment Reports on Special Disabled Veterans and Veterans Era (JAN 1988)
52.223-2	Clean Air and Water (Over $100,000) (APR 1984)
52.223-6	Drug Free Workplace (JUL 1990)
52.224-1	Privacy Act Notification (APR 1984)
52.224-4	Privacy Act (APR 1984)
52.225-11	Restrictions on Certain Foreign Purchases (MAY 1992)
52.227-1	Authorization and Consent (APR 1984) Alternate I (APR 1984)
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement (APR 1984)
52.227-11	Patent Rights - Retention by the Contractor (Short Form) (JUN 1989)

NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.

The office designated to represent the Contracting Officer in administering this clause is:

Extramural Inventions Reports Office, OER
National Institutes of Health
Building 31, Room 5B41
9000 Rockville Pike
Bethesda, MD 20892

Telephone: (301) 402-0850

	Correspondence with respect to the patent clause shall be directed to the above address with a copy to the Contracting Officer.
52.227-16	Additional Data Requirements - (JUN 1987)
52.232-9	Limitation on Withholding of Payment (APR 1984)
52.232-20	Limitation of Funds (APR 1984)
52.232-23	Assignment of Claims (JAN 1986)
52.232-25	Prompt Payment (APR 1989) NOTE: In the second sentence of Paragraph (b)(2), the words "30th day" are inserted.
52.232-28	Electronic Funds Transfer Payment Methods (APR 1989) NOTE: The office designated to receive information in paragraph (c) is: National Institutes of Health Division of Financial Management Chief, Contracts Section, FAAB Building 31, Room B1B05A 9000 Rockville Pike Bethesda, Maryland 20892
52.233-1	Disputes (DEC 1991)
52.233-3	Protest After Award (AUG 1989) - Alternate I (JUN 1985)
52.242-1	Notice of Intent to Disallow Costs (APR 1984)
52.242-13	Bankruptcy (APR 1991)
52.243-2	Changes - Cost Reimbursement (AUG 1987) Alternate V - (APR 1984)
52.243-7	Notification of Changes (APR 1984) * Insert 15 days in each blank
52.244-2	Subcontracts (Cost-Reimbursement and Letter Contracts) (JUL 1985)
52.244-5	Competition in Subcontracting (APR 1984)
52.245-5	Government Property (Cost-Reimbursement, Time-and-Material, or Labor-Hour Contract) (JAN 1986) Alternate I. (JUL 1985)

52.246-23	Limitation of Liability (APR 1984)
52.249-5	Termination for Convenience of the Government (Educational and Other Nonprofit Institutions) (APR 1984)
52.253-1	Computer Generated Forms (APR 1984)

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR Clause No.	Title and Date
352.202-1	Definitions (APR 1984) -- Alternate I (APR 1984)
352.228-7	Insurance - Liability to Third Persons (DEC 1991)
352.232-9	Withholding of Contract Payments (APR 1984)
352.233-70	Litigation and Claims (APR 1984)
352.242-71	Final Decisions on Audit Findings (APR 1984)
352.270-5	Key Personnel (APR 1984)
352.270-6	Publications and Publicity (JUL 1991)
352.270-7	Paperwork Reduction Act (APR 1984)

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS, DELETIONS, AND MODIFICATIONS OF CLAUSES

1. HHSAR Clause 352.217-72, Additional Cost Principles (OCT 1990), is hereby deleted in its entirety

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following by reference, with the same force and effect as if they were given in full text. Upon request, the contracting officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

1. FAR 52.220-4, Labor Surplus Area Subcontracting Program (APR 1984)

2. FAR 52.227-14, Rights in Data - General (JUN 1987), Alternate V (JUN 1987)

3. FAR 52.227-16, Additional Data Requirements (JUN 1987)

4. FAR 52.227-17, Rights in Data - Special Works (JUN 1987)

5. FAR 52.230-2, Cost Accounting Standards (SEP 1987)

6. FAR 52.230-4, Administration of Cost Accounting Standards (SEP 1987)

7. FAR 52.230-5, Disclosure and Consistency of Cost Accounting Practices (SEP 1987)

8. FAR 52.251-1, Government Supply Sources (APR 1984)

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATIONS/PUBLIC HEALTH SERVICE ACQUISITION REGULATIONS (HHSAR) (PHSAR) (48 CFR CHAPTER 3) CLAUSES:

This contract incorporates the following clauses by reference with the same force and effect as if they were given in full text. Upon request, the contracting officer will make their full text available.

1. HHSAR 352.224-70, Confidentiality of Information (APR 1984)

2. HHSAR 352.270-1, Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities (APR 1984)

3. PHSAR 352.223-70, Safety and Health (APR 1984)
NOTE: The codes, standards and criteria required by paragraph (a) are set forth under Section H.

4. PHSAR 352.280-1, Protection of Human Subjects (OCT 1986)

c. CONTRACT CLAUSES INCORPORATED IN FULL TEXT

The following clauses are attached and made a part of this contract:

(1) NIH(RC)-1 Invoice/Financing Request Instructions for the NIH Cost-Reimbursement Type Contracts (6/18/92)

(2) NIH(RC)-7, Procurement of Certain Equipment (APR 1984) (OMB Bulletin 81-16)

(3) NIH(RC)-11, Research Patient Care Costs, (4/1/84)

ARTICLE I.4. FAR CLAUSE 52.203-9, REQUIREMENT FOR CERTIFICATE OF PROCUREMENT INTEGRITY - MODIFICATION (NOV 1990)

(a) Definitions. The definitions set forth in FAR 3.104-4 are hereby incorporated in this clause.

(b) The Contractor agrees that it will execute the certification set forth in paragraph (c) of this clause when requested by the Contracting Officer in connection with the execution of any modification of this contract.

(c) Certification. As required in paragraph (b) of this clause, the officer or employee responsible for the modification proposal shall execute the following certification:

CERTIFICATE OF PROCUREMENT INTEGRITY - MODIFICATION (NOV 1990)

(1) I, _____ [Name of certifier] am the officer or employee responsible for the preparation of this modification proposal and hereby certify that, to the best of my knowledge and belief, with the exception of any information described in this certification, I have no information concerning a violation or possible violation of subsection 27(a), (b), (d), or (f) of the Office of Federal Procurement Policy Act, as amended* (41 U.S.C. 423), (hereinafter referred to as "the Act"), as implemented in the FAR, occurring during the conduct of this procurement (contract and modification number).

(2) As required by subsection 27(e)(1)(B) of the Act, I further certify that to the best of my knowledge and belief, each officer, employee, agent, representative, and consultant of _____ [Name of Offeror] who has participated personally and substantially in the preparation or submission of this proposal has certified that he or she is familiar with, and will comply with, the requirements of subsection 27(a) of the Act, as implemented in the FAR, and will report immediately to me any information concerning a violation or possible violation of subsections 27(a), (b), (d), or (f) of the Act, as implemented in the FAR, pertaining to this procurement.

(3) Violations or possible violations: (Continue on plain bond paper if necessary and label Certificate of Procurement Integrity - Modification (Continuation Sheet), ENTER "NONE" IF NONE EXISTS) _____

_____

_____

_____

_____

[Signature of the officer or employee responsible for the modification proposal and date]

_____

[Typed name of the officer or employee responsible for the modification proposal]

*Subsections 27(a), (b), and (d) are effective on December 1, 1990. Subsection 27(f) is effective on June 1, 1991.

THIS CERTIFICATION CONCERNS A MATTER WITHIN THE JURISDICTION OF AN AGENCY OF THE UNITED STATES AND THE MAKING OF A FALSE, FICTITIOUS, OR FRAUDULENT CERTIFICATION MAY RENDER THE MAKER SUBJECT TO PROSECUTION UNDER TITLE 18, UNITED STATES CODE, SECTION 1001.

(End of certification)

(d) In making the certification in paragraph (2) of the certificate, the officer or employee of the competing Contractor responsible for the offer or bid, may rely upon a one-time certification from each individual required to submit a certification to the competing Contractor, supplemented by periodic training. These certifications shall be obtained at the earliest possible date after an individual required to certify begins employment or association with the contractor. If a contractor decides to rely on a certification executed prior to the suspension of section 27 (i.e., prior to December 1, 1989), the Contractor shall ensure that an individual who has so certified is notified that section 27 has been reinstated. These certifications shall be maintained by the Contractor for a period of 6 years from the date a certifying employee's employment with the company ends or, for an agency, representative, or consultant, 6 years from the date such individual ceases to act on behalf of the contractor.

(e) The certification required by paragraph (c) of this clause is a material representation of fact upon which reliance will be placed in executing this modification.

PART III

LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Small Business and Small Disadvantaged Business Subcontracting Plan, undated, 6 pages

2. NIH 2706, Financial Report of Individual Project/Contract, 2 pages

3. NIH Instructions, Instructions for Completing Form NIH 2706, dated 5/92, 2 pages

4. Standard Form SF-LLL, Disclosure of Lobbying Activities, 1/90, 3 pages

5. NIH(RC)-1 Invoice/Financing Request Instructions for the NIH Cost-Reimbursement Type Contracts (6/18/92), 6 pages

6. NIH(RC)-7, Procurement of Certain Equipment (APR 1984) (OMB Bulletin 81-16), 1 page

7. NIH(RC)-11, Research Patient Care Costs, (4/1/84), 1 page

8. Optional Form 310, Protection Of Human Subjects Assurance of Identification/Certification/Declaration, dated 9-92, 1 page

9. Authorization to Use GSA Supply Sources, NIH Form 1705, 1 page

PART IV

REPRESENTATIONS AND INSTRUCTIONS

SECTION K

REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS OR QUOTERS

The following documents are incorporated by reference in this contract:

1. Representations and Certifications dated November 20, 1992.

2. Kennedy Krieger Research Institute Initial Proposal dated November 23, 1992; Revised Proposal dated May 12, 1993; Best and Final Offer dated June 4, 1993; and Clarifying Information dated June 18 - 25, 1993.

Attachment 1

KENNEDY KRIEGER RESEARCH INSTITUTE

1. Contract Number: NO1-ES-92-31

   Contract Period: 07/01/93 - 06/30/98

   Title: TOXICITY OF LEAD IN CHILDREN

   Description: A placebo controlled trial of succimer in the prevention of lead-associated cognitive delay in young children

2. Contractor Name: Kennedy Krieger Research Institute

3. Individual Completing this Plan:
   Neuman, Micheal, CPA
   Assistant VP/Controller
   Kennedy Krieger Institute
   Baltimore, MD 21205
   (410) 550 - 9472

4. Percentage Goals:

It is the policy of the Kennedy Krieger Research Institute (KKRI) that Small Business and Small Disadvantaged Business concerns be given the maximum practical opportunity to compete for the requirements of materials, equipment and services consistent with the efficient performance of this Research Project.

The KKRI establishes the following percentage goals for the proposed contract:

	Prime Contract	Percent	External Purchases	Percent
Total Estimated Dollars	$ 2,867,080	100%	$ 970,176	100%
Small Business	659,178	23.0%	659,178	67.9%
Small Disadvantaged	74,390	2.6%	74,390	7.7%

5. Comment on Goals and Subcontract Possibilities with Small businesses and Small Disadvantaged Businesses:

The percentage totals were determined by examining the total subcontracting possibilities inherent in this Research Project, and by estimating the likely Small Business and Small Disadvantaged Business utilization based on historical trends.

The KKRI will continue its attempts to find qualified Small Business and Small Disadvantaged Business Subcontractors to assist it in fulfilling its obligations under this contract.

6. Subcontracting Plan Administration:

The following individuals are designated to administer the subcontracting under this research project:

Project Manager (TBN.)
Toxicity of Lead in Children - DSMA Clinical Trial

The following KKRI procurement personnel have assisted in developing this Subcontracting Plan, and will continue to provide services and information to maximize Small Business and Small Disadvantaged Business utilization:

Gamache, Thomas, BA
Manager, Purchasing Department
Kennedy Krieger Institute
Baltimore, MD 21205
(410) 550 - 9472

Project Manager (TBN.)
Toxicity of Lead in Children - DSMA Clinical Trial

The duties of the Project Manager and Director of Purchasing with respect to Small Business concerns include the following:

(a) Identify qualified Small Business and Small Disadvantaged Business concerns as potential suppliers for KKRI requirements.

(b) Coordinate with the KKRI buyers to ensure that Small Business and Small Disadvantaged Business Concerns are considered fairly as subcontractors and supplies.

(c) Maintain appropriate records.

(d) Prepare and submit required reports.

(e) Keep abreast of current requirements, recent literature and forthcoming seminars in the field.

7. The KKRI Efforts to Assure Small Business and Small Disadvantaged Businesses Have Maximum Practical Opportunity:

The President of the KKRI has designated the Purchasing Department to carry the lead responsibility for implementing the KKRI's Small Business and Small Disadvantaged Business policy, and has confirmed the Institute's intent to take greater initiatives to encourage Small Business and Small Disadvantaged Business involvement in the procurement process. These actions are an appropriate extension of the Institute's fundamental policy of Equal Opportunity. Each individual faculty and staff member will be informed of this intent.

The Institute's efforts in this program include:

(a) Maintain directories and company brochures of Small Business and Small Disadvantaged Business Concern, keeping the KKRI

procurement staff aware of current directories and new information.

(b) Circulate company brochures to the KKRI faculty and staff.

(c) Attend Small Business and Small Disadvantaged Business Fairs and Expositions and Seminars as appropriate.

(d) Make various levels of KKRI Management, including program managers and staff members responsible for initiating procurement actions, aware of the Institute's responsibilities toward Small Business and Small Disadvantaged Business concerns.

(e) Make site visits as appropriate to Small Business and Small Disadvantaged Businesses.

(f) Receive visits from Small Businesses and Small Disadvantaged Businesses as appropriate.

(g) Include Small Businesses and Small Disadvantaged Businesses on bidder's lists where appropriate.

(h) Include appropriate instructions in the Institute's Administrative Manuals, and insert items in the Administrative Bulletin.

(i) Advise Small Business and Small Disadvantaged Business officials on problems before these result in loss of a subcontract or loss of future business opportunity.

(j) Monitor the United States Code, the Code of Federal Regulations, and the Federal Register for the purpose of keeping apprised of all applicable statutes and implementing regulations.

8. Records Maintained:

To demonstrate compliance with the procedures and goals set forth in this Plan, the following types of records will be maintained:

(a) Records showing solicitation of and awards to Small Businesses and Small Disadvantaged businesses.

(b) Summary records of buyer's bids, showing Small Business and Small Disadvantaged Business solicitations.

(c) Catalogs and brochures from Small Businesses and Small Disadvantaged Businesses.

(d) Documentation regarding site visits to Small Businesses and Small Disadvantaged Businesses.

(e) Documentation regarding site visits by Small businesses and Small Disadvantaged Businesses to the KKRI.

(f) Directories of Small Businesses and Small Disadvantaged Businesses.

(g) Computerized reports of Small Business and Small Disadvantaged Business utilization.

9. Statement of Assurances

The Kennedy Krieger Research Institute certifies that the appropriate clauses required by the General Provisions of this prime contract will be included in all subcontracts which offer further subcontracting opportunities, and that as the Prime Contractor we will require all subcontractors (except Small Business Concerns) who may received subcontracts in excess of $500,000 in case of a subcontract for all other contracts, to adopt a plan similar to this plan. Further , the Institute will submit such periodic reports as required and cooperate in any studies or surveys as may be required and in every way as required under the Solicitation Provisions outlined under Subpart 52.219.9 of the Federal Acquisition Regulations.

Neuman, Micheal, CPA
Assistant VP/Controller

KENNEDY KRIEGER RESEARCH INSTITUTE

POLICY OF COMPLIANCE WITH PUBLIC LAW 95-507

It is the policy of the Kennedy Krieger Research Institute that Small Business and Small Disadvantaged Business concerns be given the maximum practical opportunity to compete for the requirements of material, equipment and services consistent with the efficient performance of individual research projects.

The Institute establishes percentage goals for each proposed contract. These goals are determined by examining the total subcontracting possibilities inherent in each research project, and buy estimating the likely Small Business and Small Disadvantaged Business utilization based on historical trends.

The Institute continues to attempt to find qualified Small Business and Small Disadvantaged Business Subcontractors to assist it in fulfilling its obligations under the contracts.

In order to assure the Small Business and Disadvantaged Businesses have maximum practical opportunity, the University maintains catalogs, directories and brochures of Small Business and Small Disadvantaged Business concerns and circulates them among appropriate University Faculty and Staff. In addition to attending business fairs, expositions, and seminars, the University also advises and counsels business concerns regarding procurement procedures and placement on bidder's lists where appropriate.

The United States Code, the Code of Federal Regulations, and the Federal Register are regularly monitored for the purpose of keeping apprised of all applicable statues and implementing regulations.

Records showing solicitations of bids and bid awards are maintained to demonstrate compliance with the procedures and goals set forth for each subcontracting plan. Documentation of site visits made to Small and Small Disadvantaged Businesses in addition to computerized utilization reports are kept on file.

The President of the Institute has designated the Purchasing Department to carry the lead responsibility for implementing the Institute's Small Business and Small Disadvantaged Business policy, and had confirmed the Institute's intent to take greater initiatives to encourage Small Business and Small Disadvantaged Business involvement in the procurement process. These actions are an appropriate extension of the Institutes's fundamental policy and Equal Opportunity.

KENNEDY KRIEGER INSTITUTE
SMALL BUSINESS PLAN
SUMMARY OF EXTERNAL EXPENSES

PURCHASE/SERVICE	CONTEMPLATED SUPPLIER	BUSINESS CLASSIFICATION	
PROJECT MANAGEMENT			
SUPPLIES			
OFFICE SUPPLIES	LUCAS BROTHERS	LARGE	$19,615
PHOTOCOPYING SUPPLIES	LUCAS BROTHERS	LARGE	5,230
OTHER			
POSTAGE	U.S.P.S.	LARGE	9,150
SHIPPING	FEDERAL EXPRESS	LARGE	6,474
TELEPHONE	BELL ATLANTIC	LARGE	57,881
ADVERTISING	DAVIS ADVERTISING	SMALL	1,800
BOOKS & MANUALS	VARIOUS	LARGE	1,000
TYPING AND CLERICAL SERVICES	CAREERS, USA	SDB	8,602
TRAVEL	REIMBURSEABLE	LARGE	21,185
	BON VOYAGE TRAVEL	SDB	9,579
CLINICAL MANAGEMENT			
CLINICAL SUPPLIES	VWR	LARGE	6,592
PATIENT TRANSPORTATION	YELLOW CAB CO.	SMALL	228,005
VITAMINS	EDWARDS AND ANTHONY	SDB	56,209
LEAD DUST MANGEMENT			
CONSULTANTS	VARIOUS	LARGE	1,000
RANDOM DUST SAMPLES	IN-HOUSE	LARGE	28,035
HOUSE INTERVENTIONS	VARIOUS	SMALL	406,886
RELOCATION	EASTERN MOVING AND STORAGE	SMALL	13,750
QUALITY CONTROL			
STANDARD REFERENCE MATERIALS	VWR	LARGE	7,912
LABORATORY ANALYSIS			
ELECTRODE/ELECTRODE COMPARTMENT	VWR	LARGE	3,300
MAINTENANCE CONTRACTS	CHESAPEAKE LEASING	SMALL	6,735
DATA COLLECTION - FIELD			
PARTICIPATION INCENTIVES	VARIOUS	LARGE	48,700
VEHICLES	VARIOUS	LARGE	15,894
PSYCHOMETRICS			
TESTING MATERIALS	VARIOUS	LARGE	4,836
		TOTAL - LARGE BUSINESS	$234,404
		TOTAL - SMALL BUSINESS	$659,178
		TOTAL - SDB	$74,390
		TOTAL - COMBINED	$970,174

[illegible] Institutes of Health

Financial Report of Individual Project/Contract

Complete this form in accordance with accompanying instructions.

Toxicity Lead in Ch[illegible]ren's Trial -- Clinical C[illegible]ter Program

NO1-ES-35362

0990-0134
0990-0131

Reporting Period: (YEAR 1)

Contractor's Name and Address:
Kennedy Krieger Research Institute, Inc.
707 North Broadway
Baltimore, MD 21205

Expenditure Category	Percentage of Effort/Hours		Cumulative Incurred Cost at End of Prior Period	Incurred Cost–Current Period	Cumulative Cost to Date (D + E)	Estimated Cost to Complete	Estimated Cost at Completion (F + G)	Funded Contract Amount	Variance (Over or Under) (I + H)
	Funded	Actual							
A	B	C	D	E	F	G	H	I	J
Direct Labor								$156,012	
Fringe Benefits								42,124	
Project Management								15,086	
Travel								9,950	
Clinical Management								-0-	
Lead Dust Management								1,000	
QA/QC								286	
Lab Analysis								-0-	
Data Collection								1,854	
Psychometrics								-0-	
Indirect Costs								126,735	
Subcontracts									
University of Maryland - Baltimore								47,777	
Johns Hopkins University School of Medicine								44,586	
Total Estimated Costs								445,410	

NIH 2706 (5/92). *(Formerly HHS 646)*

Attachment 2

Case 1:07-cv-01120-WMN Document 1-6 Filed 05/01/07 Page 47 of 62

nal Institutes of Health

Financial Report of Individual Project/Contract

Complete this form in accordance with accompanying instructions.

Toxicity Lead in C ildren's Trial -- Clinical Center Program

NO1-ES-35362

0990-0134
0990-0131

Reporting Period

(TOTAL ESTIMATED COSTS)

Contractor's Name and Address
Kennedy Krieger Research Institute, Inc.
707 North Broadway
Baltimore, MD 21205

Expenditure Category	Percentage of Effort/Hours		Cumulative Incurred Cost at End of Prior Period	Incurred Cost–Current Period	Cumulative Cost to Date (D + E)	Estimated Cost to Complete	Estimated Cost at Completion (F + G)	Funded Contract Amount	Variance (Over or Under) (I + H)
	Funded	Actual							
A	B	C	D	E	F	G	H	I	J
Direct Labor								$1,493,627	
Fringe Benefits								403,277	
Project Management								109,755	
Travel								30,765	
Clinical Management								290,806	
Lead Dust Management								451,673	
QA/QC								7,912	
Lab Analysis								9,836	
Data Collection								64,594	
Psychometrics								4,836	
Indirect Costs								1,605,564	
Subcontracts									
University of Maryland - Baltimore								699,794	
Johns Hopkins University School of Medicine								592,591	
Total Estimated Costs								5,765,029	

NIH 2706 (5/92) *(Formerly HHS 646)*

Case 1:07-cv-01120-WMN Document 1-6 Filed 05/01/07 Page 48 of 62

Instructions for Completing Form NIH 2706— "Financial Report of Individual Project/Contract"

GENERAL INFORMATION

Purpose. Form NIH 2706 is designed to: (1) provide a management tool for use by NIH in monitoring the application of financial and personnel resources to NIH contracts, (2) provide contractors with financial and personnel management data which is usable in their management processes, (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel, and (4) obtain contractor's analyses of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

(a) **Scope.** The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

(b) **Number of Copies and Mailing Address.** An original and two (2) copies of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than the 30th working day after the end of the period reported.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate Form NIH 2706, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing Form NIH 2706. For the purpose of establishing expenditure categories in Column A the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) **Personnel—Professional.** Included are the senior level and all other personnel whose total annual salary rates are $50,000 or more. It should include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel—Other.** This will be listed as one amount unless otherwise required by the contract.

(3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property.** Nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See the DHHS "Contractor's Guide for Control of Government Property."

(5) **Supplies.** Includes the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care.** Costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) **Outpatient Care.** Costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) **Travel.** Includes all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify

Attachment 4

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OA
0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action:	2. Status of Federal Action:	3. Report Type:
☐ a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	☐ a. bid/offer/application b. initial award c. post-award	☐ a. initial filing b. material change For Material Change Only: year _____ quarter _____ date of last report _____

4. Name and Address of Reporting Entity:	5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime:
☐ Prime ☐ Subawardee Tier _____, *if known:* Congressional District, *if known:*	Congressional District, *if known:*
6. Federal Department/Agency:	7. Federal Program Name/Description: CFDA Number, *if applicable:* _____
8. Federal Action Number, *if known:*	9. Award Amount, *if known:* $
10. a. Name and Address of Lobbying Entity *(if individual, last name, first name, MI):*	b. Individuals Performing Services *(including address if different from No. 10a)* *(last name, first name, MI):*

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

11. Amount of Payment *(check all that apply):*	13. Type of Payment *(check all that apply):*
$ _____ ☐ actual ☐ planned	☐ a. retainer ☐ b. one-time fee ☐ c. commission ☐ d. contingent fee ☐ e. deferred ☐ f. other; specify: _____
12. Form of Payment *(check all that apply):* ☐ a. cash ☐ b. in-kind; specify: nature _____ value _____	

14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for Payment indicated in Item 11:

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

15. Continuation Sheet(s) SF-LLL-A attached: ☐ Yes ☐ No

16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Signature: _____

Print Name: _____

Title: _____

Telephone No.: _____ Date: _____

Federal Use Only:

Authorized for Local Reproduction
Standard Form - LLL

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee", then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).

11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material change report, enter the cumulative amount of payment made or planned to be made.

12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.

13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.

14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.

15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.

16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

DISCLOSURE OF LOBBYING ACTIVITIES
CONTINUATION SHEET

Approved by OMB
0348-0046

Reporting Entity: _____ Page _____ of _____

*U.S. G.P.O. 1990-260-705:00012

Authorized for Local Reproduction
Standard Form - LLL-A

INVOICE/FINANCING REQUEST INSTRUCTIONS FOR NIH COST-REIMBURSEMENT TYPE CONTRACTS

General: The contractor shall submit claims for reimbursement in the manner and format described herein and as illustrated in the sample invoice/financing request.

Format: Standard Form 1034, "Public Voucher for Purchases and Services Other Than Personal;" and Standard Form 1035, "Public Voucher for Purchases and Services Other Than Personal-- Continuation Sheet," or reproduced copies of such forms marked ORIGINAL should be used to submit claims for reimbursement. In lieu of SF-1034 and SF-1035, claims may be submitted on the payee's letter-head or self-designed form provided that it contains the information shown on the sample invoice/financing request.

Number of Copies: As indicated in the Invoice Submission clause in the contract.

Frequency: Invoices/financing requests submitted in accordance with the payment clause shall be submitted monthly unless otherwise authorized by the contracting officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include: (1) Costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the amount and month(s) in which such costs were incurred shall be cited.

Contractor's Fiscal Year: Invoices/financing requests shall be prepared in such a manner that costs claimed can be identified with the contractor's fiscal year.

Currency: All NIH contracts are expressed in United States dollars. Where expenditures are made in a currency other than United States dollars, billings on the contract shall be expressed, and reimbursement by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the contracting officer's approval which are not set forth in an advance understanding in the contract shall be so identified and reference the Contracting Officer's Authorization (COA) number.

Invoice/Financing Request Identification: Each invoice/financing request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request** — These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice** — The completion invoice is a final invoice which is submitted promptly upon completion of the work, but no later than one year from the contract completion date. The completion invoice should be submitted when all costs (except for finalization of indirect cost rates) have been assigned to the contract and all performance provisions have been completed.

(c) **Final Invoice** — A revised final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., final indirect cost rates and resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the explanatory notes below. These notes are keyed to the entries on the sample invoice/financing request.

(a) **Payor's Name and Address** — The paying office and address, identified in the Invoice Submission clause of the contract, shall be entered on all copies of the invoice/financing request.

(b) **Invoice/Financing Request Number** — Insert the appropriate serial number of the invoice/financing request.

(c) **Date Invoice/Financing Request Prepared** — Insert the date the invoice/financing request is prepared.

(d) **Contract Number and Date** — Insert the contract number and the date of the contract.

(e) **Payee's Name and Address** — Show the Contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) **Total Estimated Cost of Contract** — Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

(g) **Total Fixed-Fee** — Insert the total fixed-fee (where applicable).

(h) **Billing Period** — Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(i) **Amount Billed for Current Period** — Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the period.

(j) **Cumulative Amount from Inception to Date of this Billing** — Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

(k) **Direct Costs** — Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor** — This consists of salaries and wages paid (or accrued) for direct performance of the contract.

(2) **Fringe Benefits** — This represents fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.

(3) **Accountable Personal Property** — This category of cost includes permanent research equipment and general purpose equipment having a unit acquisition cost of $1000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS *Contractor's Guide for Control of Government Property.*) Show permanent research equipment separate from general purpose equipment. Prepare and attach Form HHS-565, "Report of Accountable Property," in accordance with the following instructions:

List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

(A) The item number for the specific piece of equipment listed in the Property Schedule;

(B) The Contracting Officer's Authorization letter and number, if the equipment is not covered by the Property Schedule, or;

(C) Be preceded by an asterisk (*) if the equipment is below the approval level.

Further itemization of invoices/financing requests shall only be required for items having specific limitations set forth in the contract.

(4) **Materials and Supplies** — This category includes equipment with unit costs of less than $1000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

(5) **Premium Pay** — This is remuneration in excess of the basic hourly rate.

(6) **Consultant Fee** — Fees paid to consultants. Identify consultant by name or category as set forth in the contract's advance understanding or in the COA letter, as well as the effort (i.e., number of hours, days, etc.) and rate being billed.

(7) **Travel** — Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel should be billed separately from domestic travel.

(8) **Subcontract Costs** — List subcontractor(s) by name and amount billed.

(9) **Other** — List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000 list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element should be listed separately.

(l) **Cost of Money (COM)** — Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(m) **Indirect Costs--Overhead** — Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(n) **Fixed-Fee Earned** — If the contract provides for a fixed-fee, it must be claimed as provided for by the contract. Cite the formula or method of computation.

(o) **Total Amounts Claimed** — Insert the total amounts claimed for the current and cumulative periods.

(p) **Adjustments** — This includes amounts conceded by the contractor, outstanding suspensions, and disapprovals subject to appeal.

(q) **Grand Totals**

The Contracting Officer may require the Contractor to submit detailed support for costs claimed on one or more interim invoices/financing requests.

SAMPLE INVOICE/FINANCING REQUEST

(a) Payor's Name and Address
NATIONAL INSTITUTES OF HEALTH
Division of Financial Management
Contracts Section, FAAB
Building 31, Room B1B05A
Bethesda, Maryland 20892

(b) Invoice/Financing Request No. _____

(c) Date Invoice Prepared

(d) Contract No. and Date

(e) Payee's Name and Address
ABC CORPORATION
100 Main Street
Anywhere, U.S.A. zip code

(f) Total Estimated Cost of Contract

(g) Total Fixed Fee

Attention: Name, Title, and Phone Number of Official to Whom Payment is Sent

(h) This invoice/financing request represents reimbursable costs from Aug. 1, 1982 through Aug. 31, 1982

	(i) Amount Billed for Current Period	(j) Cumulative Amount From Inception to Date of this Billing
(k) Direct Costs		
(1) Direct Labor	$ 3,400	$ 6,800
(2) Fringe Benefits	600	1,200
(3) Accountable Personal Property (Attach Form HHS-565)		
Permanent Research	3,000	8,000
General Purpose	2,000	
(4) Materials and Supplies	2,000	4,000
(5) Premium Pay	100	150
(6) Consultant Fee-Dr. Jones 1 day @ 100 (COA #3)	100	100
(7) Travel (Domestic)	200	200
(Foreign)	200	200
(8) Subcontract Costs	-0-	-0-
(9) Other	-0-	-0-
Total Direct Costs	$11,600	$20,650
(l) Cost of Money (Factor) of (Appropriate Base)	2,400	3,600
(m) Indirect Costs -- Overhead _____% of Direct Labor or Other Base (Formula)	4,000	6,000
(n) Fixed-Fee Earned (Formula)	700	1,400
(o) Total Amount Claimed	$18,700	$31,650
(p) Adjustments Outstanding Suspensions		(1,700)
(q) Grand Totals	$18,700	$29,950

"I certify that all payments requested are for appropriate purposes and in accordance with the contract."

_____ _____
Name of Official) (Title)

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SAMPLE INVOICE/FINANCING REQUEST ALTERNATE

(a) Payor's Name and Address
NATIONAL INSTITUTES OF HEALTH
Division of Financial Management
Contracts Section, FAAB
Building 31, Room B1B05A
Bethesda, MD 20892

(e) Payee's Name and Address
ABC CORPORATION
100 Main Street
Anywhere, USA zip code

Attn:
Name, Title, & Phone Number of
Official to Whom Payment is Sent

(b) Invoice/Financing Request No. _____

(c) Date Invoice Prepared _____

(d) Contract No. . . . _____

Date . . . . . _____

(f) Total Estimated Cost _____

(g) Total Fixed Fee . . _____

(h) This invoice/financing request represents reimbursable costs for the period from _____ to _____

Expenditure Category* A	Incurred Cost		Cost at Completion D	Amount Funded E	Variance F
	Current B	Cumulative C			
(k) Direct Costs:					
(1) Direct Labor					
(2) Fringe Benefits					
(3) Accountable Property (attach HHS-565)					
(4) Materials & Supplies					
(5) Premium Pay					
(6) Consultant Fees					
(7) Travel					
(8) Subcontracts					
(9) Other					
Total Direct Costs					
(l) Cost of Money					
(m) Overhead					
G&A					
(n) Fixed Fee					
(o) Total Amount Claimed					
(p) Adjustments					
(q) Grand Totals					

I certify that all payments are for appropriate purposes and in accordance with the contract.

_____ _____
(Name of Official) (Title)

* Attach details as specified in the contract

NIH(RC)-1
REV. 6/18/92

Insert this clause in all cost-reimbursement RFPs and contracts. Modify for use in fixed-price contracts.

PROCUREMENT OF CERTAIN EQUIPMENT

Notwithstanding any other clause in this contract, the contractor will not be reimbursed for the purchase, lease, or rental of any item of equipment listed in the following Federal Supply Groups, regardless of the dollar value, without the prior written approval of the contracting officer.

67 - Photographic Equipment
69 - Training Aids and Devices
70 - General Purpose ADP Equipment, Software, Supplies and Support (Excluding 7045-ADP Supplies and Support Equipment)
71 - Furniture
72 - Household and Commercial Furnishings and Appliances
74 - Office Machines and Visible Record Equipment
77 - Musical Instruments, Phonographs, and Hometype Radios
78 - Recreational and Athletic Equipment

When equipment in these Federal Supply Groups is requested by the contractor and determined essential by the contracting officer, the Government will endeavor to fulfill the requirement with equipment available from its excess personal property sources, provided the request is made under a cost-reimbursement contract. Extensions or renewals of approved existing leases or rentals for equipment in these Federal Supply Groups are excluded from the provisions of this article.

Attachment 7

Research Patient Care Costs

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicar reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs. Patient care rates or amounts shall be established by the Secretary of HHS or his duly authorized representative.

(c) Prior to submitting an invoice for patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for patient care.

(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

Approved for use through 7/31/94

Protection of Human Subjects
Assurance Identification/Certification/Declaration
(Common Federal Rule)

POLICY: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the common rule. See Section 101(b) the common rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the common rule.

Institutions with an assurance of compliance that covers the research to be conducted on file with the Department, Agency, or the Department of Health and Human Services (HHS) should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency. Institutions which do not have such an assurance must submit an assurance and certification of IRB review and approval within 30 days of a written request from the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Application or Proposal Identification No. *(If known)*
☐ ORIGINAL ☐ FOLLOWUP ☐ EXEMPTION	☐ GRANT ☐ CONTRACT ☐ FELLOWSHIP ☐ COOPERATIVE AGREEMENT ☐ OTHER: _____	
4. Title of Application or Activity		5. Name of Principal Investigator, Program Director, Fellow, or Other

6. Assurance Status of this Project *(Respond to one of the following)*

☐ This Assurance, on file with the Department of Health and Human Services, covers this activity:

Assurance identification no. M- _____ IRB identification no. _____

☐ This Assurance, on file with *(agency/dept.)* _____, covers this activity.

Assurance identification no. _____ IRB identification no. _____ *(If applicable)*

☐ No assurance has been filed for this project. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

☐ *Exemption Status:* Human subjects are involved, but this activity qualifies for exemption under Section 101 (b), paragraph _____.

7. Certification of IRB Review *(Respond to one of the following IF you have an Assurance on file)*

☐ This activity has been reviewed and approved by the IRB in accordance with the common rule and any other governing regulations or subparts on

(date) _____ by: ☐ Full IRB Review or ☐ Expedited Review.

☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.		10. Name and Address of Institution
11. Phone No. *(with area code)*	12. Fax No. *(with area code)*	
13. Name of Official		14. Title
15. Signature		16. Date

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OPTIONAL FORM 310 (9-[illegible])
Sponsored by HHS/PHS

AUTHORIZATION TO USE GSA SUPPLY SOURCES

CONTRACTOR: (Name and Address)	CONTRACT NUMBER	S. A. NUMBER
Kennedy Krieger Research Institute, Inc. 707 North Broadway Baltimore, MD 21205	NO1-ES-35362 CONTRACT AMOUNT $5,765,029 EFFECTIVE DATE Jun3 30, 1993	EXPIRATION DATE June 29, 1998
ADDRESS WHERE MAIL, FREIGHT AND BILLING DOCUMENTS ARE TO BE DIRECTED (If different from the above)		FEDSTRIP ADDRESS ACTIVITY CODE

REGULATIONS: The Contractor is authorized to purchase supplies and equipment for this Cost-Reimbursement Type Contract from GSA Supply Sources pursuant to the following:

48 CFR 51.1, Contractor Use of Government Supply Sources;
41 CFR 101-26.2, Federal Requisitioning System;
41 CFR 101-26.3, Procurement of GSA Stock Items;
41 CFR 101-26.4, Purchase of Items from Federal Supply Schedule Contracts

TITLE: Title to property acquired by the Contractor under this authorization shall vest as set forth in the provisions of this contract. (See 48 CFR 51.106.)

LEASE OR RENTAL: Equipment ordered on a lease or rental basis under Federal Supply Schedule Contracts will be used solely in the performance of this contract.

FURNISHING INFORMATION TO CONTRACTORS: When a Regional Office of the Federal Supply Service, FSS, [illegible], is notified by the FSS Central Office that it has assigned a FEDSTRIP activity address code to a cost-reimbursement contractor of an agency, the FSS Regional Office will provide initial copies of the GSA Supply Catalog and FEDSTRIP Operating Guide and other necessary information. The Regional Office will also assist the contractor to prepare initial FEDSTRIP requisitions and complete GSA Form 457, FSS Publications Mailing List Application, so that current copies of required publications are received automatically from GSA.

PAYMENT FOR GSA SHIPMENTS: GSA will not forward bills to contractors for supplies until after the supplies have been shipped by GSA. Receipt of billing is considered to be sufficient evidence of delivery to establish contractor liability and to provide a basis for payment. Accordingly contractors are to make payments promptly upon receipt of billings (see 48 CFR 51.105).

PLACING ORDERS: The Contractor shall place orders in accordance with 41 CFR 101-26.2, 101-26.3, and 101-26.4. The Federal Standard Requisitioning and Issue Procedure (FEDSTRIP) shall be used when requisitioning items required by 41 CFR 101-26.2, and the above FEDSTRIP Address Activity Code shall be included in orders.

LIMITATIONS:

SIGNATURE OF CONTRACTING OFFICER	TYPED NAME (Contracting Officer)	DATE
Thomas M. Hardee	Thomas M. Hardee	June 25, 1993

NIH 1705 (Rev. 3/84)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, N.C. 27709

June 25, 1993

ATTN: Ms. Karen Sorensen
Contract Administrator
Kennedy Krieger Research Institute
707 North Broadway
Baltimore, Maryland 21205

Reference: Contract No. N01-ES-35362 (RFP NIH-ES-92-31)
"Toxicity of Lead in Children - Clinical Center"

Dear Ms. Sorensen:

Reference is made to pending contract N01-ES-35362 entitled "Toxicity of Lead in Children -- Clinical Center". Enclosed are three copies of the contract award document. Please review the contract and, if acceptable in its present format, retain a copy, sign and return two copies no later than 12:00 p.m. June 30 to the following address:

National Institute of Environmental Health Sciences
ATTN: Thomas M. Hardee, Contract Specialist
Contracts & Procurement Management Branch, OM
79 T.W. Alexander Drive, 4401 Research Commons Building
P.O. Box 12874
Research Triangle Park, NC 27709

Failure to return the signed documents in a timely fashion could result in the forfeiture of FY'93 funding to support this project with no guarantee that other funds will be made available to replace those not obligated prior to June 30, 1993.

If for any reason you take exception to the proposed contract, please identify immediately the exact location of any questionable language, provide your complete rationale and reasoning supporting the exception(s), and make suggestions on any changes you deem appropriate. You are advised that the NIH Board of Contract Awards has not yet completed its review and may recommend changes to the pending contract. In such case, you will be informed immediately of any such changes. If received prior to award, with your acknowledgement, the changes will be inserted into the contract. If received after award, the changes will be introduced by modification.

Also forwarded herewith is a copy of the appointment of Project Officer. Please be advised that within the Government no doctrine of apparent authority exists. The limitations on the respective authorities and when they apply are explicit. Should anyone within or outside the Government other than the appointed individuals (except for NIEHS Contracts office personnel) give directions concerning the contract, or if the appointed

individuals should give directions which you believe may exceed their expressed authority, you are required to notify the Contracting Officer in accordance with FAR 15.243-7, Notification of Changes (APR 1984). Please sign and return with the two copies of the contract.

When the document is accepted by the Government, a fully executed copy will be returned to you for your files.

Should you have any questions, please contact me at telephone number (919) 541-0429 or Don Gula at (919) 541-0423. We look forward to a successful contract effort.

Sincerely yours,

Thomas M. Hardee

Thomas M. Hardee
Contracting Officer
Contracts & Procurement
Management Branch, OM

Enclosures

cc: Contract File

EXHIBIT F

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, N.C. 27709

Memorandum

Date June 25, 1993

From Contracting Officer, CPMB, OM

Subject Appointment of Project Officer, Contract No. NO1-ES-35362 (RFP 92-31)
Kennedy Krieger Research Institute

To Dr. Walter Rogan, Project Officer
Ms. Beth Ragan, Alternate Project Officer

1. You are hereby appointed as the Project Officer (or alternate) for the subject contract.

2. This appointment shall remain in effect for the life of the contract unless:

   a) The appointment is terminated in writing by the Contracting Officer.

   b) You are reassigned.

   c) Your employment with the Government is terminated.

3. You shall represent the Contracting Officer for all technical matters that arise under the contract. In this respect, the Contract, Section G.1.b. and Federal Procurement Regulations specify that you shall:

   a) Familiarize yourself with the terms and conditions of the contract, particularly with those which fall within the area of your authority.

   b) Monitor technical efforts and progress, and discuss these matters with the contractor, as appropriate.

   c) Respond to inquiries on purely technical aspects of the contract.

   d) Review progress, to determine if there has been technical and/or physical progress commensurate with the contract requirements and/or payment requests.

   e) Advise the Contracting Officer of any unusual problems affecting the progress or cost of the contract.

   f) Comply with the Billing/Payment Instructions included in the contract. Please review your "ordering and receiving" requirements (outlined in the Billing/Payment Instructions)

carefully, and insure that you promptly submit all required receiving information as required. Failure to submit receiving documents promptly may result in the payment of interest to the contractor, and such interest payments shall be charged to your account.

g) Maintain complete surveillance of the technical performance and contact with the contractor in order to give reasonable assurance that all specified contract deliverables are delivered on time and are in accordance with the specifications/requirements of the contract terms. You should receive the items listed "for submission to the Project Officer" in accordance with the cited contract provisions. You should deal directly with the contractor on these matters, and coordinate any problems which require changes to the contract in advance with the Contracts and Procurement Management Branch (CPMB).

h) Keep the Contracting Officer informed as to the adequacy of the contractor's performance, progress, and completion, or any noted discrepancies or variations from the contract terms. Copies of all correspondence between your office and the contractor should be provided by your office to me for inclusion in the official file, further assistance if requested and/or to insure my complete awareness of contract compliance problems and deficiencies.

i) Inspect the submittals/services delivered; determine conformance with the contract work statement and specification requirements and recommend to the Contracting Officer acceptance or rejection of the submittals/services.

j) Provide invoice approval (if required by the Billing and Payment Instructions, and submit receiving documents.

4. This contract is a Cost-Reimbursement, Completion type.

5. Notwithstanding the authorities delegated in paragraph 3, you:

a) Shall not redelegate any authority to any other person.

b) Shall not change any of the terms and conditions of the contract or sign any modification to the contract.

c) Shall not obligate the payment of any money by the Government.

d) Shall not cause the contractor to incur costs not otherwise covered by the contract with the expectation that such costs will be reimbursed by the Government.

6. The authority of the Alternate Project Officer only becomes effective during the unavailability of the Project Officer unless otherwise authorized by the Contracting Officer.

7. Ask the Contract Specialist for guidance if you are in doubt about the extent of your authority or any circumstances not covered herein.

8. Forward to the Contracting Officer a copy of all of your correspondence with the contractor, including memoranda on significant verbal discussions.

Thomas M. Hardee
Thomas M. Hardee

Acknowledged by:

Willis Rogan
Project Officer — 6/29/93 Date

Beth Rogan
Alternate Project Officer — 6-25-93 Date

Karen R. Cox
Contractor — 6/29/93 Date

cc: Contract File

EXHIBIT F

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National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, N.C. 27709

Memorandum

Date June 25, 1993

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Thomas M. Hardee
Thomas M. Hardee

Acknowledged by:

Willis Rogan
Project Officer — 6/29/93 Date

Beth Rogan
Alternate Project Officer — 6-25-93 Date

Karen R. Cox
Contractor — 6/29/93 Date

cc: Contract File

FILED SEPARATELY SHEET

Civil Docket No. WMN-07-CV-1120

Criminal Docket No.

FILED SEPARATELY

- ☐ Answer
- ☐ Answer and attachment(s)
- ☐ Attachment(s)
- ☒ Exhibit(s) H to Notice of Removal
- ☐ Motion:
- ☐ Sealed
- ☐ Transcript of Proceedings before the Court on
- ☐ Transcript of Proceedings before SSA
- ☐ Deposition of taken on
- ☐ Other __

MARGINAL ORDER

For Pleading No.

See Pleading No.

NO. 1

EXHIBIT J

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Institutional Review Board Guidebook

* INTRODUCTION *

A. History of the Human Subjects Protection System
B. The Belmont Report || C. Suggestions for Further Reading

A. THE HISTORY OF THE HUMAN SUBJECTS PROTECTION SYSTEM

The modern story of human subjects protections begins with the *Nuremberg Code,* developed for the Nuremberg Military Tribunal as standards by which to judge the human experimentation conducted by the Nazis. The Code captures many of what are now taken to be the basic principles governing the ethical conduct of research involving human subjects. The first provision of the Code states that "the voluntary consent of the human subject is absolutely essential." Freely given consent to participation in research is thus the cornerstone of ethical experimentation involving human subjects. The Code goes on to provide the details implied by such a requirement: capacity to consent, freedom from coercion, and comprehension of the risks and benefits involved. Other provisions require the minimization of risk and harm, a favorable risk/benefit ratio, qualified investigators using appropriate research designs, and freedom for the subject to withdraw at any time. Similar recommendations were made by the World Medical Association in its *Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*, first adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, and subsequently revised by the 29th World Medical Assembly, Tokyo, Japan, 1975, and by the 41st World Medical Assembly, Hong Kong, 1989. The Declaration of Helsinki further distinguishes therapeutic from nontherapeutic research.

In the United States, regulations protecting human subjects first became effective on May 30, 1974. Promulgated by the Department of Health, Education and Welfare (DHEW), those regulations raised to regulatory status NIH's Policies for the Protection of Human Subjects, which were first issued in 1966. The regulations established the IRB as one mechanism through which human subjects would be protected.

In July of 1974, the passage of the National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission met from 1974 to 1978. In keeping with its charge, the Commission issued reports and recommendations identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and recommending guidelines to ensure that research is conducted in accordance with those principles. The Commission also recommended DHEW administrative action to require that the guidelines apply to research conducted or supported by DHEW. References for the Commission's reports are listed in Appendix 1 (General Bibliography). The Commission's report setting forth the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects is titled *The Belmont Report*, and is discussed in depth below.

In 1981, in response to the Commission's reports and recommendations, both the Department of Health and Human Services (DHHS, formerly DHEW) and the FDA promulgated significant revisions of their human subjects regulations. As Levine (1986) points out, these revisions "do not alter the general principles of IRB review as they had evolved over the preceding three decades. Rather, they are concerned with some of the details of what the IRB is expected to accomplish and some of the procedures it must follow" [p. 324].

The DHHS regulations are codified at Title 45 Part 46 of the Code of Federal Regulations. Those "basic" regulations became final on January 16, 1981, and were revised effective March 4, 1983, and June 18, 1991. The June 18, 1991, revision involved the adoption of the Federal Policy for the Protection of Human Subjects. The Federal Policy (or "Common Rule," as

it is sometimes called) was promulgated by the sixteen federal agencies that conduct, support, or otherwise regulate human subjects research; the FDA also adopted certain of its provisions. As is implied by its title, the Federal Policy is designed to make uniform the human subjects protection system in all relevant federal agencies and departments. The Federal Policy is discussed in depth in Chapter 2, Section A(i).

Additional protections for various vulnerable populations have been adopted by DHHS, as follows:

> Subpart B, "Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women and Human in Vitro Fertilization" became final on August 8, 1975, and was revised effective January 11, 1978, and November 3, 1978.
>
> Subpart C, "Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects" became final on November 16, 1978.
>
> Subpart D, "Additional Protections for Children Involved as Subjects in Research" became final on March 8, 1983, and was revised for a technical amendment on June 18, 1991.

FDA regulations on the protection of human subjects are codified at Title 21 Parts 50 and 56 of the Code of Federal Regulations. Part 50, which sets forth the requirements for informed consent, became final on May 30, 1980, and was revised effective January 27, 1981, March 3, 1989, and June 18, 1991. Subpart C, which provides special protections for prisoners, was adopted on July 7, 1981; the effective date of Subpart C has been stayed until further notice. Part 56, which sets forth the provisions for institutional review boards, was adopted on January 27, 1981, with revisions to some sections effective February 27, 1981, March 3, 1989, and June 18, 1991.

Additional FDA regulations that are relevant to IRB review of research are Parts 312 (Investigational New Drug Application), 812 (Investigational Device Exemptions) and 860 (Medical Device Classification Procedures).

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, which met from 1980 to 1983, produced numerous reports on various aspects of medical ethics and biomedical and behavioral research. Its mandate with respect to the protection of human subjects was, first, to review the federal rules and policies governing human subjects research, and second, to determine how well those rules were being implemented or enforced. References for the President's Commission's reports are listed in Appendix 1 (General Bibliography).

Several excellent sources trace the history of human subjects research and the development of the IRB system as a mechanism for the protection of human subjects. An account of the history of human subjects research and the human subjects protection system in the United States can be found in David J. Rothman's Strangers at the *Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* (Chapters 1-5 and Epilogue) and in Dennis Maloney's *Protection of Human Research Subjects*. Rothman details the abuses to which human subjects were exposed, culminating in Henry Beecher's 1966 article, "Ethics and Clinical Research," published in the *New England Journal of Medicine*, and ultimately contributing to the impetus for the first NIH and FDA regulations. Other equally useful sources include Robert J. Levine's *Ethics and Regulation of Clinical Research* (Chapter 14), Joan E. Sieber's *Planning Ethically Responsible Research*, Robert M. Veatch's "Human Experimentation Committees: Professional or Representative?," and William J. Curran's "Government Regulation of the Use of Human Subjects in Medical Research: The Approaches of Two Federal Agencies."

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B. THE BELMONT REPORT

On September 30, 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research submitted its report entitled "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The Report, named after the Belmont Conference Center at the Smithsonian Institution where the discussions which resulted in its formulation were begun, sets forth the basic ethical principles underlying the acceptable conduct of research involving human subjects. Those principles, **respect for persons, beneficence**, and **justice**, are now accepted as the three quintessential requirements for the ethical conduct of research involving human subjects.

> *Respect for persons* involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.

Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.

Justice requires that the benefits and burdens of research be distributed fairly.

The Report also describes how these principles apply to the conduct of research. Specifically, the principle of *respect for persons* underlies the need to obtain informed consent; the principle of *beneficence* underlies the need to engage in a risk/benefit analysis and to minimize risks; and the principle of *justice* requires that subjects be fairly selected. As was mandated by the congressional charge to the Commission, the Report also provides a distinction between "practice" and "research." The text of the *Belmont Report* is thus divided into two sections: (1) boundaries between practice and research; and (2) basic ethical principles. The full text of the *Belmont Report*, which describes each of the three principles and its application, is provided in the Guidebook in Appendix 6; a summary follows.

Boundaries Between Practice and Research

While recognizing that the distinction between research and therapy is often blurred, *practice* is described as "interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment, or therapy to particular individuals." The Commission distinguishes *research* as designat[ing] an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective. "The Report recognizes that "experimental" procedures do not necessarily constitute research, and that research and practice may occur simultaneously. It suggests that the safety and effectiveness of such "experimental" procedures should be investigated early, and that institutional oversight mechanisms, such as medical practice committees, can ensure that this need is met by requiring that "major innovation[s] be incorporated into a formal research project."

Applying the Ethical Principles

Respect for Persons. Required by the moral principle of respect for persons (*see* definition, above), **informed consent** contains three elements: information, comprehension, and voluntariness. First, subjects must be given sufficient information on which to decide whether or not to participate, including the research procedure(s), their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Responding to the question of what constitutes adequate information, the Report suggests that a "reasonable volunteer" standard be used: "the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation." Incomplete disclosure is justified only if it is clear that: (1) the goals of the research cannot be accomplished if full disclosure is made; (2) the undisclosed risks are minimal; and (3) when appropriate, subjects will be debriefed and provided the research results.

Second, subjects must be able to comprehend the information that is given to them. The presentation of information must be adapted to the subject's capacity to understand it; testing to ensure that subjects have understood may be warranted. Where persons with limited ability to comprehend are involved, they should be given the opportunity to choose whether or not to participate (to the extent they are able to do so), and their objections should not be overridden, unless the research entails providing them a therapy unavailable outside of the context of research. [*See* discussions on this issue in other sections of the Guidebook, including Chapter 6, "Special Classes of Subjects."] Each such class of persons should be considered on its own terms (*e.g.*, minors, persons with impaired mental capacities, the terminally ill, and the comatose). Respect for persons requires that the permission of third persons also be given in order to further protect them from harm.

Finally, consent to participate must be voluntarily given. The conditions under which an agreement to participate is made must be free from coercion and undue influence. IRBs should be especially sensitive to these factors when particularly vulnerable subjects are involved.

Beneficence. Closely related to the principle of beneficence (*see* definition, above), **risk/benefit assessments** "are concerned with the probabilities and magnitudes of possible harms and anticipated benefits." The Report breaks consideration of these issues down into defining the nature and scope of the risks and benefits, and systematically assessing the risks and benefits. All possible harms, not just physical or psychological pain or injury, should be considered. The principle of beneficence requires both protecting individual subjects against risk of harm and consideration of not only the benefits for the individual,

but also the societal benefits that might be gained from the research.

In determining whether the balance of risks and benefits results in a favorable ratio, the decision should be based on thorough assessment of information with respect to all aspects of the research and systematic consideration of alternatives. The Report recommends close communication between the IRB and the investigator and IRB insistence upon precise answers to direct questions. The IRB should: (1) determine the "validity of the presuppositions of the research;" (2) distinguish the "nature, probability and magnitude of risk...with as much clarity as possible;" and (3) "determine whether the investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies."

Five basic principles or rules apply when making the risk/benefit assessment: (1) "brutal or inhumane treatment of human subjects is never morally justified;" (2) risks should be minimized, including the avoidance of using human subjects if at all possible; (3) IRBs must be scrupulous in insisting upon sufficient justification for research involving "significant risk of serious impairment" (e.g., direct benefit to the subject or "manifest voluntariness of the participation"); (4) the appropriateness of involving vulnerable populations must be demonstrated; and (5) the proposed informed consent process must thoroughly and completely disclose relevant risks and benefits.

Justice. The principle of justice mandates that the **selection of research subjects** must be the result of fair selection procedures and must also result in fair selection outcomes. The "justness" of subject selection relates both to the subject as an individual and to the subject as a member of social, racial, sexual, or ethnic groups.

With respect to their status as individuals, subjects should not be selected either because they are favored by the researcher or because they are held in disdain (*e.g.*, involving "undesirable" persons in risky research). Further, "social justice" indicates an "order of preference in the selection of classes of subjects (*e.g.*, adults before children) and that some classes of potential subjects (*e.g.*, the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions."

Investigators, institutions, or IRBs may consider principles of distributive justice relevant to determining the appropriateness of proposed methods of selecting research subjects that may result in unjust distributions of the burdens and benefits of research. Such considerations may be appropriate to avoid the injustice that "arises from social, racial, sexual, and cultural biases institutionalized in society."

Subjects should not be selected simply because they are readily available in settings where research is conducted, or because they are "easy to manipulate as a result of their illness or socioeconomic condition." Care should be taken to avoid overburdening institutionalized persons who "are already burdened in many ways by their infirmities and environments." Nontherapeutic research that involves risk should use other, less burdened populations, unless the research "directly relate[s] to the specific conditions of the class involved."

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SUGGESTIONS FOR FURTHER READING

- **Beauchamp**, Tom L., and Childress, James F. *Principles of Biomedical Ethics*, 3d ed. New York: Oxford University Press, 1989.
- **Beecher**, Henry K. "Ethics and Clinical Research." *New England Journal of Medicine* 274 (1966): 1354-1360.
- **Curran**, William J. "Government Regulation of the Use of Human Subjects in Medical Research: The Approaches of Two Federal Agencies." In *Experimentation with Human Subjects*, edited by Paul A. Freund, pp. 402-454. New York: George Braziller, 1970.
- **Fried**, Charles. Medical Experimentation: *Personal Integrity and Social Policy*. New York: American Elsevier Company, 1974.
- **Levine**, Robert J. *Ethics and Regulation of Clinical Research*. 2d ed. Baltimore: Urban and Schwarzenberg, 1986. *See* especially Chapter 14, "The Institutional Review Board."
- **Maloney**, Dennis M. *Protection of Human Research Subjects: A Practical Guide to Federal Laws and Regulations*. New York: Plenum Press, 1984.
- **McCarthy**, Charles R. "Experience with Boards and Commissions Concerned with Research Ethics in the United States." In *Research Ethics*, edited by Kare Berg and Knut Erik Tranoy, pp. 111-122. New York: Alan R. Liss, 1983.
- **McCarthy**, Charles R. "Current Regulations for the Protection of Human Subjects." In *Alzheimer's Dementia: Dilemmas in Clinical Research*, edited by Vijaya L. Melnick and Nancy N. Dubler, pp. 13-18. Clifton, NJ: Humana

Press, 1985.

- **Marshall**, Ernest. "Does the Moral Philosophy of the Belmont Report Rest on a Mistake?" *IRB* 8 (No. 6, November/December 1986): 5-6.
- **Rothman**, David J. *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making*. New York: Basic Books, 1991.
- **Rothman**, David J. "Ethics and Human Experimentation: Henry Beecher Revisited." *New England Journal of Medicine* 317 (No. 19, November 5, 1987): 1195-1199.
- **Sieber**, Joan E. *Planning Ethically Responsible Research: A Guide for Students and Internal Review Boards*. Applied Social Research Methods Series, vol. 31. Newbury Park, CA: Sage Publications, 1992.
- **Twenty Years After:** The Legacy of the Tuskegee Syphilis Study. *The Hastings Center Report* 22 (No. 6, November/December 1992): 29-40. Includes articles by Arthur L. Caplan, Harold Edgar, Patricia A. King, and James H. Jones.
- **U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.** A complete list of the National Commission's reports and recommendations is provided in Appendix 1.
- **U.S. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.** A complete list of the President's Commission's reports is provided in Appendix 1.
- **Veatch**, Robert M. "Human Experimentation Committees: Professional or Representative?" *Hastings Center Report* 5 (No. 5, October 1975): 31-40.

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Introduction

EXHIBIT J

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Institutional Review Board Guidebook

* INTRODUCTION *

A. History of the Human Subjects Protection System
B. The Belmont Report || C. Suggestions for Further Reading

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>
> Subpart D, "Additional Protections for Children Involved as Subjects in Research" became final on March 8, 1983, and was revised for a technical amendment on June 18, 1991.

FDA regulations on the protection of human subjects are codified at Title 21 Parts 50 and 56 of the Code of Federal Regulations. Part 50, which sets forth the requirements for informed consent, became final on May 30, 1980, and was revised effective January 27, 1981, March 3, 1989, and June 18, 1991. Subpart C, which provides special protections for prisoners, was adopted on July 7, 1981; the effective date of Subpart C has been stayed until further notice. Part 56, which sets forth the provisions for institutional review boards, was adopted on January 27, 1981, with revisions to some sections effective February 27, 1981, March 3, 1989, and June 18, 1991.

Additional FDA regulations that are relevant to IRB review of research are Parts 312 (Investigational New Drug Application), 812 (Investigational Device Exemptions) and 860 (Medical Device Classification Procedures).

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, which met from 1980 to 1983, produced numerous reports on various aspects of medical ethics and biomedical and behavioral research. Its mandate with respect to the protection of human subjects was, first, to review the federal rules and policies governing human subjects research, and second, to determine how well those rules were being implemented or enforced. References for the President's Commission's reports are listed in Appendix 1 (General Bibliography).

Several excellent sources trace the history of human subjects research and the development of the IRB system as a mechanism for the protection of human subjects. An account of the history of human subjects research and the human subjects protection system in the United States can be found in David J. Rothman's Strangers at the *Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* (Chapters 1-5 and Epilogue) and in Dennis Maloney's *Protection of Human Research Subjects*. Rothman details the abuses to which human subjects were exposed, culminating in Henry Beecher's 1966 article, "Ethics and Clinical Research," published in the *New England Journal of Medicine*, and ultimately contributing to the impetus for the first NIH and FDA regulations. Other equally useful sources include Robert J. Levine's *Ethics and Regulation of Clinical Research* (Chapter 14), Joan E. Sieber's *Planning Ethically Responsible Research*, Robert M. Veatch's "Human Experimentation Committees: Professional or Representative?," and William J. Curran's "Government Regulation of the Use of Human Subjects in Medical Research: The Approaches of Two Federal Agencies."

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B. THE BELMONT REPORT

On September 30, 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research submitted its report entitled "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The Report, named after the Belmont Conference Center at the Smithsonian Institution where the discussions which resulted in its formulation were begun, sets forth the basic ethical principles underlying the acceptable conduct of research involving human subjects. Those principles, **respect for persons, beneficence**, and **justice**, are now accepted as the three quintessential requirements for the ethical conduct of research involving human subjects.

> *Respect for persons* involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.

Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.

Justice requires that the benefits and burdens of research be distributed fairly.

The Report also describes how these principles apply to the conduct of research. Specifically, the principle of *respect for persons* underlies the need to obtain informed consent; the principle of *beneficence* underlies the need to engage in a risk/benefit analysis and to minimize risks; and the principle of *justice* requires that subjects be fairly selected. As was mandated by the congressional charge to the Commission, the Report also provides a distinction between "practice" and "research." The text of the *Belmont Report* is thus divided into two sections: (1) boundaries between practice and research; and (2) basic ethical principles. The full text of the *Belmont Report*, which describes each of the three principles and its application, is provided in the Guidebook in Appendix 6; a summary follows.

Boundaries Between Practice and Research

While recognizing that the distinction between research and therapy is often blurred, *practice* is described as "interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment, or therapy to particular individuals." The Commission distinguishes *research* as designat[ing] an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective. "The Report recognizes that "experimental" procedures do not necessarily constitute research, and that research and practice may occur simultaneously. It suggests that the safety and effectiveness of such "experimental" procedures should be investigated early, and that institutional oversight mechanisms, such as medical practice committees, can ensure that this need is met by requiring that "major innovation[s] be incorporated into a formal research project."

Applying the Ethical Principles

Respect for Persons. Required by the moral principle of respect for persons (*see* definition, above), **informed consent** contains three elements: information, comprehension, and voluntariness. First, subjects must be given sufficient information on which to decide whether or not to participate, including the research procedure(s), their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Responding to the question of what constitutes adequate information, the Report suggests that a "reasonable volunteer" standard be used: "the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation." Incomplete disclosure is justified only if it is clear that: (1) the goals of the research cannot be accomplished if full disclosure is made; (2) the undisclosed risks are minimal; and (3) when appropriate, subjects will be debriefed and provided the research results.

Second, subjects must be able to comprehend the information that is given to them. The presentation of information must be adapted to the subject's capacity to understand it; testing to ensure that subjects have understood may be warranted. Where persons with limited ability to comprehend are involved, they should be given the opportunity to choose whether or not to participate (to the extent they are able to do so), and their objections should not be overridden, unless the research entails providing them a therapy unavailable outside of the context of research. [*See* discussions on this issue in other sections of the Guidebook, including Chapter 6, "Special Classes of Subjects."] Each such class of persons should be considered on its own terms (*e.g.*, minors, persons with impaired mental capacities, the terminally ill, and the comatose). Respect for persons requires that the permission of third persons also be given in order to further protect them from harm.

Finally, consent to participate must be voluntarily given. The conditions under which an agreement to participate is made must be free from coercion and undue influence. IRBs should be especially sensitive to these factors when particularly vulnerable subjects are involved.

Beneficence. Closely related to the principle of beneficence (*see* definition, above), **risk/benefit assessments** "are concerned with the probabilities and magnitudes of possible harms and anticipated benefits." The Report breaks consideration of these issues down into defining the nature and scope of the risks and benefits, and systematically assessing the risks and benefits. All possible harms, not just physical or psychological pain or injury, should be considered. The principle of beneficence requires both protecting individual subjects against risk of harm and consideration of not only the benefits for the individual,

but also the societal benefits that might be gained from the research.

In determining whether the balance of risks and benefits results in a favorable ratio, the decision should be based on thorough assessment of information with respect to all aspects of the research and systematic consideration of alternatives. The Report recommends close communication between the IRB and the investigator and IRB insistence upon precise answers to direct questions. The IRB should: (1) determine the "validity of the presuppositions of the research;" (2) distinguish the "nature, probability and magnitude of risk...with as much clarity as possible;" and (3) "determine whether the investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies."

Five basic principles or rules apply when making the risk/benefit assessment: (1) "brutal or inhumane treatment of human subjects is never morally justified;" (2) risks should be minimized, including the avoidance of using human subjects if at all possible; (3) IRBs must be scrupulous in insisting upon sufficient justification for research involving "significant risk of serious impairment" (e.g., direct benefit to the subject or "manifest voluntariness of the participation"); (4) the appropriateness of involving vulnerable populations must be demonstrated; and (5) the proposed informed consent process must thoroughly and completely disclose relevant risks and benefits.

Justice. The principle of justice mandates that the **selection of research subjects** must be the result of fair selection procedures and must also result in fair selection outcomes. The "justness" of subject selection relates both to the subject as an individual and to the subject as a member of social, racial, sexual, or ethnic groups.

With respect to their status as individuals, subjects should not be selected either because they are favored by the researcher or because they are held in disdain (*e.g.*, involving "undesirable" persons in risky research). Further, "social justice" indicates an "order of preference in the selection of classes of subjects (*e.g.*, adults before children) and that some classes of potential subjects (*e.g.*, the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions."

Investigators, institutions, or IRBs may consider principles of distributive justice relevant to determining the appropriateness of proposed methods of selecting research subjects that may result in unjust distributions of the burdens and benefits of research. Such considerations may be appropriate to avoid the injustice that "arises from social, racial, sexual, and cultural biases institutionalized in society."

Subjects should not be selected simply because they are readily available in settings where research is conducted, or because they are "easy to manipulate as a result of their illness or socioeconomic condition." Care should be taken to avoid overburdening institutionalized persons who "are already burdened in many ways by their infirmities and environments." Nontherapeutic research that involves risk should use other, less burdened populations, unless the research "directly relate[s] to the specific conditions of the class involved."

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SUGGESTIONS FOR FURTHER READING

- **Beauchamp**, Tom L., and Childress, James F. *Principles of Biomedical Ethics*, 3d ed. New York: Oxford University Press, 1989.
- **Beecher**, Henry K. "Ethics and Clinical Research." *New England Journal of Medicine* 274 (1966): 1354-1360.
- **Curran**, William J. "Government Regulation of the Use of Human Subjects in Medical Research: The Approaches of Two Federal Agencies." In *Experimentation with Human Subjects*, edited by Paul A. Freund, pp. 402-454. New York: George Braziller, 1970.
- **Fried**, Charles. Medical Experimentation: *Personal Integrity and Social Policy*. New York: American Elsevier Company, 1974.
- **Levine**, Robert J. *Ethics and Regulation of Clinical Research*. 2d ed. Baltimore: Urban and Schwarzenberg, 1986. *See* especially Chapter 14, "The Institutional Review Board."
- **Maloney**, Dennis M. *Protection of Human Research Subjects: A Practical Guide to Federal Laws and Regulations*. New York: Plenum Press, 1984.
- **McCarthy**, Charles R. "Experience with Boards and Commissions Concerned with Research Ethics in the United States." In *Research Ethics*, edited by Kare Berg and Knut Erik Tranoy, pp. 111-122. New York: Alan R. Liss, 1983.
- **McCarthy**, Charles R. "Current Regulations for the Protection of Human Subjects." In *Alzheimer's Dementia: Dilemmas in Clinical Research*, edited by Vijaya L. Melnick and Nancy N. Dubler, pp. 13-18. Clifton, NJ: Humana

Press, 1985.

- **Marshall**, Ernest. "Does the Moral Philosophy of the Belmont Report Rest on a Mistake?" *IRB* 8 (No. 6, November/December 1986): 5-6.
- **Rothman**, David J. *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making*. New York: Basic Books, 1991.
- **Rothman**, David J. "Ethics and Human Experimentation: Henry Beecher Revisited." *New England Journal of Medicine* 317 (No. 19, November 5, 1987): 1195-1199.
- **Sieber**, Joan E. *Planning Ethically Responsible Research: A Guide for Students and Internal Review Boards*. Applied Social Research Methods Series, vol. 31. Newbury Park, CA: Sage Publications, 1992.
- **Twenty Years After:** The Legacy of the Tuskegee Syphilis Study. *The Hastings Center Report* 22 (No. 6, November/December 1992): 29-40. Includes articles by Arthur L. Caplan, Harold Edgar, Patricia A. King, and James H. Jones.
- **U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.** A complete list of the National Commission's reports and recommendations is provided in Appendix 1.
- **U.S. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.** A complete list of the President's Commission's reports is provided in Appendix 1.
- **Veatch**, Robert M. "Human Experimentation Committees: Professional or Representative?" *Hastings Center Report* 5 (No. 5, October 1975): 31-40.

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Introduction

EXHIBIT K

WARANCH & BROWN, LLC
ATTORNEYS AT LAW
SUITE 300
1301 YORK ROAD
LUTHERVILLE, MARYLAND 21093-6080

www.waranch-brown.com

BARRY C. GOLDSTEIN (MD)
DIRECT LINE: (410) 821-3511
E-mail: bgoldstein@waranch-brown.com

TELEPHONE (410) 821-3500
FACSIMILE (410) 821-3501

April 16, 2007

VIA FACSIMILE
Evan K. Thalenberg, Esquire
Evan K. Thalenberg, P.A.
216 E. Lexington Street
Baltimore, Maryland 21202

Re: Wallace, et al. v. Kennedy Krieger Institute, Inc., et al.
Featherstone, et al. v. Kennedy Krieger Institute, Inc., et al.
File No.: 5397.028

Dear Mr. Thalenberg:

I have been advised that your firm has filed Complaints on behalf of (1) Shayonna Featherstone and Keona Featherstone; and (2) Dontae Wallace and Searra Wallace. I will accept service of these Complaints on behalf of Kennedy Krieger Institute, Inc. and Cecilia Davoli, M.D. in the Featherstone case and on behalf of Kennedy Krieger Institute, Inc. and Mark Farfel, Sc.D. in the Wallace case.

At your earliest convenience, please provide me copies of these Complaints by facsimile and by U.S. Mail.

Thank you for your anticipated cooperation.

Very truly yours,

Barry C. Goldstein

BCG:vmb

SHAYONNA FEATHERSTONE, et al	*	IN THE
Plaintiffs	*	CIRCUIT COURT
VS.	*	FOR
KENNEDY KRIEGER INSTITUTE, INC et al	*	BALTIMORE CITY
Defendants	*	CASE NO.: 24-C-07-002027

* * * * * * * * * * * *

ANSWER TO COMPLAINT

Now comes the Defendants, Pythagoras Passas and Anne L. Passas, by and through their attorney, Timothy P. Knepp, and respectfully answers Complaint as follows:

GENERAL DENIAL

THE DEFENDANTS DID NOT COMMIT THE WRONG ALLEGED.

THE DEFENDANTS ARE NOT INDEBTED AS ALLEGED.

1. The Defendants deny the allegations contained in paragraph one.
2. The Defendants deny the allegations contained in paragraph two.
3. The Defendants deny the allegations contained in paragraph three.
4. The Defendants deny the allegations contained in all parts of paragraph four.
5. The Defendants deny the allegations contained in paragraph five.
6. The Defendants deny the allegations contained in paragraph six.
7. The Defendants deny the allegations contained in paragraph seven.
8. The Defendants deny the allegations contained in paragraph eight.
9. The Defendants deny the allegations contained in paragraph nine.

10. The Defendants deny the allegations contained in paragraph ten.

11. The Defendants deny the allegations contained in paragraph eleven.

12. The Defendants deny the allegations contained in paragraph twelve.

13. The Defendants deny the allegations contained in paragraph thirteen.

14. The Defendants deny the allegations contained in paragraph fourteen.

15. The Defendants deny the allegations contained in paragraph fifteen.

16. The Defendants deny the allegations contained in paragraph sixteen.

17. The Defendants deny the allegations contained in paragraph seventeen.

18. The Defendants deny the allegations contained in paragraph eighteen.

19. The Defendants deny the allegations contained in paragraph nineteen.

20. The Defendants deny the allegations contained in paragraph twenty.

21. The Defendants deny the allegations contained in paragraph twenty-one.

22. The Defendants deny the allegations contained in paragraph twenty-two.

23. The Defendants deny the allegations contained in paragraph twenty-three.

24. The Defendants deny the allegations contained in paragraph twenty-four.

25. The Defendants deny the allegations contained in paragraph twenty-five.

26. The Defendants deny the allegations contained in paragraph twenty-six.

27. The Defendants deny the allegations contained in paragraph twenty-seven.

28. The Defendants deny the allegations contained in paragraph twenty-eight.

29. The Defendants deny the allegations contained in paragraph twenty-nine.

30. The Defendants deny the allegations contained in paragraph thirty.

31. The Defendants deny the allegations contained in paragraph thirty-one.

32. The Defendants deny the allegations contained in paragraph thirty-two.

33. The Defendants deny the allegations contained in paragraph thirty-three.

34. The Defendants deny the allegations contained in paragraph thirty-four.

35. The Defendants deny the allegations contained in paragraph thirty-five.

COUNT ONE

36. Paragraph thirty-six does not require an affirmative response.

37. The Defendants deny the allegations contained in paragraph thirty-seven.

38. The Defendants deny the allegations contained in paragraph thirty-eight.

39. The Defendants deny the allegations contained in paragraph thirty-nine.

40. The Defendants deny the allegations contained in all parts of paragraph forty.

41. The Defendants deny the allegations contained in paragraph forty-one.

COUNT TWO

42. Paragraph forty-two does not require an affirmative response.

43. The Defendants deny the allegations contained in paragraph forty-three.

44. The Defendants deny the allegations contained in paragraph forty-four.

45. The Defendants deny the allegations contained in paragraph forty- five.

COUNT THREE

46. Paragraph forty-six does not require an affirmative response.

47. The Defendants deny the allegations contained in paragraph forty-seven.

48. The Defendants deny the allegations contained in paragraph forty-eight.

49. The Defendants deny the allegations contained in paragraph forty-nine.

COUNT FOUR

50. Paragraph fifty does not require an affirmative response.

51. The Defendants deny the allegations contained in paragraph fifty-one.

52. The Defendants deny the allegations contained in paragraph fifty-two.

53. The Defendants deny the allegations contained in paragraph fifty-three.

54. The Defendants deny the allegations contained in paragraph fifty-four.

55. The Defendants deny the allegations contained in paragraph fifty-five.

56. The Defendants deny the allegations contained in paragraph fifty-six.

57. The Defendants deny the allegations contained in paragraph fifty-seven.

58. The Defendants deny the allegations contained in paragraph fifty-eight.

59. The Defendants deny the allegations contained in paragraph fifty-nine.

COUNT FIVE

60. Paragraph sixty does not require an affirmative response.

61. The Defendants deny the allegations contained in paragraph sixty-one.

62. The Defendants deny the allegations contained in paragraph sixty-two.

63. The Defendants deny the allegations contained in paragraph sixty-three.

64. The Defendants deny the allegations contained in paragraph sixty-four.

65. The Defendants deny the allegations contained in paragraph sixty-five.

COUNT SIX

66. Paragraph sixty-six does not require an affirmative response.

67. The Defendants deny the allegations contained in paragraph sixty-seven.

68. The Defendants deny the allegations contained in paragraph sixty-eight.

69. The Defendants deny the allegations contained in paragraph sixty-nine.

70. The Defendants deny the allegations contained in paragraph seventy.

71. The Defendants deny the allegations contained in paragraph seventy-one.

72. The Defendants deny the allegations contained in paragraph seventy-two.

73. The Defendants deny the allegations contained in paragraph seventy-three.

74. The Defendants deny the allegations contained in paragraph seventy-four.

75. The Defendants deny the allegations contained in paragraph seventy-five.

COUNT SEVEN

76. Paragraph seventy-six does not require an affirmative response.

77. The Defendants deny the allegations contained in paragraph seventy-seven.

78. The Defendants deny the allegations contained in paragraph seventy-eight.

79. The Defendants deny the allegations contained in paragraph seventy-nine.

80. The Defendants deny the allegations contained in paragraph eighty.

81. The Defendants deny the allegations contained in paragraph eighty-one.

82. The Defendants deny the allegations contained in paragraph eighty-two.

COUNT EIGHT

83. Paragraph eighty-three does not require an affirmative response.

84. The Defendants deny the allegations contained in paragraph eighty-four.

85. The Defendants deny the allegations contained in paragraph eighty-five.

86. The Defendants deny the allegations contained in paragraph eighty-six.

87. The Defendants deny the allegations contained in paragraph eighty-seven.

88. The Defendants deny the allegations contained in paragraph eighty-eight.

89. The Defendants deny the allegations contained in paragraph eighty-nine.

AFFIRMATIVE DEFENSES

1. The Defendants assert the defense of assumption of risk.

2. The Defendants assert the defense of contributory negligence.

3. The Defendants assert the defense of statute of limitations.

4. The Defendants assert the defense of laches.

Timothy P. Knepp
Attorney for Defendants
106 North Marlyn Avenue
P.O. Box 34019
Baltimore, Maryland 21221
(410) 686- 5151

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 27th day of April, 2007, a copy of the foregoing **Answer To Complaint** was mailed, first-class, postage prepaid to the following:

Nicholas A. Szokoly
Law Offices of Evan K. Thalenberg, P.A.
216 East Lexington Street
Baltimore, Maryland 21202

Raymond L. Marshall
Whiteford, Taylor & Preston L. L. P.
Seven Saint Paul Street
Baltimore, Maryland 21202

Kennedy Krieger Institute, Inc.
707 North Broadway
Baltimore, Maryland 21205

Ms. Cecilia Davoli
707 North Broadway
Baltimore, Maryland 21205

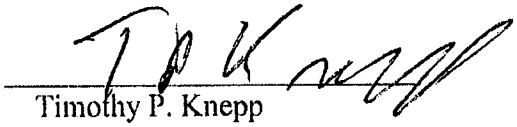
N. A. C. I. Corporation
(A Maryland Corporation)
416 East 25th Street
Baltimore, Maryland 21218

Shenan Management, Inc.
(A Maryland Corporation)
1900 Lexington Street
Baltimore, Maryland 21228

Mr. Marc Medin
7955 Starburst Drive
Pikesville, Maryland 21208

Ms. Nancy Medin
7955 Starburst Drive
Pikesville, Maryland 21208

Ms. Helen Heath
Lady "H" Enterprises
5317 West North Avenue
Gwynn Oak, Maryland 21207



Timothy P. Knepp
Attorney for Defendants
106 North Marlyn Avenue
P.O. Box 34019
Baltimore, Maryland 21221
(410) 686- 5151

EXHIBIT M

SHAYONNA FEATHERSTONE, et al.	*	**IN THE**
Plaintiffs	*	**CIRCUIT COURT**
v.	*	**FOR**
KENNEDY KRIEGER INSTITUTE, INC., et al.	*	**BALTIMORE CITY**
Defendants	*	**Case No. 24-C-07-002027**

* * * * * * * * * * *

KENNEDY KRIEGER INSTITUTE, INC. AND CECILIA DAVOLI, M.D.'S NOTICE TO THE CIRCUIT COURT FOR BALTIMORE CITY OF FILING NOTICE OF REMOVAL TO THE UNITED STATES DISTRICT COURT

PLEASE TAKE NOTICE that on the 1st day of May, 2007, pursuant to 28 U.S.C. §§§1331, 1441 and 1446, Defendants Kennedy Krieger Institute and Cecilia Davoli, M.D. ("Kennedy Krieger Defendants"), filed a Notice of Removal to the United States District Court for the District of Maryland, a copy of which is attached hereto as Exhibit 1. The Kennedy Krieger Defendants state that no other proceedings will take place in the Circuit Court for Baltimore City unless further ordered.

Respectfully submitted,

Barry C. Goldstein
Nicole A. McCarus
Waranch & Brown, LLC
1301 York Road, Suite 300
Lutherville, Maryland 21093
(410) 821-3511
ATTORNEYS FOR DEFENDANTS KENNEDY KRIEGER INSTITUTE, INC., and CECILIA DAVOLI, M.D.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this _____ day of May, 2007, a copy of the foregoing Notice of Removal was mailed first-class, postage prepaid, to:

Evan K. Thalenberg, Esquire
Evan K. Thalenberg, P.A.
11 E. Chase Street, Suite 7F
Baltimore, Maryland 21202

Attorney for Plaintiffs

Timothy P. Knepp, Esquire
P. O. Box 21221
Baltimore, Maryland 21221

Attorney for Pythagoras Passas and Anne L. Passas

Michael D. Vogelstein, Esquire
201 N. Charles Street
Suite 801
Baltimore, Maryland 21201

Attorney for Marc Medin, Nancy Medin and Shenan Management, Inc. and N.A.C.I. Corporation

Natalie Magdeburger, Esquire
Raymond Marshall, Esquire
Whiteford, Taylor & Preston, L.L.P.
210 W. Pennsylvania Avenue
Towson, MD 21204-4514

Attorneys for The Johns Hopkins University, The Institutional Review Board of The Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman, Hayden G. Braine and Peter Lees.

_____
Barry C. Goldstein

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al.	*	
Plaintiffs	*	
v.	*	**Case No. 1:07-cv-01120**
KENNEDY KRIEGER INSTITUTE, INC., et al.	*	
Defendants	*	

* * * * * * * * * * * * *

MOTION TO DISMISS FOR PLAINTIFFS' FAILURE TO JOIN A RULE 19 PARTY OR, IN THE ALTERNATIVE, MOTION TO JOIN THE NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES AS A PARTY

Pursuant to Federal Rules of Civil Procedure 12(b)(7), 19, and 21, Defendants Kennedy Krieger Institute ("Kennedy Krieger") and Cecilia Davoli, M.D., (collectively referred to as "Kennedy Krieger Defendants"), by their undersigned counsel, respectfully request that the Court dismiss Plaintiffs' Complaint for failure to join the National Institute of Environmental Health Sciences ("NIEHS") as a party to the above-entitled action.

Alternatively, the Kennedy Krieger Defendants request that, pursuant to Rule 21, the Court join NIEHS as a party to this action. In support of this Motion, the Kennedy Krieger Defendants refer to their accompanying Memorandum of Law, which is incorporated herein by reference.

A proposed order is attached.

/s/ Barry C. Goldstein

Barry C. Goldstein, Esquire
(Federal Bar No. 24796)
Nicole A. McCarus, Esquire
(Federal Bar No. 27971)
John T. Sly, Esquire
(Federal Bar No. 26608)
Waranch & Brown, LLC
1301 York Road, Suite 300
Lutherville, Maryland 21093
(410) 821-3511
Attorneys for Kennedy Krieger Institute, Inc., and Cecilia Davoli, M.D.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 18th day of May, 2007, a copy of the foregoing Motion to Dismiss for Plaintiffs' Failure to Name a Rule 19 Party or, In The Alternative, Motion to Join The National Institute Of Environmental Health Sciences as a Party, was electronically filed and mailed, first class, postage prepaid, to:

Evan K. Thalenberg, Esquire
Evan K. Thalenberg, P.A.
216 E. Lexington Street
Baltimore, Maryland 21202
Attorney for Plaintiffs

Natalie Magdeburger, Esquire
Raymond Marshall, Esquire
Whiteford, Taylor & Preston, L.L.P.
210 W. Pennsylvania Avenue
Towson, Maryland 21204-4514
Attorneys for Defendants The Johns Hopkins University, The Institutional Review Board of The Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, M.D., Lewis C. Becker, M.D, David R. Cornblath, M.D., Paul Lietman, M.D., Hayden G. Braine, M.D. and Peter Lees, M.D.

Michael D. Vogelstein, Esquire
Law Offices of Michael D Vogelstein
201 N Charles St Ste 801
Baltimore, MD 21201
Attorneys for Defendants, Marc and Nancy Medin, N.A.C.I. Corporation, and Shenan Management

By U.S. Mail To:
Timothy P. Knepp, Esquire
Law Office of Timothy P. Knepp
106 N. Marlyn Avenue
P. O. Box 34019
Essex, Maryland 21221
Attorneys for Defendants Pythagoras and Anne Passas

By U.S. Mail To:
Helen Heath, Individually and Trading As
Lady "H" Enterprises
6732 Wilmont Drive
Gwynn Oak, Maryland 21207
***Pro Se* Defendant**

/s/ Barry C. Goldstein
Barry C. Goldstein

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al. *

Plaintiffs *

v. *

Case No. 1:07-cv-01120

KENNEDY KRIEGER INSTITUTE, INC., et al. *

Defendants *

* * * * * * * * * * * * *

DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS FOR PLAINTIFFS' FAILURE TO JOIN A RULE 19 PARTY, OR IN THE ALTERNATIVE, MOTION TO JOIN THE NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES AS A PARTY

I. INTRODUCTION

This action is brought by Shayonna Featherstone, a minor, and Keona Featherstone, a minor, by their mother and next friend, Sharon Jackson ("Plaintiffs"), and arises out of Plaintiff Keona Featherstone's participation in the National Institute of Environmental Health Sciences ("NIEHS") study conducted by Kennedy Krieger Institute, Inc. and others, known as the Treatment of Lead-Exposed Children ("TLC") Study.

Plaintiffs seek damages in the amount of Four Million Dollars ($4,000,000). Plaintiffs' Complaint asserts claims of negligence, negligent misrepresentation, civil conspiracy and breach of fiduciary duty against Kennedy Krieger Institute, Inc., Cecilia Davoli, M.D. (collectively referred to as the "Kennedy Krieger Defendants") and The Johns Hopkins University, The Institutional Review Board of The Johns Hopkins University School of Medicine Joint Committee on Clinical Investigation, Thomas R.

Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman, Hayden G. Braine (collectively referred to as "IRB"), N.A.C.I. Corporation, Shenan Management, Inc., Marc and Nancy Medin, Pythagoras and Anne Passas, and Helen Heath, Individually and Trading As Lady "H" Enterprises.

The federal government, through NIEHS, directed and controlled all of Kennedy Krieger's activity in the design, implementation and follow-up of the TLC Study. Furthermore, the NIEHS Institutional Review Board ("IRB") approved the informed consent utilized to enroll Study participants.[1] NIEHS maintained detailed, hands-on control over all phases of this government-sponsored and funded study.

Plaintiffs have failed to name NIEHS as a party to this litigation. Absent participation in this litigation by NIEHS, complete relief cannot be afforded among those already parties, and this action will impair or impede NIEHS' ability to protect its interests in this litigation and future litigation. In addition, absence of NIEHS will place the parties in this litigation at a substantial risk of incurring double, multiple, or inconsistent obligations. Accordingly, the Kennedy Krieger Defendants request that the Court issue an order dismissing Plaintiffs' Complaint or, in the alternative, requiring Plaintiffs to join NIEHS as a party to this proceeding.

The following paragraphs provide a summary of the intimate and meticulous control that NIEHS maintained over the TLC Study.

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[1] In their Complaint, Plaintiffs allege that the Informed Consent form was inaccurate and misleading. *See* Plaintiffs' Complaint, a copy of which is attached hereto as **Exhibit A**.

II. STATEMENT OF FACTS

In 1992, the federal government, through the National Institute of Environmental Health Sciences ("NIEHS")2, issued a Request for Proposal ("RFP") seeking clinical centers for a study entitled "Treatment of Lead-Exposed Children." The purpose of the Study was to determine whether succimer, a drug approved by the United States Food and Drug Administration ("FDA") for use in treating individuals with blood lead levels greater than 45 micrograms per deciliter, could prevent cognitive delay in young children with blood lead levels less than 45 micrograms per deciliter.

Specifically, Plaintiffs' negligence claims directly call into question Kennedy Krieger's compliance with the contract it entered into with NIEHS as well as Kennedy Krieger's compliance with the detailed and comprehensive framework of federal regulations that govern research on human subjects.

The genesis of the TLC Study was an RFP issued by NIEHS without any input from Kennedy Krieger. NIEHS unequivocally articulated in the RFP that control over the timing parameters for each and every aspect of the TLC Study would rest with NIEHS. Furthermore, NIEHS directed the criteria for enrollment into this Study, and mandated the areas of focus in analyzing the Study's data. Kennedy Krieger drafted its "proposal" within the specific criteria set forth by NIEHS.

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2 NIEHS is a subsidiary of the National Institutes of Health ("NIH"), a branch of the United States Department of Health and Human Services.

In response to Kennedy Krieger's "proposal," NIEHS drafted a contract and forwarded it to Kennedy Krieger for signature[3]. No one from Kennedy Krieger participated in the preparation of that contract. *See* Affidavit of Merrill Brophy attached hereto as **Exhibit B**, paragraph 3. This government contract served as the basis for the relationship between NIEHS and Kennedy Krieger in conducting the TLC Study. *See* Contract attached hereto as **Exhibit C**. The NIEHS, through one of its Project Officers, was required to:

> Maintain complete surveillance of the technical performance and contact with the contractor in order to give reasonable assurance that all specified contract deliverables are delivered on time and are in accordance with the specifications/requirements of the contract terms.

See June 25, 1993 Department of Health and Human Services Memorandum attached as **Exhibit D**.

Moreover, the Principal Investigator at Kennedy Krieger (and all clinical sites) was required to seek approval from NIEHS in order to allocate funds for *any* purpose that deviated *in any way* from the contract as drafted by NIEHS. *See* Affidavit of Cecilia Davoli, M.D., attached hereto as **Exhibit E**, paragraph 11; *see also* June 26, 1995 letter from Kennedy Krieger to NIEHS regarding approval for funds attached hereto as **Exhibit F**.

Further, the Statement of Work section of the contract, in describing the specific criteria to be used in protocol development, adopted *verbatim* the study criteria initially set forth by NIEHS in its RFP.

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[3] This was a multi-center study and, accordingly, NIEHS contracted with three other Clinical Centers to conduct the TLC study in addition to Kennedy Krieger. Those other sites were Cincinnati, Philadelphia and New Jersey.

> The trial shall proceed as follows: 9-12 months for planning; about 1 year for patient enrollment and treatment; the remaining 3 years for follow-up....The trial is of oral chelation therapy with the drug succimer in lead exposed children (blood leads of about 20 ug/dl to 45 ug/dl) of about 18 to 36 months of age. The endpoints are the scores on developmental tests; other endpoints of interest include evidence of drug efficiency and compliance, such as urine and blood lead levels; excretion of other ions like iron, zinc, and calcium; and nervous system, renal and hematopoietic function/toxicity.

See **Exhibit C** at 10.

NIEHS directed the Steering Committee, subject to federal government approval, to further develop the protocol and strategies for the TLC trial. The NIEHS Project Officer and Alternate Project Officer participated in nearly every subcommittee created for the TLC Study. *See* Protocol attached hereto as **Exhibit G** at 40-42.

The Project Officer of NIEHS supervised regular meetings and conference calls with Kennedy Krieger and the other centers regarding study design to ensure that the plans developed consistent with NIEHS objectives. *See* Affidavit of Cecilia Davoli, M.D. attached hereto as **Exhibit E** at paragraph 4; *see also*, and **Exhibit B** at paragraph 4. Final authority over each and every aspect of this Study rested with the Project Officer of NIEHS. *Id.* at paragraph 5; *see also* **Exhibit C** at 21. Pursuant to the contract, Kennedy Krieger did not have the authority to deviate from the approved study protocol of NIEHS. Indeed, NIEHS retained the ability to terminate the contract if Kennedy Krieger deviated from the Study protocol. "Failure of the contractor to abide by the approved shared protocol may result in the termination in accordance with the termination clause." *See* **Exhibit C** at 19.

Pursuant to federal regulation, Kennedy Krieger was required to obtain IRB approval of the Informed Consent Form to be utilized with enrolling study participants. After the local IRB utilized by Kennedy Krieger approved a form, Kennedy Krieger was required to forward that form to the IRB of NIEHS, for further review. The IRB of NIEHS initially rejected the Kennedy Krieger Informed Consent Form because the reading level required for comprehension was too high. *See* **Exhibit B** at paragraph 10 and **Exhibit E** at paragraph 12. Only after Kennedy Krieger revamped its form, secured local IRB approval again, and resubmitted the form to NIEHS, was it approved such that the Study could proceed. *Id.*

NIEHS also imposed substantial reporting requirements on the Clinical Centers participating in the Study. Kennedy Krieger was required to submit to NIEHS technical reports as well as racial/ethnic enrollment reports. **Exhibit C** at 15. During the first year of the Study, Kennedy Krieger submitted semi-annual reports that described the progress in planning, recruitment, community activity and screening, with particular emphasis on the material not covered in the Steering Committee meetings. *Id.* For all subsequent years, Kennedy Krieger submitted quarterly reports outlining the numbers of families contacted and screened, all activities planned and all activities executed during the reporting periods, again with particular emphasis on the materials not covered in the Steering Committee meetings. *Id.* NIEHS also required Kennedy Krieger to submit enrollment reports providing a summary of the planned study population and a summary of the actual number of participants enrolled according to designated racial/ethnic categories. *Id.*

NIEHS also maintained oversight of the study's implementation through periodic site visits. *See* **Exhibit B** at paragraph 6 and **Exhibit E** at paragraph 7. These visits were conducted to ensure that Kennedy Krieger was complying with the TLC Study protocol. *Id.* During these visits, the Project Officer of NIEHS reviewed study participant charts[4] to ensure compliance with federal regulations, observed the study facilities, and conducted visits to houses involved in the Study. *Id.*

The TLC Study involved assessment of the drug Succimer under certain clinical conditions. Because this drug was not approved by the FDA for use under those conditions, NIEHS submitted an Investigational New Drug ("IND") application to the FDA. *See* **Exhibit C** at 13; *see also* **Exhibit B** and **Exhibit E** at paragraph 8. Because NIEHS held the IND for the use of Succimer in children with blood lead levels less than 45 micrograms per deciliter, the Project Officer of NIEHS was actively engaged in ensuring that the Clinical Centers understood Succimer's biochemical behavior. *See* **Exhibit B** and **Exhibit E** at paragraph 8.

The TLC Study was fully funded by NIEHS with support from the Office of Research on Minority Health of the National Institutes of Health ("ORMH, NIH"). *See* **Exhibit G** at paragraph 2.2.

The intimate control exercised by NIEHS over the TLC Study extended through to the Study's conclusion. Indeed, NIEHS prohibited Kennedy Krieger from summarizing the results of the Study absent NIEHS approval. *See* **Exhibit C** at 13.

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[4] The FDA imposes regulations regarding how researchers should document their use of investigational new drugs.

III. LEGAL STANDARDS

A. Federal Rule 12(b)(7) – Dismissal For Failure to Join A Rule 19 Party

A motion to dismiss for failure to join an indispensable party pursuant to Federal Rule 12(b)(7) requires a two-step process. *See* Rule 19, Fed.R.Civ.P.; *Owens-Illinois, Inc. v. Meade*, 186 F.3d 435, 440 (4th Cir. 1999). First, it must be determined whether a party is "necessary" pursuant to Rule 19(a). *Id.* Second, if a necessary party is unavailable, it must be determined whether the party is "indispensable" to the case in that the party's appearance is so necessary that the case must be dismissed. *Id.* The Court's analysis of the necessity and indispensability of a party under Rule 19 must be judged on a case by case basis, however, and "the court must consider the particular potential for prejudice in the context of the particular factual setting presented by the case at bar." *See Schlumberger Indus., Inc. v. Nat'l Sur. Corp*, 36 F.3d 1274, 1286(4th Cir. 1994).

B. Federal Rule 19 – Joinder of Persons Needed For Just Adjudication

Federal Rule 19 governs the "Joinder of Persons Needed for Just Adjudication," and provides, in pertinent part, as follows:

> "a person who is subject to service of process and whose joinder will not deprive the court of jurisdiction over the subject matter of the action shall be joined as a party in the action if (1) in the person's absence complete relief cannot be accorded among those already parties, or (2) the person claims an interest relating to the subject of the action and is so situated that the disposition of the action in the person's absence may (i) as a practical matter impair or impede the person's ability to protect that interest or (ii) leave any of the persons already parties subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by reason of the claimed interest. If the person has not been so joined, the court shall order that the person be made a party."

See Fed. R. Civ. P. 19(a).

Pursuant to Rule 19(b), the Court should consider the following factors to determine whether the action should proceed among the existing parties or whether the action should be dismissed if a necessary party is indispensable:

> The factors to be considered by the Court include: first, to what extent a judgment rendered in the person's absence might be prejudicial to the person or those already parties; second, the extent to which, by protective provisions in the judgment, by a shaping of relief or other measures, the prejudice can be lessened or avoided; third, whether a judgment rendered in the person's absence would be adequate; fourth, whether the plaintiff will have an adequate remedy if the action is dismissed for non-joinder.

See Fed. R. Civ. P. 19(b)

The purpose of Federal Rule 19 is to provide for the full and complete adjudication of a dispute with a minimum of litigation effort, so that the interests of the plaintiff, defendants, and the public will be best served. *See Schutten v. Shell Oil Co.*, 421 F.2nd 869, 873 (5th Cir. 1970). Federal Rule 19 forces a court to question whether the action before it will affect parties not before it. *Teamsters Local Union No. 171 v. Keal Driveaway Co.*, 173 F.3d 915, 917 (4th Cir. 1999).

C. Federal Rule 21 – Misjoinder and Non-Joinder of Parties

Federal Rule 21 governs the "Misjoinder and Non-Joinder of Parties," and provides, in relevant part as follows: "Misjoinder of parties is not ground for dismissal of an action. Parties may be dropped or added by order of the court on motion of any party or of its own initiative at any stage of the action and on such terms as are just."

This Rule grants a trial judge broad discretion to join additional parties as defendants in order to prevent a multiplicity of suits, or to grant complete relief. *See A.S.*

Abell Co. v. Chell, 412 F.2d 712, 717 (4th Cir. 1969); *Caperton v. Beatrice Pocahontas Coal Co.*, 585 F.2nd 683, 691-92 (4th Cir. 1978).

IV. LEGAL ARGUMENT

Dismissal, pursuant to Federal Rule 12(b)(7), requires the court to determine if an "absent" party is "necessary" and, if so, determine whether that party is available to participate in the litigation. NIEHS' control over, and involvement with, the TLC Study makes NIEHS a "necessary" party, which is available to participate in this matter.

A. NIEHS is a necessary party pursuant to Federal Rule 19(a).

The allegations contained in Plaintiffs' Complaint are directly based on Kennedy Krieger's contract with NIEHS to implement the TLC Study. NIEHS funded the TLC Study. The Kennedy Krieger Defendants did not have authority to deviate from its contract with NIEHS, as NIEHS exhibited intimate and detailed control over the TLC Study. Furthermore, the actions of the IRB Defendants regarding the TLC Informed Consent Form and other matters, were approved by the IRB of NIEHS. NIEHS is an indispensable and necessary party to this action given its very detailed level of control over every aspect of the TLC Study.

NIEHS is a subsidiary of the National Institutes of Health, itself a branch of the United States Department of Health and Human Services. Therefore, the Kennedy Krieger Defendants believe that, NIEHS is available to be made a party to this case. *See* Fed. R. Civ. P. 19(b). Assuming, *arguendo*, the NIEHS is not available to be made a party, the NIEHS is nevertheless an indispensable party pursuant to the factors identified in Federal Rule 19(b). First, without the NIEHS as a party Defendant, substantial prejudice will be incurred. The Kennedy Krieger Defendants have been sued as a result

of performing and approving a Study directed, controlled and managed by the NIEHS. In other words, if the NIEHS had not requested such a Study be performed, the Kennedy Krieger Defendants would never have been sued in the first instance. The Kennedy Krieger Defendants are entitled to present the reasons why the NIEHS wanted such a Study performed, and, additionally, why the City of Baltimore was chosen as a Study site. The Court cannot fashion an effective remedy without the NIEHS' involvement as a party. Second, prejudice to the Kennedy Krieger Defendants cannot be avoided absent the presence of NIEHS as a party Defendant. Third, a judgment rendered absent the presence of NIEHS as a party Defendant will be inadequate. For example, the fact finder determines that NIEHS, not the Kennedy Krieger Defendants, was responsible for the design and implementation of the TLC Study, they may find in favor of the Kennedy Krieger Defendants. In that instance, the Plaintiffs may be denied appropriate relief. Alternatively, if the fact finder determines that the Kennedy Krieger Defendants, and NIEHS, were culpable, the Kennedy Krieger Defendants would be denied relief afforded by having another Defendant present in the litigation responsible for the judgment. Fourth, both of the minor Plaintiffs had elevated blood lead levels prior to enrolling in the TLC Study. Therefore, to the extent the Plaintiffs have any causes of action, they would have remedies against the source or sources of those blood lead levels if this matter was dismissed.

B. Complete relief in this case cannot be accorded among the existing parties without the addition of NIEHS.

NIEHS must be added as a party to this matter in order provide complete relief to the existing parties. First, the present Defendants may file third party claims against NIEHS given that it designed, implemented, funded and controlled the TLC Study. The

Kennedy Krieger Defendants were directed and controlled by NIEHS. If the current Defendants do not file third party claims against NIEHS, and if Plaintiffs prevail at trial, it is likely that several Defendants will file actions against NIEHS for indemnification and contribution given its detailed control over the TLC Study.

Moreover, complete relief may not be afforded Plaintiffs if NIEHS is not added as a party. Defendants strongly believe that the jury will find in their favor. Under this scenario, Plaintiffs would likely file suit against NIEHS in a subsequent action. NIEHS must be added as a party to this action in order for all existing parties to obtain complete relief.

C. The failure to include NIEHS as a party will impede its ability to protect its interests involving the TLC Study.

As previously discussed, NIEHS must be a party to this action to protect its interests. There will be extensive testimony from numerous witnesses regarding NIEHS' intimate involvement and control over the TLC Study. Without being a party to this litigation, NIEHS will be unable to defend itself regarding its actions pursuant to the TLC Study. In addition, there will be certain findings of fact that will impair or impede NIEHS' ability to protect its interests in this litigation and subsequent litigation.

As noted above, the parties in the instant matter might file claims against NIEHS. This would expose NIEHS to the risk of incurring multiple or inconsistent obligations based on the TLC Study. For example, if this Court ruled that NIEHS designed, directed, and controlled the TLC Study, that finding would have an adverse effect on NIEHS in subsequent litigation. NIEHS must be added as a party in order to prevent potential inconsistent judgments pursuant to its role in directing the TLC Study. See *Owens-Illinois, Inc. v. Meade*, 186 F.3d 435, 441 (4th Cir. 1999)(non-diverse Plaintiffs were

necessary parties to litigation in order to avoid conflicting legal obligations.) See also *Cleland Construction Co., Inc. v. Balfour Beatty Construction, Inc.*, 229 F.R.D. 521, 525 (D.S.C. 2005)(subcontractor was necessary party with respect to sub-subcontractors' claim against prime contractor given that subcontractor's absence would create the possibility of inconsistent judgments.)

Recently, the Fourth Circuit ruled that both parties to a contract are necessary and indispensable parties involving actions taken pursuant to the contract. See *Yashenko v. Harrah's NC Casino Co., LLC*, 446 F.3d 541 (4th Cir. 2006)(Indian tribe which contracted with casino management company was necessary party to terminated employee's cause of action.) Moreover, in an unreported case involving similar legal issues, the Federal Court for the Southern District of West Virginia ordered a plaintiff, pursuant to Federal Rule 19, to join a party who contracted with a defendant to perform construction that was the subject of the litigation. *See Palmer v Kokosing*, 2005 WL 1389177 (S.D.W.Va., June 2005)(Not Reported in F.Supp 2d). Attached as **Exhibit H** is a copy of the opinion for the Court's convenience.

In *Palmer*, defendant, Kokosing-Frucon, LLC ("Kokosing"), was involved in a construction project from which plaintiffs alleged nuisance and filed suit requesting both damages and injunctive relief. Kokosing argued that plaintiffs failed to join a necessary party - the United States Army Corp of Engineers ("Corp"). Kokosing argued that the Corp was a necessary party to the action because the Corp bought the homes and contracted with Kokosing to work on the development of the housing community. The Court held that, pursuant to Federal Rule 19, plaintiffs failed to join a necessary party and that the Corp should be joined in the action. The Court explained that the project was

controlled by the Corp in that the Corp defined the project's dimensions, specifications, and type of equipment used. *Id.* at 2. Moreover, if the Corp was not joined, Kokosing could be faced with conflicting obligations from the Court, which could result in additional litigation. Also, the Court stated that if there was a finding against Kokosing, it might file a claim against the Corp in a subsequent action. *Id.* The Court reasoned that joining the Corp as a necessary party served to avoid multiple litigation, provided the parties with complete and effective relief in a single action, while simultaneously protecting absent persons from the possible prejudicial effect of deciding the case without them. *Id.* 5

Just as the *Palmer* Court joined a necessary party, NIEHS should also be joined as a party in order to avoid inconsistent results regarding potential litigation in other jurisdictions. In addition to conducting the TLC Study in Baltimore, NIEHS conducted the TLC Study in Newark, Philadelphia, and Columbus. Any rulings by this Court regarding NIEHS' degree of direction and control involving the TLC Study in Baltimore, will certainly impact NIEHS' ability to defend itself in litigation that may ensue from its direction and control of TLC Studies in Newark, Philadelphia, and Columbus.

V. CONCLUSION

NIEHS is an indispensable party to this litigation. Without the presence of NIEHS as a party in this case, complete relief cannot be afforded the existing parties and NIEHS will be unable to protect its interests as they relate to the TLC Study. Because Plaintiffs have failed to name NIEHS as a party, this matter should be dismissed.

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5 After the plaintiffs joined the Corp, the Court later held, in that particular instance, that the Corp was not an indispensable party and therefore denied Kokosing's Motion to Dismiss. See *Id.*, 2006 W.L. 890009 (S.D.W.Va. March 29, 2006), which is attached as **Exhibit I.**

Alternatively, in the event that this Court does not grant dismissal of this matter, this Court should order Plaintiffs to amend their Complaint and add NIEHS as a Defendant in order to provide complete relief to all parties in this litigation, and to protect NIEHS' interests by preventing additional suits against it in subsequent proceedings.

WHEREFORE, Defendants Kennedy Krieger Institute and Cecilia Davoli, M.D., respectfully request that this Court grant their Motion to Dismiss or, in the alternative, require Plaintiffs to amend their Complaint and add NIEHS as an additional Defendant to this matter.

/s/ Barry C. Goldstein
Barry C. Goldstein, Esquire
(Federal Bar No. 24796)
Nicole A. McCarus, Esquire
(Federal Bar No. 27971)
John T. Sly, Esquire
(Federal Bar No. 26608)
Waranch & Brown, LLC
1301 York Road, Suite 300
Lutherville, Maryland 21093
(410) 821-3511
Attorneys for Kennedy Krieger Institute, Inc., and Cecilia Davoli, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al.	*	
Plaintiffs	*	
v.	*	
		Case No. 1:07-cv-01120
KENNEDY KRIEGER INSTITUTE, INC., et al.	*	
Defendants	*	

* * * * * * * * * * *

REQUEST FOR HEARING

Defendants, Kennedy Krieger Institute ("Kennedy Krieger") and Cecilia Davoli, M.D., hereby request a hearing on their Motion to Dismiss for Plaintiffs' Failure to Join a Rule 19 Party, or in the Alternative, Motion to Join The National Institute of Environmental Health Sciences as a Party.

/s/ Barry C. Goldstein

Barry C. Goldstein, Esquire
(Federal Bar No. 24796)
Nicole A. McCarus, Esquire
(Federal Bar No. 27971)
John T. Sly, Esquire
(Federal Bar No. 26608)
Waranch & Brown, LLC
1301 York Road, Suite 300
Lutherville, Maryland 21093
(410) 821-3511
Attorneys for Kennedy Krieger Institute, Inc., and Cecilia Davoli, M.D.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al. *

Plaintiffs *

v. *

Case No. 1:07-cv-01120

KENNEDY KRIEGER INSTITUTE, INC., et al. *

Defendants *

****

ORDER

Upon Defendants', Kennedy Krieger Institute and Cecilia Davoli, M.D.'s Motion to Dismiss for Plaintiffs' Failure to Join a Rule 19 Party or, In The Alternative, Motion to Join The National Institute of Environmental Health Sciences As A Party, and any Opposition thereto, it is this _____ day of _____, 2007, ORDERED:

1. That the Defendants' Motion to Dismiss for Plaintiffs' Failure to Join a Rule 19 Party BE and the same hereby is GRANTED and this matter is dismissed with prejudice; or alternatively:

2. That Plaintiffs join The National Institute of Environmental Health Sciences as a party to the above-entitled action.

_____
Judge,
United States District Court For The
District of Maryland
(Northern Division)

LIST OF EXHIBITS

Exhibit A	-	Complaint
Exhibit B	-	Affidavit of Merrill Brophy
Exhibit C	-	Award/Contract between National Institute of Environmental Health Sciences ("NIEHS") and Kennedy Krieger Research Institute, Inc.
Exhibit D	-	Memorandum dated June 25, 1993 from Contracting Officer of the Department of Health & Human Service of NIEHS Sciences to Dr. Walter Rogan and Ms. Beth Ragan
Exhibit E	-	Affidavit of Cecilia Davoli, M.D.
Exhibit F	-	Letter dated June 26, 1995 to Tom Hardee of the NIEHS from Merrill Brophy
Exhibit G	-	Treatment of Lead-Exposed Children Trial – Protocol Dated October 17, 1994
Exhibit H	-	*Palmer v. Kokosing West Virginia, LLC*, 2005 WL 1389177 (S.D.W.Va.)
Exhibit I	-	*Palmer v. Kokosing West Virginia, LLC*, 2006 WL 890009 (S.D.W.Va.)

UNITED STATES DISTRICT COURT
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Defendants	*	

* * * * * * * * * * * * * *

EXHIBIT LIST

Exhibit 1	*Grimes et. al., v. Kennedy Krieger Institute, Inc., et al.*, 366 Md. 29 (2001).
Exhibit 2	November 23, 1992, Technical Plan Prepared by KKI, et al.
Exhibit 3	*Myron Higgins, et al., v. Lawrence Polakoff, et al.,* Baltimore City Circuit Court Case No. 950660671; Kennedy Krieger Institute's Memorandum of Points and Authorities in Support of Motion to Dismiss.
Exhibit 4	November 23, 1992, Technical Plan Prepared by KKI, et al., page 15.
Exhibit 5	June 29, 1993, NIEHS Award/Contract for the TLC study to KKI, pages 9-10.
Exhibit 6	June 29, 1993, NIEHS Award/Contract for the TLC study to KKI, page 11.
Exhibit 7	June 29, 1993, NIEHS Award/Contract for the TLC study to KKI, pages 11-12.
Exhibit 8	June 29, 1993, NIEHS Award/Contract for the TLC study to KKI, page 12.
Exhibit 9	September 20, 1995, Correspondence from Janet Serwint to Jeanne Butta.
Exhibit 10	Transcript of May 5, 1997, deposition of Mark Farfel, *Higgins, et al., v. Polakoff, et al.,* Baltimore City Circuit Court Case No. 95066067, page 6 @ line 17-21.
Exhibit 11	June 21, 1995, Clinical Investigation Consent Form for Keona Featherstone.

Exhibit 12 February 10, 1993, Correspondence of Thomas R. Hendrix, Chairman-JCCI to J. Julian Chisolm approving Research Proposal Number 92-11-19-01.

Exhibit 13 December 26, 2001, Motion of KKI for Protective Order, *Quyaisha Coles, et al., v. KKI, et al.,* Baltimore City Circuit Court Case No. 24-C-01-004337, at 4.

Exhibit 14 Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Coles, et al., v. Kennedy Krieger Institute, et al.,* Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 49.

Exhibit 15 Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Coles, et al., v. Kennedy Krieger Institute, et al.,* Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 38, lines 15-21.

Exhibit 16 December 7, 1994, IRB submission from subcontractor to KKI.

Exhibit 17 January 2, 1996, Correspondence from KKI subcontractor Judith Rubin, to Merrill Brophy.

Exhibit 18 September 28, 1995, correspondence from Merrill Brophy to Naline Bhargava.

Exhibit 19 Medical records of Shayonna Featherstone.

Exhibit 20 Medical records of Shayonna Featherstone.

Exhibit 21 Baltimore City Health Department, Lead Paint Poisoning Prevention Program, records for Keona Featherstone.

Exhibit 22 November 23, 1992, Technical Plan Prepared by KKI, et al.

Exhibit 23 November 23, 1992, Technical Plan Prepared by KKI, et al., page 30.

Exhibit 24 Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Coles, et al., v. Kennedy Krieger Institute, et al.,* Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 66.

Exhibit 25 Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Coles, et al., v. Kennedy Krieger Institute, et al.,* Circuit Court for Baltimore City Case No.: 24-C-01-004337, pages 49-50.

Exhibit 26 August 29, 2005, Arc Environmental Report.

Exhibit 27 Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Coles, et al., v. Kennedy Krieger Institute, et al.*, Circuit Court for Baltimore City Case No.: 24-C-01-004337, 44-45.

Exhibit 28 January 25, 1993, Correspondence from J. Julian Chisolm to Thomas R. Hendrix.

Exhibit 29 Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Coles, et al., v. Kennedy Krieger Institute, et al.*, Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 37, lines 5-21.

Exhibit 30 June 12, 1995, loan agreement for 2418 Jefferson Street between the NACI Corporation and the Maryland Department of Housing and Community Development.

Exhibit 31 Transcript of August 26, 2003, Deposition of Lawrence Polakoff, *Coles, et al., v. Kennedy Krieger Institute, et al.*, Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 91, line 1-7.

Exhibit 32 Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Coles, et al., v. Kennedy Krieger Institute, et al.*, Circuit Court for Baltimore City Case No.: 24-C-01-004337, pages 62-69.

Exhibit 33 Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Coles, et al., v. Kennedy Krieger Institute, et al.*, Circuit Court for Baltimore City Case No.: 24-C-01-004337, pages 34-37.

Exhibit 34 April 19, 2007, Affidavit of Cecilia Davoli.

Exhibit 35 Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Coles, et al., v. Kennedy Krieger Institute, et al.*, Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 167.

Exhibit 36 Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Coles, et al., v. Kennedy Krieger Institute, et al.*, Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 177.

Exhibit 37 Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Coles, et al., v. Kennedy Krieger Institute, et al.*, Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 178-179.

Exhibit 38 Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Coles, et al., v. Kennedy Krieger Institute, et al.*, Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 198.

Exhibit 39 Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Coles, et al., v. Kennedy Krieger Institute, et al.*, Circuit Court for Baltimore City Case No.: 24-C-01-004337, pages 198-199.

Exhibit 40 September 21, 1994, Protocol for the TLC Trial, page 3.

UNITED STATES DISTRICT COURT
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KENNEDY KRIEGER INSTITUTE, INC., et al.	*	
Defendants	*	

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MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR JOINDER OR TO DISMISS

I. Introduction

The Defendants Motion is a blatant attempt at forum shopping. The Defendants have not responded to Plaintiffs' discovery propounded in the Circuit Court for Baltimore City; however, these same Defendants produced discovery in prior cases in that court regarding this exact study. The self-serving documents and affidavits which they have selectively chosen to submit to this Court in the instant case should be viewed with skepticism. The Defendants choose to characterize their actions as those of obedient servants of the National Institute of Environmental Health Services ("NIEHS"), despite, as set forth more fully herein, the explicit statement within their Award/Contract that KKI was conducting the Treatment of Lead Exposed Children, (TLC), study "**Independently and not as an agent of the Government**." *See* Page 6, *Supra.* Further, the Defendants' arguments find no support in the opinion of the Maryland Court of Appeals in *Grimes et. al., v. Kennedy Krieger Institute, Inc., et al.*, 366 Md. 29, 50 (2001)(Exhibit 1), regarding a strikingly similar non-therapeutic study. Additionally, the depositions of witnesses in

other cases involving the TLC study and documents produced by the Defendants in this and other cases reveal that the Defendants' assertion is baseless inasmuch as the Kennedy Krieger Institute, (KKI) and principal investigator Cecilia Davoli, (Davoli), the Johns Hopkins University, (Hopkins), and the members of the Hopkins' institutional review board (IRB) had a non-delegable duty to ensure the safety of the children used as research subjects in the study for which KKI designed the architecture and instrumentalities.

A. The duties of KKI and the Principal Investigators to children used as human research subjects as recognized by the Maryland Court of Appeals in *Grimes*.

The contours of the Lead-based Paint Abatement Repair and Maintenance study, (R&M study), the subject of the *Grimes* opinion, closely track those of the TLC study. As set forth *Supra*, one of the contractors used by KKI in both the R&M study and the TLC study gave sworn testimony that the levels of environmental intervention and the manner by which the homes of children in the two studies were assigned the interventions specified by KKI were virtually identical. As Mr. McNutt sworn testimony reveals, "[t]he repair and maintenance and the TLC were the same thing, but there was a few hundred dollars difference between each one." *See* Exhibit 24, *Supra.* Thus, it is useful to examine the opinion of the Maryland Court of Appeals regarding the cases of two children used as human research subjects in the R&M study as a threshold to understanding the TLC study, which was undertaken by KKI immediately after the conclusion of the R&M study.

Non-therapeutic research programs create a special relationship between the researchers and their human subjects and concomitant duties of those researchers to protect their human subjects. The breaches of such duties may ultimately result in viable negligence actions. *Grimes,*

Id. 366 Md. at 48.

In the case of *Myron Higgins, et al., v. Lawrence Polakoff, et al.,* Baltimore City Circuit Court Case No. 950660671; *Sub nom. Grimes et. al., v. Kennedy Krieger Institute, Inc., et al.,* 366 Md. 29 (2001), the Plaintiffs were lead-poisoned as a result of participating in the R&M study.

> [T]he purpose of the [R&M] experiment was to determine whether there was a less expensive way than full abatement that would be cost-effective in reducing lead poisoning in children from a lower economic background. The study, by its design, placed and/or retained children in areas where they might come into contact with elevated levels of lead dust. Clearly, KKI contemplated that at least some of the children would develop elevated blood lead levels while participating in the study.

Grimes, Id. 366 Md. at 103.

> [T]he risks associated with exposing children to lead-based paint [in the R&M study] were not only foreseeable, but were well known by KKI, and, in fact, it had to have been reasonably foreseeable by KKI that the children's blood might be contaminated by lead because the extent of contamination of the blood of the children would, in significant part, be used to measure the effectiveness of the various abatement methods. Moreover, in the present cases, the consent forms did not directly inform the parents that it was possible, even contemplated, that some level of lead, a harmful substance depending upon accumulation, might contaminate the blood of the children.

Grimes, Id. 366 Md. at 98. As will be set forth more fully herein, the Court's opinion is equally applicable to the TLC study. The similarities between the most offensive parts of the R&M study, and the TLC study are clear. For example, as KKI stated to the NIEHS, "[i]t is expected that some patients [in the TLC study] will experience increasing blood lead levels during the course of the trial." (November 23, 1992, Technical Plan Prepared by KKI, et al. Exhibit 2).

> One simply does not expose otherwise healthy children, incapable of personal assent (consent), to a nontherapeutic research environment that is known at the inception of the research, might cause the children to ingest lead dust. It is especially troublesome, when a measurement of the success of the research experiment is, in

> significant respect, to be determined by the extent to which the blood of the children absorbs, and is contaminated by, a substance that the researcher knows can, in sufficient amounts, whether solely from the research environment or cumulative from all sources, cause serious and long term adverse health effects. Such a practice is not legally acceptable.

Grimes, Id. 366 Md. at 105.

In the *Higgins* case, KKI sought summary judgment by asserting that it had no duty to warn or protect the child research subjects used in the R&M study. (*Myron Higgins, et al., v. Lawrence Polakoff, et al.,* Baltimore City Circuit Court Case No. 950660671; Kennedy Krieger Institute's Memorandum of Points and Authorities in Support of Motion to Dismiss, Exhibit 3). Not surprisingly, the Maryland Court of Appeals rejected this assertion and issued a scathing opinion castigating KKI and the IRB for their complacency, careless behavior, and wanton disregard for the safety of children for whom they had a special duty to protect. After noting that "it is, first and foremost, the responsibility of the researcher and the research entity to see to the harmlessness of such nontherapeutic research," *Grimes, Id.* 366 Md. at 100, the Court of Appeals observed that the vulnerability of the children used in the R&M study by the Defendants as research subjects was similar to that of the subjects experimented upon in other notorious examples of nontherapeutic research such as the Tuskegee study, the post-war Jewish hospital studies, the "plague bomb" experiments carried out by the Japanese, and the experimentation of the Nazis at Buchenwald. *Grimes, Id.* 366 Md. at 44-45. As explicated more fully below, the TLC study also employed the use of children as research subjects many of whom were from the same geographical area, also referred to as a catchment area, as those used in the R&M study.[1]

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[1]Assumedly for the sake of convenience to the researchers, the R&M catchment area consisted almost exclusively of homes adjacent to KKI in eastern Baltimore City. The families who lived in the areas mined by KKI for research subjects for both the TLC and R&M studies

Further, one of the selling points used by KKI to secure funding for the TLC study was that, the Pediatric Lead Clinic at KKI provided a ready source of lead-poisoned children to use as study subjects.[2] As the Maryland Court of Appeals stated, "[n]othing about the research was designed for treatment of the subject children. They were presumed to be healthy at the commencement of the project. As to them, the research was clearly nontherapeutic in nature." *Grimes, Id.*, 366 Md. at 42-43. Likewise, the TLC researchers conceded in their published report that the TLC study therapeutic in nature. "[T]he very nature of nontherapeutic scientific research on human subjects can, and normally will, create special relationships out of which duties arise." *Grimes, Id.* 366 Md. at 74.

The IRB was charged with the duty to implement additional safeguards to protect the child research subjects, was required to independently monitor the study, and was empowered to suspend the research activities of KKI and or Davoli during the TLC study, if necessary, to protect the safety of the children being used as research subjects. *Id.* at §46.111(b), §46.112, and §46.113, respectively. "Some analysts contend that IRB review tends to focus exclusively on consent requirements, rather than fully evaluating the merits of the research. Yet, it is important to recognize *that, even before consent becomes an issue, the scientific merits and the acceptability of risks need to be appraised." Grimes, Id.* 366 Md. at 79 (Internal citations and quotations omitted)(Emphasis supplied). In any event, "[a] researcher's duty is not created by, or

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were characteristically poor and African American. Not surprisingly, and likely for the same reasons, many of the children used by KKI in the TLC study, including the Plaintiffs, resided within close geographical proximity to KKI.

[2](November 23, 1992, Technical Plan Prepared by KKI, et al., page 5, Exhibit 4)(Stating, "[o]ver the years a number of clinical research studies have been carried out in this clinic population, including studies on succimer and household lead remediation...").

extinguished by, the consent of a research subject **or by IRB approval**. ... All of this is especially so when the subjects of research are children. Such legal duties, and legal protections, might additionally be warranted because of the likely conflict of interest between the goal of the research experimenter and the health of the human subject, especially, but not exclusively, when such research is commercialized." *Grimes, Id.* 366 Md. at 100 (Emphasis added).

Hence, the level of involvement of the NIEHS *vel non*, in the activities of KKI and Davoli pertaining to the TLC study has no bearing upon the Plaintiffs' claims against Hopkins and the IRB because the duties of Hopkins and the IRB to the Plaintiffs were non-delegable and distinct from those of KKI and Davoli. 45 CFR §46.114 (Stating that where, as here, cooperative research involves more than one institution, and absent conditions precedent which are inapplicable to the instant matter, "[i]n the conduct of cooperative research projects, **each institution is responsible for safeguarding the rights and welfare of human subjects** and for complying with this policy." (Emphasis added).[3] The duties of Hopkins and the IRB to the Plaintiffs could not be ceded to the control of the NIEHS nor the United States Government.

Exhibit C to the Defendants' Motion undercuts nearly all of their assertions that they were not primarily responsible for the safety of the minor plaintiffs during the TLC study. More precisely the duties of KKI under the TLC contract were as follows:

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[3] "[45 C.F.R. 46.116(e)] specifically provides: 'The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.' Those various federal or state conditions, recommendations, etc., may well be relevant at a trial on the merits as to whether any breach of a contractual or other duty occurred, or whether negligence did, in fact, occur; **but have no limiting effect** on the issue of whether, at law, legal duties, via contract or 'special relationships' are created **in Maryland** in experimental nontherapeutic **research involving Maryland children**." *Grimes, Id.* 366 Md. at 50 (Emphasis added)..

ARTICLE C.2. STATEMENT OF WORK

a. **Independently and not as an agent of the Government, [KKI]** shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the government, as need to perform the work below...

. . .

The criteria by which homes will be evaluated and the clean-up protocol shall be decided during the planning phase, but clean-up will not be identical at each site, and will consist of means suited to the catchment area of each Clinical Center.

(June 29, 1993, NIEHS Award/Contract for the TLC study to KKI, pages 9-10)(Exhibit 5).

In **cooperation with** the Coordinating Center, the other Clinical Centers, and NIEHS staff, [KKI] shall participate in the design of the trial protocol, and then recruit, evaluate, **treat**, and follow-up patients according to trial protocol.

(June 29, 1993, NIEHS Award/Contract for the TLC study to KKI, page 11)(Exhibit 6)

[KKI] shall identify the potential lead sources in the child's environment and decrease the exposure in those who need it.

. . .

[KKI] shall provide short term housing as it considers necessary.

(June 29, 1993, NIEHS Award/Contract for the TLC study to KKI, pages 11-12)(Exhibit 7).

Nutritional management: [KKI] shall evaluate the children for iron deficiency and treat it...

. . .

[KKI] shall perform clinical monitoring of children, and including any laboratory procedures necessary for safety monitoring because the children are being treated under an IND.

. . .

Safety and efficacy monitoring: [KKI] has the **primary responsibility for the monitoring of the safety of the children and monitoring the efficacy of the drug.**...

(June 29, 1993, NIEHS Award/Contract for the TLC study to KKI, page 12)(Exhibit 8).[4]

The instant Motion is yet another demonstration of the Defendants abject refusal to accept responsibility for their actions.

B. The stark similarities between the R&M study and the TLC study

The R&M study was designed to study the effects, if any, of various degrees of partial lead-based paint abatements. *Grimes, Id.* 366 Md. at 56. The TLC study was designed to study the effects, if any, of the off-label use of succimer, a chelating agent used to expedite the removal of lead from a child's body, on children with significantly elevated levels of lead in their blood while the children resided in homes which received virtually identical levels of partial lead-based paint abatements as those used in the R&M study. While the use of succimer was a part of the standard of care for children with blood lead levels higher than those of the children used in the TLC study, it was not indicated for use on children with blood lead levels within the range of the study participants.

The R&M study was funded partially by the EPA and partially by the Maryland Department of Housing and Community Development. (Transcript of May 5, 1997, deposition of Mark Farfel, *Higgins, et al., v. Polakoff, et al.,* Baltimore City Circuit Court Case No. 95066067,

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[4]It is important to note that the Plaintiffs have contended that KKI, in furtherance of the TLC study failed to adhere to the standard of care for lead-poisoned children. Specifically, iron anemia facilitates the absorption of lead into a child's body; as such, the standard of care for lead-exposed children who are anemic dictates the administration of an iron supplement, such as Fer-in-sol. On or about September 20, 1995, Keona Featherstone, one of the minor Plaintiffs, was determined to be anemic by her treating physician. The physician, in accordance with the standard of care, prescribed an iron supplement. However, rather than protect Keona's safety, the TLC researchers "advise[d] mom to stop giving the iron" during the next course of study drug administration. (September 20, 1995, Correspondence from Janet Serwint to Jeanne Butta, Exhibit 9).

page 6 @ line 17-21, Exhibit 10). The TLC study was partially funded by the NIEHS and by the Baltimore City Department of Housing and Community Development. KKI was paid at least $200,000.00 for authoring and conducting the R&M study. KKI was compensated in excess of $ 5,000,000.00 for the TLC study, a figure which included payment for the salaries of KKI employees J. Julian Chisolm, Gary W. Goldstein, and Martha B. Denckla. *See* Exhibit C to Defendants' Motion for Joinder at page 5. "The 'for profit' nature of some research may well increase the duties of researchers to insure the safety of research subjects, and may well increase researchers' or an institution's susceptibility for damages in respect to any injuries incurred by research subjects." *Grimes, Id.* 366 Md. at 94, Fn. 12.

Both the R&M study and the TLC study required KKI to obtain initial approval for, and continuing oversight of the research activities by an IRB. *See* 45 C.F.R. § 46.101, *et seq.* The IRB for the TLC study was the same IRB that grossly mishandled the R&M study, to wit the Joint Committee on Clinical Investigations (JCCI) which was constituted and staffed by Hopkins. The JCCI's stamp of approval appears on the consent form signed by Shayonna Featherstone's mother. (June 21, 1995, Clinical Investigation Consent Form for Keona Featherstone, Exhibit 11) and (February 10, 1993, Correspondence of Thomas R. Hendrix, Chairman-JCCI to J. Julian Chisolm approving Research Proposal Number 92-11-19-01, Exhibit 12). As evinced by the JCCI-IRB letter to Dr. Chisolm, the Treatment of Lead Exposed Children study was originally called the "Toxicity of Lead in Children" study. Apparently, truth in advertising was not a chief aim of the researchers or the IRB.

The following chart illustrates some of the key similarities between the studies:

The R&M study	The TLC study
Partially funded by the EPA and the Maryland Department of Housing and Community Development [5]	**Partially funded by the NIEHS and the Baltimore City Department of Housing and Community Development** [6]
KKI conducted research on Maryland children in economically depressed areas of Baltimore City	**KKI conducted research on Maryland children in economically depressed areas of Baltimore City**
Research was non-therapeutic [7]	**Research was non-therapeutic**
KKI arranged for contractors to perform less than full lead-based paint abatements on the homes of study participants [8]	**KKI arranged for contractors to perform less than full lead-based paint abatements on the homes of study participants** [9]
Interventions were virtually identical to those in the TLC study [10]	**Interventions were virtually identical to those in the R&M study** [11]

[5] *Grimes, Id.,* 366 Md. at 50.

[6] December 26, 2001, Motion of KKI for Protective Order, *Quyaisha Coles, et al., v. KKI, et al.,* Baltimore City Circuit Court Case No. 24-C-01-004337, at 4. (Exhibit 13).

[7] *Grimes, Id.,* 366 Md. 42-43.

[8] *Grimes, Id.,* 366 Md. At 36.

[9] December 26, 2001, Motion of KKI for Protective Order, *Id.*

[10] Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Coles, et al., v. Kennedy Krieger Institute, et al.,* Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 49, Exhibit 14.

[11] Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Id.*, page 38, lines 15-21, Exhibit 15.

Research subjects were vulnerable children [12]	**Research subjects were vulnerable children** [13]
Study required continued exposure of small children to lead-based paint and lead-based paint dust to determine if partial interventions were effective [14]	**Study required continued presence of of children in homes containing lead-based paint and lead-based paint dust to control for the evaluation of the effectiveness of off-label use of drug upon the long-term psychological outcome of the research subjects** [15]
Level of interventions a home received were randomly assigned [16]	**The child research subjects were randomly assigned, through a double-blinded administration, either Succimer or a placebo** [17]
Parents were not adequately informed that the research activity increased the risk that the amount of lead in the child research subject's bodies could increase suffer lead-poisoning[18]	**Parents were not adequately informed that the research activity increased the risk that the amount of lead in the child research subject's bodies could increase suffer lead-poisoning** [19]

[12] *Grimes, Id.,* 366 Md. 42-43

[13] December 7, 1994, IRB submission from subcontractor to KKI, Exhibit 16.

[14] *Grimes, Id.,* 366 Md. at 103.

[15] January 2, 1996, Correspondence from KKI subcontractor Judith Rubin, to Merrill Brophy regarding IRB concerns over continued use of an untreated group of lead-exposed children as controls. Exhibit 17.

[16] *Grimes, Id.,* 366 Md. at 55.

[17] *Rogan, et al., The Effect of Chelation Therapy With Succimer on Neuropsychological Development in Children Exposed to Lead*, May 10, 2001, N. Engl. J. Med., Vol 344, No. 19, page 1421.

[18] *Grimes, Id.,* 366 Md. at 90.

[19] June 21, 1995, Clinical Investigation Consent Form for Keona Featherstone. *See*, Exhibit 11.

Research activity and consent protocols required approval and supervision by local IRB [20]		Research activity and consent protocols required approval and supervision by local IRB [21]

However, there was at least one difference between the two studies. Rather than entice children and their families into living in lead-infested housing only to study how much lead accumulated in their bodies, the TLC researchers took the premise one step further. In the TLC study, the human research subjects were experimented upon by KKI personnel to determine both the amount of lead they would accumulate in their bodies and the long-term health effects. Unfortunately, this distinction offers no succor to the Defendants. As stated by the Maryland Court of Appeals:

> Otherwise healthy children, in our view, should not be enticed into living in, or remaining in, potentially lead-tainted housing and intentionally subjected to a research program, which contemplates the probability, or even the possibility, of lead poisoning or even the accumulation of lower levels of lead in blood, in order for the extent of the contamination of the children's blood to be used by scientific researchers to assess the success of lead paint or lead dust abatement measures.

Grimes, Id. 366 Md. at 41.

II. Factual Summary

The Plaintiffs are Shayonna Featherstone, born October 22, 1992, and Keona Featherstone, born September 11, 1993. The Featherstone family resided in 2418 Jefferson Street in Baltimore, Maryland from approximately 1994 through 1996. During the above period, both children were enrolled in the Kennedy Krieger Institute (KKI) Treatment of Lead Exposed

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[20] *Grimes, Id.,* 366 Md. At 79; 45 C.F.R. § 46.101, *et seq.*

[21] July 1, 1994, Correspondence from Walter Rogan to J. Julian Chisolm, (Exhibit xx); *Grimes, Id.,* 366 Md. At 79; 45 C.F.R. § 46.101, *et seq.*

Children (TLC) study and their home received interventions from agents of the TLC program. Shayonna was referred to KKI by her treating physician Dr. J. Julian Chisolm in 1994 and both she and her sister were followed by KKI until as late as March of 1999.

Consistent with the Maryland Court of Appeals assessment that children in the R&M study were used as canaries in the coal mines, correspondence of Merrill Brophy to the research subject's treating physicians bore the following admonition:

> Because of the double blind nature of this clinical trial we ask that you refrain from monitoring lead levels **during the treatment phase of the study**, for each participant. If you feel you must check levels, **please do not inform the families** or us of any results.

(September 28, 1995, correspondence from Merrill Brophy to Naline Bhargava, M.D., Exhibit 18).

However, Shayonna's referring doctor, J. Julian Chislom, Jr. of KKI, needed no such admonition inasmuch as he was intimately familiar with the TLC study. Dr. Chisolm, recruited the Plaintiffs to enroll in the TLC study. Despite Shayonna's history of chronic lead-exposure, KKI placed emphasis upon the success of the study instead of her care. Dr. Chisolm, indicated that "[i]f [Shayonna] joins [the TLC study], that takes precedence over return to this **regular** Kennedy Lead Clinic." (Medical records of Shayonna Featherstone, Exhibit 19) (Emphasis supplied). Dr. Chisolm clearly possessed unique knowledge of the parameters of the TLC study and the concomitant environmental treatments to the family home. He knew from prior research conducted by KKI that the environmental treatments were not sufficient to remove the lead hazards from the home. Thus, his referral of the Shayonna to the TLC study is at odds with his prior observation:

> Review of serial laboratory data show that during the past five months there has

> been no essential change in this child's blood lead concentration. Measurements have fluctuated between 18 and 21 µg Pb/dL whole blood. **One wonders whether there is a whole lot of lead paint in this dwelling although when given the address one would certainly expect that.**

(Medical records of Shayonna Featherstone, Exhibit 20)(Emphasis added).

During the children's participation in the study, their mother signed several consent forms wherein **KKI** explicitly promised that:

> All children in the TLC study will have their homes repaired and/or cleaned to get rid of lead dust and chipped paint. We will take a careful look at your home to see if it can be repaired and/or cleaned to reduce lead paint and dust hazards.
> . . .
> The benefits to your child of letting us find out if they are eligible for the TLC study are that:
> * **We** will look **carefully** at your home to **identify lead hazards** and tell you about it.
> * If your house doesn't qualify, **we** will offer you any information we have about ways to relocate your family to housing that is known to be lead safe[.][22]
> * **We** will **clean-up the lead** if it looks like your child and house are eligible.

See Clinical Investigation Consent Form, Exhibit 11.

In approximately December of 1994, agents of KKI performed an inspection of 2418 Jefferson Street. In January of 1995, the Baltimore City Health Department noted "flaking paint around windows, hole in wall [,] steps and peeling surfaces on wall between front windows." (Baltimore City Health Department, Lead Paint Poisoning Prevention Program, records for Keona Featherstone, Exhibit 21). Sometime prior to December of 1995, KKI and/or its agents conducted interventions within 2418 Jefferson Street. The work undertaken was limited to

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[22]The obvious implication of this statement was that if the family home did "qualify" to participate in the study the home must be "lead safe." The language is unambiguous by design, inasmuch as it was "geared to a 6th grade school education level." TLC Trial Protocol v.9.

replacing some windows and covering the kitchen floor in linoleum tiles. The efficacy, *vel non*, of those steps should have been readily apparent to the researchers at KKI, given the following blood-lead levels of the children:[23]

Keona Featherstone

Date	**Blood-lead Level (µg/dL)**	**Date**	**Blood-lead Level (µg/dL)**
3/16/94	5	8/21/95	*Blinded*
9/4/94	20	9/18/95	26
9/14/94	20	10/17/95	*Blinded*
12/12/94	23	11/7/95	27
12/14/94	22	11/15/95	*Blinded*
4/14/95	20	11/28/95	*Blinded*
6/12/95	28	1/16/96	23
6/21/95	28	2/96	20
7/11/95	*Blinded*		

Shayonna Featherstone

Date	**Blood-lead Level (µg/dL)**
7/22/94	32
9/7/94	21

[23]Levels of blood-lead concentrations are measured in micrograms of lead per deciliter of blood (*ug*/dl). There is no safe level of lead in a child's body and the Centers for Disease Control and Prevention have continually lowered to level of concern to where it currently stands at 10 µg/dL. *See USAA v. Riley*, 393 Md. 55, 62 Fn.4 (2006).

> Nearly 2.5 Million U.S. pre-school children are estimated to have [had] blood-lead concentrations [of 15 µg/dL or higher in 1992] that place[d] them at risk for lead's adverse health effects. Of greatest concern is the contribution of lead to neuro-behavioral and learning deficits in young children which are long lasting, if not indeed permanent.

Quality Assurance Project Plan for the Kennedy Krieger Institute Lead-Based Paint Abatement and Repair and Maintenance Study, July 22, 1992, pages 1 and 2.

12/7/94	22
2/8/95	19
7/31/95	19
11/7/95	27

Simply put, after enrolling into the TLC study, Keona's lead levels **increased**. But this likely came as no surprise to KKI inasmuch as the Technical Statement for the TLC study, prepared by KKI contained the following caveat:

> For a number of reasons, our protocol is predicated upon assurance of "lead-safe" housing...for participating families. First we have evidence that where there is an ongoing residential lead exposure, children's [blood-lead levels] may actually increase while on succimer. Secondly, the **standard of care in Baltimore is to give succimer to children on an outpatient basis only if they are residing in "lead safe" housing. Furthermore, the local standard of care includes intensive assistance to families in moving to "lead-safe" housing since they must be out of the house during abatements ordered by the Baltimore City Health Department. Lastly, we belive that the less intensive forms of dust-control alluded to in the NIEHS request for proposal are more likely to be successful in the better maintained types of housing defined herein as "lead safe".**

(November 23, 1992, Technical Plan Prepared by KKI, et al., Exhibit 22).

Similarly, KKI recognized that it alone bore responsibility for monitoring the safety of the child participants:

> **Safety Monitoring:**
>
> We expect that safety monitoring will be a joint effort between the clinical center [KKI] and the Coordinating Center. **At the clinical sites the focus of the clinical monitoring will be on side effect of drug therapy and of evidence of continued exposure to lead.**

(November 23, 1992, Technical Plan Prepared by KKI, et al., page 30, Exhibit 23).

Contrary to the assurances of KKI that it would tell the Featherstone family about any lead hazards identified at 2418 Jefferson Street, KKI failed to fulfill its responsibility to this

family. Further, despite KKI's assurances from 1995 through 1999, via the consent forms, that the above actions would be undertaken in exchange for the participation of the Featherstone family in the TLC study, no additional "interventions" were ever taken within their home(s) after 1995. Arguably, the interventions performed, which were known by KKI at the time to be insufficient to abate existing lead-hazards, amounted to little more than arranging deck chairs on the Titanic.

Dust samples and XRF readings were taken by KKI from 2418 Jefferson Street prior to cleaning and during the study. It is apparent that despite its explicit promise, KKI completely failed to inform the Featherstone family about the levels of lead which existed in the dust in their home prior to or after the interventions; a clear breach of the special duty between investigator and research subject recognized by the Maryland Court of Appeals. More importantly, despite the continued rise of the Plaintiffs' lead levels, the fact that KKI was acutely aware of the dangers of lead-based paint dust to children, and Dr. Chisolm's awareness that the home likely contained "a whole lot of lead paint" the protocols focused upon using only the least-expensive testing methods and provided that the Housing and Urban Development (HUD) lead-dust loading clearance levels were to be ignored. As Fred McNutt, the principal of one of KKI's contractors, testified, the "treatment" which 2418 Jefferson Street received during the TLC study, "...was designed to lower the dust levels, but we weren't and we couldn't be held to a clearance standard because we **weren't treating the hazards**. All we were doing was cleaning existing lead dust." (Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Id.*, page 66, Exhibit 24). KKI was made aware by contractors such as Mr. McNutt that the interventions outlined in the KKI study protocols were insufficient, would not abate any of the existing lead-hazards in the

dwelling and presented an ongoing dangerous lead hazard to the residents.

The cavalier attitude of the TLC researchers towards the environmental hazards to which their child research subjects were exposed stands in stark contrast to the following statement authored by two KKI doctors years prior to the TLC study: "Exposure to lead-bearing dust is particularly hazardous for children because hand-to-mouth activity is recognized as a major route of entry of lead into the body and because absorption of lead is inversely related to particle size." Mark R. Farfel & J. Julian Chisolm, *Health and Environmental Outcomes of Traditional and Modified Practices for Abatement of Residential Lead-Based Paint*, 80 American Journal of Public Health 1240, 1243 (1990).

The families who "qualified" for the TLC study received "three different levels of intervention on properties. It was level one . . .a level two, and then a level three. Each level of intervention had a price cap. I believe the level one was $1,750; the level two was $3,500; and the level three was $ 7,000 or $ 7,500. . . The repair and maintenance and the TLC were the same thing, but there was a few hundred dollars difference between each one." (Transcript of the October 8, 2003, Deposition testimony of Mr. Fred McNutt, *Id.*, pages 49-50, Exhibit 25). KKI was certainly aware that the only effective means of "clean[ing] up the lead," as they had promised, was to remove the lead-based paint from the home.

On August 22, 2005, 2418 Jefferson Street was tested for the presence of lead-based paint by Arc Environmental. (August 29, 2005, Arc Environmental Report, Exhibit 26). Lead-based paint was detected at levels much higher than allowed by Maryland Department of the Environment (MDE) and HUD guidelines. KKI showed little concern for the continued exposure of their young experiment subjects to lead-based paint and lead-based paint dust.

Prevention and Toxics, July 22, 1992, pages 1-2.

III. KKI designed the TLC study and the environmental interventions employed in 2418 E. Jefferson Street.

It is important to note that despite the convenient arguments of KKI that the NIEHS exercised total control over the TLC study, the sworn testimony of KKI's contractor tells a different tale:

> Q: Did ERI exercise its own discretion as to what should be done to each property?
> A: No.
> Q: So the discretion was Kennedy Krieger's as to what should be done?
> [Counsel for KKI]: Objection, form, foundation.
> A: Well, we didn't identify the areas or the components. We were given these field sheets to put together a proposal on our own letterhead. They were Kennedy Krieger's specifications, Kennedy Krieger's field notes, so...I think a lot of times we wouldn't even go out and see the properties, because all the dimensions and everything else were in these field notes, so...

(Transcript of the October 8, 2003, Deposition testimony of Mr. Fred McNutt, *Id.*, pages 44-45, Exhibit 27).

KKI personnel designed the TLC study. The semantics employed by Davoli and Ms. Brophy in their respective affidavits are an insult to this Court. The Defendants hope to mislead the Court into believing that, "The genesis of the TLC study was an RFP issued by NIEHS without any input from Kennedy Krieger." Defendants' Motion at 3. More accurately, KKI submitted an application to the NIEHS in response to a Request for Application from the NIEHS. An RFA, "[i]dentifies a more narrowly defined area for which one or more NIH institutes have set aside funds for awarding grants, usually has a single receipt (received on or before) date specified in the RFA announcement, and is usually reviewed by a Scientific Review Group convened by the issuing awarding component." *See* web-site of the NIH:

http://grants1.nih.gov/grants/guide/description.htm, Accessed June 1, 2007. Regarding the TLC study, the NIEHS RFA "invited proposals **designed along the general outlines** provided by them, with the understanding that the three proposals which they considered best would be funded and that the principal investigators [such as Davoli] for these three proposals would get together and agree to a single, common protocol." (January 25, 1993, Correspondence from J. Julian Chisolm to Thomas R. Hendrix, Exhibit 28). 00620. Put simply, KKI submitted **their version** of the TLC study to the NIEHS in response to the RFA for study designs centered around a general hypothesis, KKI's version was selected for funding.

Clark H. McNutt was a contractor hired by KKI to perform the R&M study interventions, the specifications of which were later used *in pari materia* in the TLC study. Mr. McNutt's sworn testimony was that personnel from KKI, a landlord, and Mr. McNutt developed the contract specifications for the interventions used in the R&M study. His testimony is illuminating about who was, and was not present, at meetings crucial to the execution of the R&M study; "**We** developed specifications for that contract, and then we did different levels of intervention. Levels ones, twos, and threes on, I think it was 225 or 250 homes." (Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Coles, et al., v. Kennedy Krieger Institute, et al.,* Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 37, lines 5-21, Exhibit 29) (Emphasis added). Thus, the Defendants contentions that the NIEHS designed the TLC study and the specifications for the interventions to the research subjects' home is nonsense inasmuch as KKI created the specifications years prior to the TLC study.

"In return for permitting the properties to be used in the study, and in return for renting the study homes to families with young children, KKI assisted the landlords in applying for and

receiving grants or loans of money to be used to perform the levels of abatement required by KKI for each class of home." Grimes, *Id.* 366 Md. at 52; *See* June 12, 1995, loan agreement for 2418 Jefferson Street between the NACI Corporation and the Maryland Department of Housing and Community Development, note the upper right hand corner: "**Loan Program: RELAP KENNEDY KRIEGER INSTITUTE ONLY**", Exhibit 30). However, at least one landlord recognized, albeit in hindsight, that the study was flawed.

> **A: ...It turned out to be a major fiasco. They wanted us to put children at risk in the properties so that they could study them.**
> **Q: Kennedy Krieger did?**
> **A: Yes....**

(Transcript of August 26, 2003, Deposition of Lawrence Polakoff, *Coles, et al., v. Kennedy Krieger Institute, et al.,* Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 91, line 1-7, Exhibit 31)(Emphasis added).

KKI and Davoli were personally made aware by contractors such as Mr. McNutt, who, at the direction of KKI personnel performed TLC study interventions, that the interventions, as specified by KKI, would require ongoing monitoring and maintenance and were insufficient to ensure the safety of children living in the home. (Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Id.*, pages 62-69, Exhibit 32).[24]

As recognized by KKI researchers Mark Farfel and J. Julian Chisolm, "[e]xposure to lead-bearing dust is particularly hazardous for children because hand-to-mouth activity is

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[24]Mr. McNutt's deposition was taken in the matter of Quyaisha Coles v. KKI, et al. The Coles case involved the exact study involved in this case, to wit the TLC study. Mr McNutt testified that the specifications for the interventions he performed at the direction of Farfel and KKI pursuant to the R&M study and the manner in which the homes of research subjects were assigned the various levels of intervention were virtually identical to those he subsequently performed at the direction of KKI pursuant to the TLC study. (Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Id.,* pages 34-37, Exhibit 33).

recognized as a major route of entry of lead into the body and because absorption of lead is inversely related to particule size." [25] Lead poisoning poses a distinct danger to young children. It adversely effects cognitive development, growth, and behavior.[26] Of greatest concern is the contribution of lead to neuro-behavioral and learning deficits in young children which are long lasting, if not indeed permanent. Prevention is the only rational way to approach the problem. Once poisoning occurs it is doubtful that any of the current methods of treatment can fully reverse the damage.[27]

Both Shayonna and Keona have suffered from marked academic failures which have consistently rendered them unable to progress academically with their peers. Neuropsychological testing of Shayonna reveals that she is borderline mentally retarded and has a full scale IQ of 79. Tragically, Keona's level of intellectual functioning is virtually identical to that of her sister inasmuch as she has a full scale IQ of 78.

IV. Procedural Posture

The Defendants have removed the instant action from the Circuit Court for Baltimore City on the untested assertion that KKI and Davoli are entitled to removal based upon 28 U.S.C. 1442(a)(2). The Defendants conveniently fail to mention in their Motion that claims virtually

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[25]Mark R. Farfel & J. Julian Chisolm, *Health and Environmental Outcomes of Traditional and Modified Practices for Abatement of Residential Lead-Based Paint*, 80 American Journal of Public Health 1240, 1243 (1990).

[26]Centers for Disease Control and Prevention. *Recommendations for Blood Lead Screening of Young Children Enrolled in Medicaid: Targeting a Group at High Risk*, 49 Morbidity and Mortality Weekly Report 1 (Dec. 8, 2000).

[27]*Final Report: Quality Assurance Project Plan for the Kennedy-Krieger Institute Lead-Based Paint Abatement Repair and Maintenance Study. To: U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics*, July 22, 1992, pages 1-2.

identical to those in the case at bar were previously litigated. The Defendants' desire to litigate this matter in Federal Court is a transparent attempt at forum shopping and a continued effort to unnecessarily delay the resolution of this matter. Further, while the Defendants have filed virtually identical motions in this case and in the case of *Wallace, et al., v. KKI, et al.,* 1:07-CV-1140, wherein they claim that various agencies and sub-agencies of the United States Government are responsible for the Defendants' negligence, the Defendants' newly adopted position stands in stark contrast to the following observation of the Maryland Court of Appeals:

> We, however, are unaware of, and have not been directed to, any federal or state statute or regulation that imposes limits on this Court's powers to conduct its review of the issues presented. **None of the parties have questioned this Court's jurisdiction in these cases**. Moreover, 45 Code Federal Regulations (C.F.R.) 46.116(e) specifically provides: "The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective." Those various federal or state conditions, recommendations, etc., may well be relevant at a trial on the merits as to whether any breach of a contractual or other duty occurred, or whether negligence did, in fact, occur; but have no limiting effect on the issue of whether, at law, legal duties, via contract or "special relationships" are created in Maryland in experimental nontherapeutic research involving Maryland children.

Grimes, Id. 366 Md. at 50.

However, the inconsistencies between the positions of the Defendants in the instant case with those taken in the *Grimes* case do not end there. In support of the Notice of Removal in the instant case, Dr. Davoli swore to the following:

> 6. The NIEHS, directly controlled and approved the information provided to the Study participants and their families as well as the information contained in the Informed Consent forms.

(April 19, 2007, Affidavit of Cecilia Davoli, Exhibit 34). Davoli's affidavit is clearly intend to leave this Court with the impression that the NIEHS controlled every aspects of the TLC study.

However, Davoli's recent affidavit is at odds with her prior sworn testimony:

> This consent form, I agree with that. This consent form has several parts. The first part of the consent form is a general summary of information about lead, and to the best of my recollection, that all of the consent – this is for the TLC study – and all of the consent forms in all four centers contain essentially the same language, and were written by a group of investigators from all four centers. And the language was reviewed by **the IRB at Johns Hopkins for our particular center**. And also by the NIEHS IRB.

(Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Coles, et al., v. Kennedy Krieger Institute, et al.,* Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 167, Exhibit 35)(Emphasis added).

Further, when examined about the contents of the consent form used in the TLC study, the same one approved by the Hopkins IRB and signed by the Plaintiffs' mother, Davoli painted a markedly different picture of the scope of KKI's involvement than she seeks to do now:

> Q: I didn't ask you about the other centers. In your meeting with [the mother of Quyaisha Coles] when you are reading this to [her] and it says, 'We will look carefully at your home to identify lead hazards and tell you about it,' in this context the 'we' is Kennedy Krieger?
> A: In this particular form it would have been someone in the environmental arm of the TLC study, yes, who was **employed by Kenned Krieger**.

(Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Id.*, page 177, Exhibit 36)(Emphasis added).

> Q: ... Doctor, let's go to the next one. It says, 'If your house doesn't qualify, we will offer you any information we have about ways to relocate your family to housing that is known to be lead safe.' 'We,' again in that context, is Kennedy Krieger, isn't it?
> A: It would have been, yes, people working within the TLC study that **worked at Kennedy Krieger.**

(Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Id.*, page 178-179, Exhibit 37)(Emphasis added). Further, Davoli's sworn testimony reveals that KKI was responsible, not

the NIEHS, for the treatment of the children being experimented upon in the TLC study:

Q: When you read this [part of the consent form to the mother of Quyaisha Coles] and you said 'We will have a doctor examine your child,' you didn't mean that a doctor would come from Philadelphia to examine the child?
A: No.
Q: She would reasonably assumed someone from Kennedy Krieger would examine her child?
A: **Yes, the doctor would be from Kennedy Krieger, I agree with that.**

(Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Id.*, page 198, Exhibit 38)(Emphasis added).

Q: Doctor, the last [promise in the consent form to parents of the study subjects], 'We will check the amount of lead in your child's body carefully.' In this context as read by [Quyaisha Coles' mother], the 'we' is Kennedy Krieger?
A: Well, we would draw the blood, that is correct. **We Kennedy Krieger draw the blood.**
Q: It says, 'We will check the amount of lead in your child's body.' Was there any other doctor in the room when you were reading this to [Quyaisha Cole's mother]?
A: Not to my recollection.

(Transcript of the November 21, 2003 deposition of Cecilia Davoli, *Id.*, pages 198-199, Exhibit 39)(Emphasis added). Patently lacking from the sworn testimony of Davoli is the day to day oversight she now alleges was exercised by the NIEHS.

The Defendants through their pleadings and affidavits again attempt to mislead this Court into believing that the "Steering Committee" was controlled by NIEHS and that the same committee controlled their actions in the TLC study. This is simply untrue.

> Central policy for the [TLC study] will be set by a Steering Committee composed of **one member from each of the above-mentioned organizations [including KKI] and the Project Officer (from NIEHS) who will serve *ex officio,* making a total of seven members.** The Project Officer will **vote to resolve ties.** The Committee will elect its own Chair.

(September 21, 1994, Protocol for the TLC Trial, page 3, Exhibit 40)(Emphasis added). Hence, only 1 of the 7 members of the Committee was from the NIEHS and, absent a tie, he was a non-voting member. Further, the lone member of the Committee from NIEHS was not even the Chairman of the Committee.

To be sure, the Defendants do not seek joinder of the "NIEHS" in order to prevent disparate results; rather, they cling to this thin reed in the hopes of obtaining a different result than that which they obtained in the Maryland Courts regarding the R&M study.

V. The "NIEHS" is not a person capable of joinder in this action.

In order to sue a federal agency in its own name, Congressional consent must clearly be found. "When Congress authorizes one of its agencies to be sued *eo nomine*, it does so in explicit language, or impliedly because the agency is the offspring of such a suable entity." *Blackmar v. Guerre*, 342 U.S. 512, 515 (1952). Congress has not established that the NIEHS may be sued in that manner. *See e.g. Lloyd Ammons, et al., v. Great Lakes Chemical Corp., et al.,* 1986 WL 10743, 4 (W.D. Wash. 1986).

A motion to dismiss for failure to join alleged indispensable parties fails when the movant does not identify the individuals who should be joined. *In re Stat-tech Secs. Litigation,* 905 F. Supp. 1416 (D.C. Colo. 1995), *Charles Alan Wright and Arthur F. Miller, Federal Practice and Procedure*, 5C Fed. Prac. & Proc. Civ.3d § 1359 (2007 Supp.). The defendants have failed to establish that Congress has authorized the NIEHS to be sued *eo nomine*. Thus, The Defendants' Motion should be denied for this reason alone.

VI. Neither the NIEHS, nor the United States, are necessary parties to the instant litigation.

"A party is not necessary simply because joinder would be convenient, or because two

claims share common facts, for that would render the distinction between permissive joinder under Rule 20, Fed.R.Civ.P., and joinder under Rule 19 'practically meaningless.'" *Southern Co. Energy Marketing, L.P. v. Va. Elec. & Power Co.,* 190 F.R.D. 182, 185 (E.D. Va. 1999), (Citing to *Field v. Volkswagenwerk AG,* 626 F.2d 293, 301 (3d Cir.1980)).

Fed.R.Civ.P. 19 provides for the joinder of persons needed for just adjudication and sets out a two-part inquiry. First, under Rule 19(a), the Court must determine whether a person is necessary to the proceedings because of his relationship to the matters under consideration. *Owens-Illinois, Inc. v. Meade*, 186 F.3d 435, 440 (4th Cir. 1999). A person is necessary to the action if: (1) in the person's absence complete relief cannot be accorded among those already parties, or (2) the person claims an interest relating to the subject matter of the action and is so situated that the disposition of the action in the person's absence may (i) as a practical matter impair or impede the person's ability to protect that interest or (ii) leave any of the persons already parties subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by reason of the claimed interest.

A. Joinder is not necessary to afford complete relief to the Plaintiffs for the injuries caused by the Defendants.

"[I]t must be noted that complete relief refers to relief as between the parties already parties, and not as between a party and the absent person whose joinder is sought." 3A *Moore's Federal Practice* ¶ 19.07-1[1], at 19-93-96 (2d ed.1991). The Plaintiffs have asserted claims for money damages against the Defendants. Those claims sound in Maryland common-law tort, civil conspiracy, and fiduciary duty. No part of the relief requested by the Plaintiffs requires the joinder of the NIEHS or the United States.

Arguendo, any implication by the Defendants that joinder is required because they

themselves may bring a claim against the NIEHS, or the United States, for contribution or indemnification, is both circular and counter-intuitive and distorts the plain meaning of complete relief. The Rule 19 analysis refers only to relief between the persons already parties. No part of the analysis is contingent upon claims which the Defendants may bring against each other or another party. *Heinrich v. Goodyear Tire & Rubber Co.*, 532 F.Supp. 1348, 1359 (D.Md. 1982). Thus, any claims of the instant Defendants against the NIEHS, the United States, or anyone else are irrelevant to the joinder analysis.

The Defendants the Court to an opinion from the United States District Court for the Southern District of West Virginia. *See*, Defendants' Motion @ 13, (Citing to *Palmer v*[.] *Kokosing*, No. 2:05-0091, 2005 WL 1389177 (S.D.W.Va. June 9, 2005).

The Defendants assert as a threshold matter that the *Palmer* case and the instant case "involv[e] similar legal issues." The Defendants are wrong. The Plaintiffs in *Palmer* sought injunctive relief against a contractor hired by the Corps of Engineers. The Corps had hired the contractor to raze a housing development for a then-ongoing project of the United States. The *Palmer* Plaintiffs sought an injunction ordering the contractor to cease and desist the demolition which would have had the effect of halting the Corps' project. The Court in that matter did indeed order that the Corps be joined into the case, for obvious reasons. However, the claims in the instant case seek, *inter alia*, to hold the Defendants liable for their negligent experimentation upon children from nearly ten years ago in connection with a human research regime that has been over for several years. The Defendants argument that NIEHS must be joined because they were a party to the contract between NIEHS and KKI to fund the TLC study is superficial and ignores the clear nature of the Plaintiffs claims against them. The instant Plaintiffs seek

compensatory damages for injuries they sustained as a result of lead-poisoning, not the reformation or recision of any contract and certainly not injunctive relief, where such relief even possible. The Plaintiffs have asserted claims against the Defendants for breaches of duties, as recognized by the Court of Appeals in the *Grimes* case, none of which involve the NIEHS.

The Defendants relegate to a footnote that less than one year later, the *Palmer* Court revisited it's Order joining the United States. In dismissing the claims against the United States, the Court found that, "the United States is **not** an indispensable party under Rule 19(b) and, therefore, the claims against [the Defendant] will not be dismissed by virtue of the fact that the United States has been dismissed." *Palmer, et al., v. Kokosing West Virginia, LLC, et al.*, 2006 WL 890009, 2 (S.D.W.Va. March 29,2006, emphasis added).

Lacking any legal basis to claim that without joinder of the NIEHS, or the United States, that complete relief cannot be accorded amongst the parties to this action, the Defendants seek to muddy the waters by implying that the study was engineered by the NIEHS. Again, the Defendants are wrong. As set forth herein, KKI designed the TLC study. And as set-forth in the *Grimes* opinion, a special relationship existed between KKI and the subjects, not the NIEHS.

B. Neither the NIEHS nor the United States have sought to be joined as a party in this matter nor do either have any interests in the decade-old negligent conduct of the Defendants. Joinder is not necessary to protect the interests of the NIEHS, or the United States.

As a threshold matter, neither the NIEHS nor the United States have asserted any interest relating to the instant action between private parties which they assert requires protection. Therefore, the burden rests squarely upon the Defendants to show the nature of the unprotected interests of the unprotected party. *Cornhill Ins. PLC, v. Valsamis, Inc.*, 106 F.3d 80, 84. The Defendants baldly assert, "Without being a party to this litigation, NIEHS will be unable to

defend itself regarding its actions pursuant to the TLC Study. In addition, there will be certain findings of fact that will impair or impede the NIEHS's ability to protect its interests in this litigation and subsequent litigation." (Defendant's Motion at 12). The Defendants seek to either ignore or to altogether re-write history. The Maryland Court of Appeals clearly, unmistakably, and unequivocally condemned KKI for the manner in which the prior study was conducted. It defies reason to believe that the NIEHS was not aware of the *Grimes* opinion. However, there was no outcry from the NIEHS nor from the United States government in 2001; *a fortiori* because no interests of the agency or the United State were impinged by requiring research institutions to comply with then existing law. Were the NIEHS so inclined to protect the interests to which the Defendants cite, Fed.R.Civ.P. 24 already provides a method for the agency to voluntarily seek joinder in the instant case. *See e.g. Dyke, et al., v. Gulf Oil Corp., et al.*, 601 F.2d 557, 568, Fn. 29 (Em. App. 1979). Further still, if the NIEHS or the United States had such compelling interests on the line in the instant litigation as the Defendants contend, it defies reason why the Defendants would not have notified the agency of the instant Motion so as to afford it the opportunity to join this case of its own volition.

Neither the NIEHS nor the United States has any continuing interest in the subject matter of this case. The study has long since been concluded and the results were long since published. The Defendants' assertion that a Court, and/or a jury, is entitled to hear the interests of the NIEHS that are at stake in this case, is nonsensical and circuitous. The Defendants refer to vague interests such as a potential "chilling effect" upon current and future federally-sponsored research involving lead exposure in children. This is exactly the same "the sky is falling" argument made by KKI and Hopkins after the 2001 opinion of the Court of Appeals. ("If allowed to stand, the

court's August 16 [2001] ruling would cripple pursuit of critical medical and public health research..." (September 17, 2001, Press Release of Hopkins, Exhibit 22). However, the Defendants continue to conduct research upon human subjects.

Further, the Defendants misunderstand Rule 19 to read that the potential that the NIEHS may "face the risk of multiple and inconsistent results" warrants joinder. To the contrary, the rule clearly states, "...(ii) leave any of the persons **already parties** subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by reason of his claimed interest. " Fed. R.Civ.Pro. 19 (a)(2)(ii), (Emphasis added).

C. The "risks" alleged by the Defendants for failing to join the NIEHS, or the United States, are neither substantial nor sufficient to require joinder.

It is not enough to merely allege that an unprotected party may have unprotected interests. Assuming, without conceding, that the NIEHS or the United States actually have any interests in the instant case, those interests must be substantial to merit a conclusion that they are necessary parties.

The instant suit is one for money damages. The "risk" to which the Defendants speak, to wit, inconsistent findings by a trier of fact in other cases involving the TLC study, is not a cognizable risk under Rule 19.

> Inconsistent obligations arise only when a party to the case risks facing conflicting judgments, so that compliance with one would conflict with the other. Inconsistent adjudications, on the other hand, are those in which a party might prevail on one theory of liability in one case, and then fail on that same theory, and even on the same or similar facts, in another case against another party; **while inconsistent as a matter of logic, these judgments would not necessarily subject the party to inconsistent legal obligations.**

Southern Co. Energy Marketing, L.P. v. Va. Elec. & Power Co., 190 F.R.D. 182, 186 (E.D. Va. 1999)(Emphasis added); *Delgado v. Plaza Las Americas, Inc.,* 139 F.3d 1, 3 (1st Cir. 1998)

(Holding that inconsistent obligations occur when a party is unable to comply with one court's order without breaching another court's order concerning the same incident); *Field v. Volkswagenwerk, AG,* 626 F.3d. 293, 301-302 (3d Cir. 1980) (Holding that potentially inconsistent tort judgments in two separate suits arising from the same set of facts did not render a plaintiff in one case party to the other case).

The only possible outcome of the instant case is an Order of Judgment against the Defendants for a sum certain or an Order of Judgment for the Defendants. Neither has the effect of collateral estoppel or res judicata on any other case between other parties, even as it relates to the TLC study.

VII. Neither the NIEHS, nor the United States, are indispensable parties to the instant litigation.

Assuming, without conceding that the NIEHS or the United States are found to be necessary parties to this matter, they are not indispensable parties. Where it is determined that a necessary party cannot be joined, the Court must determine whether the action can continue in his absence, or whether the person is indispensable pursuant to Rule 19(b) and the action must be dismissed. *Owens-Illinois*, 186 F3d. At 440. Rule 19(b) directs the Court to determine whether in equity and good conscience the action should proceed among the parties before it. The factors which the Court must consider to make this determination are: (1) to what extent a judgment rendered in the person's absence might be prejudicial to the person or those already parties; (2) the extent to which, by protective provisions in the judgment, by the shaping of relief, or other measures, the prejudice can be lessened or avoided; (3) whether a judgment rendered in the person's absence will be adequate; and (4) whether the plaintiff will have an adequate remedy if the action is dismissed for non-joinder. *Fed.R.Civ.P. 19(b)*. Rule 19(b) provides the Court the

ability to ascribe weight to each of the factors based upon the facts of the particular case and in light of equity and good conscience. *Assoc. Dry Goods Corp., v. Towers Fin. Corp.,* 920 F.2d 1121, 1124 (2d Cir. 1990); *See also 7 Charles Alan Wright, et al., Federal Practice and Procedure § 1608 (3d ed. 2001).*

While the trial Court is afforded discretion in the practical application of the Rule 19 inquiry, dismissal of a case for nonjoinder is a drastic remedy and should be employed sparingly. *Heinrich v. Goodyear Tire & Rubber Co.*, 532 F.Supp. 1348, 1359 (D.Md. 1982); *Nat'l Union Fire Ins. Co. of Pittsburgh, Pa., v. Rite Aid of South Carolina, Inc.*, 210 F.3d 246, 250 (4th Cir. 2000). Generally, dismissal is only ordered when the resulting defect cannot be remedied and prejudice or inefficiency will certainly result from continuing with the action without the absent person. *Owens-Illinois,* 186 F.3d at 441. This is not such a case.

A. Neither the NIEHS nor the United States can be joined in this matter.

As set forth herein above, the NIEHS cannot be sued *eo nomine* in tort. In *Blackmar v. Guerre, supra*, the Supreme Court held that the United States Civil Service Commission was not a suable entity, stating: "Congress has not constituted the Commission a body corporate or authorized it to be sued *eo nomine*." 342 U.S. at 514. In order to sue a federal agency in its own name, Congressional consent must clearly be found, "[w]hen Congress authorizes one of its agencies to be sued *eo nomine*, it does so in explicit language, or impliedly because the agency is the offspring of such a suable entity." *Id.* at 512.

Moreover, a suit against a federal agency is a suit against the federal government. *Blackmar v. Guerre*, 342 U.S. 512 (1952); *Chacon v. Granata*, 515 F.2d 922, 924 n.2 (5 Cir. 1975); *Fort Worth Nat. Corp. v. Federal Savings and Loan Ins. Corp.*, 469 F.2d 47 (5 Cir.

1972); *Krouse v. United States Gov't Treas. Dept. Int. Rev. Service*, 380 F.Supp. 219 (C.D.Cal.1974); *Hartke v. Federal Aviation Administration*, 369 F.Supp. 741 (E.D.N.Y.1973). It is well established law that the United States cannot be sued without its consent, and that a court has no jurisdiction over such a suit. *United States v. Sherwood*, 312 U.S. 584, 586-588, (1941); *Nickerson v. United States*, 513 F.2d 31 (1 Cir. 1975).

Thus, the United States would be the proper party were joinder required. However, the Federal Tort Claims Act requires that a claimant exhaust administrative remedies as a prerequisite to filing suit. Federal Tort Claims Act (FTCA), 28 U.S.C. §§ 1346(b) and 2671-79. The Plaintiffs have not filed a claim with the NIEHS because it was not indicated. The Plaintiffs have asserted state-law claims against the Defendants for violations of Maryland law in connection with experimentation upon Maryland children in Maryland. Consonant with the holding of the Maryland Court of Appeals in *Grimes*, nothing inherent in the claims advanced herein requires the joinder of the NIEHS. The Grimes Court held that the was no question that Maryland Courts had jurisdiction over claims identical to those raised herein by other children used as research subjects against these same Defendants. A *fortiori*, the Plaintiffs have not lodged an agency claim with the NIEHS for the negligence of KKI, Davoli, Hopkins, and the IRB.

B. Equity and good conscience clearly weigh in favor of the Plaintiffs being permitted to continue the instant action without the joinder of the NIEHS or the United States.

The Defendants next contend, not surprisingly, that if the NIEHS cannot be made a party that the Plaintiffs' complaint should be dismissed. The Defendants again avail themselves of the use of circular reasoning in making their argument that if the "if the NIEHS had not requested

such a Study be performed, the Kennedy Krieger Defendants would never have been sued in the first instance." (Defendants Motion at 11).

KKI, Hopkins, Davoli, and the IRB are being sued because they, not the NIEHS nor the United States, had a non-delegable duty to protect the children they used in the TLC study. KKI, Hopkins, Davoli, and the IRB are being sued because they, not the NIEHS nor the United States, breached that duty; the same duties addressed by the Maryland Court of Appeals in the *Grimes* case which dealt with virtually identical circumstances.

The Defendants cries of "prejudice" sound in the fact that they will be held liable for doing that which they contend was the work of another, the NIEHS. This stands in stark contrast to the Defendants paternalistic assertions that the interests of the NIEHS must be protected, and serves only to underscore the untenable nature of their arguments.

If the Defendants wish to cross-claim the NIEHS, the United States, or anyone else, those provisions already exist within the Federal Rules and joinder is not required. It is utterly disingenuous for the Defendants to assert that the Plaintiffs could pursue an action against others for lead poisoning which occurred prior to the TLC study, were this action dismissed, because such a result gives the Defendants a free pass for their own negligence and leaves the Plaintiffs without a remedy for the injuries caused by their participation in the TLC study. If the instant action is dismissed the Plaintiffs will have no forum in which to assert their claims against KKI, Hopkins, Davoli, or the IRB. Dismissal of a case for nonjoinder is a drastic remedy and should be employed sparingly. *Heinrich*, 532 F.Supp. 1359.

Equity and good conscience dictate that the Defendants' Motion should be denied.

Respectfully submitted,

Evan K. Thalenberg
(Federal Bar No. 06619)

Nicholas A. Szokoly
(Federal Bar No. 28157)
Law Offices of Evan K. Thalenberg, P.A.
216 East Lexington Street
Baltimore, Maryland 21202
(410) 625-9100

Attorneys for Plaintiffs Dontae Wallace and Searra Wallace

Exhibit 2

graphite furnace atomic absorption spectrometry (GFAA) with Zeman background correction as found on a Perkin-Elmer instrument model 5100. Standard laboratory tests (SMA-12, CBC, routine urinalysis) will be performed at the clinical laboratories serve the JHH-HPLC and the UM-PAC. A figure in Appendix F summarizes performance of the KKI-TML in the Centers for Disease Control's external proficiency testing program for blood lead determinations. Performance data is for analysis by anodic stripping voltammetry during the period July 1989 to September 1992.

Safety Monitoring:

We expect that safety monitoring will be a joint effort between the clinical center and the Coordinating Center. At the clinical sites the focus of the clinical monitoring will be on side effects of drug therapy and of evidence of continued exposure to environmental lead. Should the need arise (e.g. evidence of significant drug toxicity or extreme elevations of blood lead) to break the code on an individual patient, the Coordinating Center will alone have access to the treatment allocation scheme (see above) and therefore will need to provide a safety officer available on a 24-hour basis in case of emergency.

The duplicate blood leads (analyzed at KKI-TML and the central study laboratory) and other selected laboratory tests specified above will facilitate clinical monitoring and enable prompt remediation of any adverse situations that occur. Individual treatment decisions may need to be made at the clinical center on an emergency basis (see below). It will be the responsibility of the Steering Committee to define stop points for the entire study and it will be the responsibility of the Coordinating Center to monitor for circumstances that could cause the trial to be stopped prematurely.

- **Removal from trial/breaking the code**

It is expected that some patients will experience increasing blood lead levels during the course of the trial. This could occur when a patient continues to experience exposure to one or more sources of environmental lead or when the endogenous lead burden is very high. The blood lead level at which chelation therapy is universally recommended is 45 μg/dL. Therefore, if a subject reaches or exceeds 40 μg/dL, chelation therapy may be instituted in accordance with our usual medical practice, i.e. in the in-patient setting to assure removal from further sources of environmental lead. This occurrence will also necessitate reinstitution of a search for the lead sources in the child's environment. It should not necessitate removal of the child from the trial for methodological reasons, as analysis by 'intention to treat' is the preferred mode of analysis for randomized clinical trials. However, it is important to recognize that such an occurrence may be perceived as an adverse outcome by the subject's family, resulting in voluntary withdrawal from the trial.

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Exhibit 4

following these changes, referrals to the Kennedy Krieger Institute Lead Clinic have nearly tripled in comparison with the comparable period in 1991. The most recent data from all three clinical sites indicate increases in the numbers of children identified with PbB 20 - 39 µg/dL as a result of increased screening activities in the region.

The Baltimore Clinical Center will be a consortium consisting of the Kennedy Krieger Institute (KKI), the Pediatric Ambulatory Clinic (PAC) at the University of Maryland at Baltimore, and the Harriet Lane Pediatric Primary Care Clinic (HLPCC) at the Johns Hopkins Hospital. Subjects will be recruited both at these three clinical sites and also directly at identified housing (see secondary recruitment mechanism described below). For the primary recruitment mechanism, each of the participating institutions will recruit study subjects from among their regular patient populations:

- **Kennedy Krieger Institute:** Pediatric Lead Clinic (patients referred from primary care providers);
- **University of Maryland at Baltimore:** Pediatric Ambulatory Center (enrolled primary care patients);
- **Johns Hopkins Hospital:** Harriet Lane Pediatric Primary Care Clinic (enrolled primary care patients).

Procedures for enrollment of study subjects will be similar at all three clinical sites. Each site will have a nurse-coordinator, among whose duties will be responsibility for recruitment of study subjects. This section discusses the recruitment strategies at each clinical site and then summarizes the total pool of subjects expected for the Baltimore Clinical Center Consortium.

1) Kennedy Krieger Institute Lead Clinic

Children referred to the Pediatric Lead Clinic at Kennedy Krieger have previously been found to have elevated venous lead levels at their primary care sites. The KKI Lead Clinic has an active case load of approximately 550 children with lead poisoning. This clinic, which has been in operation since 1973, meets every Wednesday throughout the year; recently, because of increased referrals a weekly Friday clinic has been added. From April 1, 1992 through September 30, 1992, 56 children between the ages of 12 and 36 months were referred to the clinic with blood lead levels between 20 and 39 µg/dL (excluding referrals from University of Maryland and Johns Hopkins).

Over the years a number of clinical research studies have been carried out in this clinic population, including studies on succimer and household lead remediation. The Trace Metals Laboratory (TML) attached to the clinic provides blood lead and FEP results while the patient waits and before the patient is seen by the physician. Parents of children in the target age and blood lead ranges (see eligibility criteria below) presenting to

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Exhibit 5

SECTION C

DESCRIPTION/SPECIFICATION/WORK STATEMENT

ARTICLE C.1. BACKGROUND

Precedents: Since 1980, NIEHS has supported a series of longitudinal studies of childhood lead poisoning. These studies have shown small deficits in the cognitive development of young children in association with levels of blood lead commonly found in the US. NIEHS has also supported clinical studies leading to the licensure of the drug succimer, an orally administered chelating drug now labelled for use in children with blood lead levels above 45 μg/dl, a level thought to indicate a high risk for symptomatic lead poisoning and above the levels that produce cognitive delay.

General Background: Cognitive delay in toddlers has been associated with maternal lead levels in the 10-20 μg/dl range, and delays in four year olds with similar lead concentrations when they themselves were 2 years old. The Centers for Disease Control and the American Academy of Pediatrics have revised downward the blood lead levels of concern in young children, and children with blood lead levels greater than 10 μg/dl are now thought to have unacceptable exposure to lead. There are, however, no data on whether treatment of children with chelating agents prevents the cognitive delay associated with these levels. There are about four million children who fulfill the new criteria for unacceptable exposure to lead. NIEHS believes that large numbers of children with blood lead levels below 45 μg/dl will be treated with succimer, and that a clinical trial of the use of succimer in the prevention of lead-associated cognitive delay in young children is both necessary and timely. The objective of this Contract is to conduct, analyze, and issue a report of a randomized, multi-center, placebo controlled trial of succimer in the prevention of lead-associated cognitive delay in young children. This Contract is for one (1) of three (3) or possibly four (4) Clinical Centers. A separate, companion contract, NO1-ES-35360 has been awarded for the support of the Coordinating Center.

ARTICLE C.2. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the work set forth below, including recruitment, treatment, retention, and follow-up of children in a clinical trial. In doing so, the Contractor shall comply with all local, state, and Federal laws and regulations pertinent to the various aspects of the trial. The Contractor shall conduct performance predicated on the agreements and understandings reached through discussions and negotiations leading to award based on the following documents which are incorporated by reference:

(1) Original Proposal dated November 24, 1992
(2) Revised Proposal dated May 10, 1993

(3) Best and Final Offer dated June 4, 1993
(4) Clarifying Information dated June 13, 1993

If there is any inconsistency between the referenced documents and the work described in Paragraph a. of this ARTICLE, the terms and conditions of Paragraph a. of this ARTICLE shall control.

(BASIC CONTRACT)

The protocol and strategies for the trial will result from the deliberations of the Steering Committee during the planning phase. The Steering Committee, as initially constituted, shall consist of the PIs of the Clinical Centers, the PI of the Coordinating Center, and the NIEHS Project Officer. The PI of the central lab will be a member of the Steering Committee ex officio. The Manual of Operations and Final Protocol shall be incorporated by reference into this Statement of Work when they are completed by the Steering Committee and approved by the Data and Safety Monitoring Committee. The clean up protocol at each site will be incorporated by reference into this Statement of Work when completed by the Clinical Center PI and approved by the Project Officer. The Steering Committee may elect to alter its composition at any time after it has been constituted; it must notify the PO of plans to do so. The trial shall proceed as follows: 9-12 months for planning; about 1 year for patient enrollment and treatment; the remaining 3 years for follow-up. Each child will be followed to age 4 at a minimum; longer follow-up is desirable for those children randomized early. Most close out activities should be completed by the final (5th) year of the contract. The activities, none of which are currently anticipated, of any center beyond five years from the initial award except for work specified herein will depend on the issuance of a continuation RFP by the Institute and successful re-competition. The trial is of oral chelation therapy with the drug succimer in lead exposed children (blood leads of about 20 µg/dl to 45 µg/dl) of about 18 to 36 months of age. The endpoints are the scores on developmental tests; other endpoints of interest include evidence of drug efficacy and compliance, such as urine and blood lead levels; excretion of other ions like iron, zinc, and calcium; and nervous system, renal and hematopoietic function/toxicity.

The Clinical Center shall evaluate the children prior to randomization for iron, vitamin, or other nutrient deficiency, and treat such deficiencies. Clinical Center staff, as may be augmented by local/state health officials, shall evaluate children's homes, and, if necessary, their day care or other sites where they spend time, and provide clean-up according to trial protocol. The criteria by which homes will be evaluated and the clean-up protocol shall be decided during the planning phase, but clean-up will not be identical at each site, and will consist of means suited to the catchment area of each Clinical Center. The Steering Committee shall, among their other functions, appoint a Clean-Up subcommittee, whose function will be to coordinate the various clean-up activities. However, the ultimate decision about clean-up methods at each site rests with the PI of the site and the PO. Chelation challenge and XRF studies are separately budgeted options, which may be included at some of the Clinical Centers (see "Options"below.

Exhibit 6

In cooperation with the Coordinating Center, the other Clinical Centers, and NIEHS staff, the Clinical Center shall participate in the design of the trial protocol, and then recruit, evaluate, treat and follow-up patients according to trial protocol. The Clinical Center shall provide data to the Coordinating Center, and monitor for efficacy and adverse effects. The Clinical Center shall participate in the randomization according to trial protocol and document that randomization has occurred according to assignment; and collect, monitor and edit data. The Clinical Center principal investigator (PI) shall participate, along with the other Clinical Center PIs, the Coordinating Center PI, and NIEHS program staff, in the final analyses and write-up of the studies.

Patient population: For purposes of planning the study, the Clinical Center shall provide to the Steering Committee the source population from which the Clinical Center will draw patients eligible for the trial, including numbers, ages, racial composition, and regular sources of health care. For all Centers combined, NIEHS estimates that evaluating the drug treatment for an effect of 3 developmental quotient points will require that the trial have 786 evaluable children with complete data at an absolute minimum; each Clinical Center shall recruit enough children so that on the order of 333 children per center are randomized. Stratified or blocked sampling may be desirable.

Recruitment: For purposes of planning the study, the Clinical Center shall provide to the Steering Committee a description of any previous efforts at recruiting patients into clinical studies at the institution, and plans for recruitment into this one. If referred patients are to be the source, then the referral sources shall be discussed and the rates of referral estimated.

If the Clinical Center must screen their population (or otherwise deal with children who have no information on recent blood lead levels) then it the Clinical Center shall provide blood lead analyses in support of the screening program; however, the blood lead level determination that actually determines eligibility will be performed centrally for the study (see Laboratory section below.)

Eligibility: Children eligible for the trial should be about two years old and have blood lead levels between about 20 and 45 μg/dl at the time of randomization, i.e., on at least two occasions and after iron deficiency is treated. (See women and minority recruitment below.)

Data collection schedules: The Clinical Center shall schedule and see the children according to trial protocol.

Source identification and clean-up: The Clinical Center will evaluate and clean-up the children's homes and other sites as necessary according to trial protocol. The Clinical Center shall identify lead sources in the child's environment and decrease the exposure in those who need it. If clean-up efforts involve other institutions, such as health departments, then the Clinical Center shall coordinate plans for working with them. Each Clinical Center shall be responsible for preparing its own clean up efforts, in consultation with the Clean-up Subcommittee.

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Data collection schedules: The Clinical Center shall schedule and see the children according to trial protocol.

Source identification and clean-up: The Clinical Center will evaluate and clean-up the children's homes and other sites as necessary according to trial protocol. The Clinical Center shall identify potential lead sources in the child's environment and decrease the exposure in those who need it. If clean-up efforts involve other institutions, such as health departments, then the Clinical Center shall coordinate plans for working with them. Each Clinical Center shall be responsible for preparing its own clean up efforts, in consultation with the Clean-up Subcommittee.

Each Clinical Center shall provide short term housing as it considers necessary.

Nutritional management: The Clinical Center shall evaluate the children for iron deficiency and treat it, and insure that all children meet RDAs for relevant micronutrients, such as zinc and calcium, according to trial protocol. It is possible that there may be a high prevalence of iron deficiency, deficiency of micronutrients such as zinc, and diets deficient in calcium or other nutrients. The Clinical Center shall be responsible for monitoring compliance with such supplementation according to trial protocol.

Laboratory Support: Laboratory activities in support of this project are in three parts: blood lead levels used to determine the possible eligibility of the children for the trial (screening); clinical testing of the children, for iron status, hematocrit, etc., and monitoring of blood lead or urine lead levels immediately prior to randomization and during and after therapy. Each Clinical Center shall be responsible for those blood lead level determinations necessary to go from their catchment population to about 350-400 children who are iron-replete and who meet the trial's blood lead level criteria.

Each Clinical Center shall perform clinical monitoring of children, and including any laboratory procedures necessary for safety monitoring because the children are being treated under an IND.

Drug therapy: The Clinical Centers shall treat the children according to trial protocol. The treatment regimen will be decided upon by the Steering Committee during the planning phase.

Safety and efficacy monitoring: The Clinical Centers have the primary responsibility for the monitoring of the safety of the children and monitoring the efficacy of the drug. The Clinical Center shall be responsible for safety monitoring, and shall implement a means of following compliance, blood lead and urine lead according to trial protocol. The Clinical Center shall schedule the follow-up and evaluation of children.

Developmental testing: The Clinical Centers shall perform developmental testing of the children according to trial protocol.

Retention: The Clinical Center is primarily responsible for the retention of the children in the trial. A high percentage is absolutely necessary for the trial to succeed. The Clinical Center shall implement plans for keeping families active in the study, including contact with other than immediate family members, newsletters, etc. according to trial protocol and as appropriate for their catchment areas.

Clinical Center involvement with the Coordinating Center: The initial activity of the selected Coordinating Center and Clinical Centers shall be the development of a common protocol and study manual of operations. The Clinical Center PI shall cooperate with both the other Clinical Centers and with the Coordinating Center in carrying out the trial.

Exhibit 8

Each Clinical Center shall provide short term housing as it considers necessary.

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Exhibit 9

FEATHERSTONE, KEONA
TLC #0051-9

September 20, 1995

HISTORY #0-266-6357

JANET:

Keona came in on September 6 for her T3 visit. T3 blood was not obtained until September 18. Also on Sept 18, Keona had her 2 year check-up with Sue Porter in the TAC clinic. Sue also wanted certain labs, so we both were able to get our specimens on this one visit.

I received a telephone call from Sue Porter today. She advised that Keona's spun hct from 9/18 indicated anemia and she put Keona on an iron prescription - 1/2 tsp, 3x/day.

Question: Is an iron prescription permitted since we do not know the results of the T3 blood, which will determine whether Keona goes through another round of treatment or follow-up?

Thanks,

Jeanne

Retreat - T4 - once Keona starts on Round 2, advise Mom to stop giving the iron.

Exhibit 11

Form C (Revised 6/93)

CLINICAL INVESTIGATION CONSENT FORM

The Johns Hopkins Medical Institutions
(The Johns Hopkins Hospital
The Francis Scott Key Medical Center, etc.)

0537 Featherstone, Keira
V2

Patient I.D. Plate

Title of Research Project: Treatment of Lead-Exposed Children (TLC) Trial Enrollment

Explanation of Research Project to Subject:

Your child has been exposed to a moderate amount of lead. This amount of lead does not make your child sick, but it may be enough to harm your child's development, thinking and learning as they get older. Children get exposed to lead mostly from dust and chipped paint in their homes. It is important to keep lead dust and chipped paint away from children. We do not know if giving a child medicine to get rid of some of the lead in her/his body will keep the lead from harming her/him. We do know that medicines that take lead out of the body have side effects, like all medicines.

Your child is eligible for our study, which is called the Treatment of Lead-Exposed Children study, or TLC for short. Children will be in this study for 3 years. There is no charge for the study. We want to see whether a medicine prevents lead in children's bodies from harming them as they grow older. This medicine is called succimer, and it gets rid of some of the lead in children's bodies. It is now used for children who have more lead in their bodies than your child has.

All children in the TLC study will have their homes repaired and/or cleaned to get rid of lead dust and chipped paint, will get vitamins and minerals, will get regular check ups and blood tests, and will get tests of their thinking, learning and development. The parent or parents, usually the mother, will also have a short intelligence quotient (IQ) test, which is a test of their thinking and reasoning skills, but will not get check-ups or blood tests.

Half the children in the TLC study will get capsules that have succimer in them. The other half of the children in this study will get capsules that look the same, but have no succimer in them.

Now that we know that your child is eligible, we are asking your permission for her/him to be in the treatment part of the study. Participation is completely voluntary. If you agree to participate, then this is what will happen:

1. Medicine and medicine diaries: We will give you enough capsules to give to your child for 26 days, Taking capsules for 26 days is called a course of therapy, or just a course. Since the capsules are too big for your child to take, we will show you how to open them and sprinkle the beads of medicine that are inside into some food or drink. We will give you a diary and ask you or someone else (relative or babysitter) to write down each day when you have given the capsule, and whether your child is sick. Some people find the capsules smelly; this does not mean that they are spoiled or that they will make your child sick.

Chisolm.Succimer.Enrollment

The medicine used in this study, succimer, is now used for children with more lead in their bodies than your child has. In this study, we are giving a higher total dose of succimer than is used in treating children with higher blood lead levels because we are giving succimer for a week longer than it is given to such children. We are doing this because we have to get enough lead out of your child's body to make a difference. Many children have to take more than one course of succimer to get enough lead out of their bodies. We think that using succimer the way we are using it will cut down the number of children who need more than one course. Children will not get study capsules for longer than three courses.

Half the children in this study will get capsules that have succimer in them. Succimer should remove some of the lead from children's bodies, but may have some side effects. Side effects from succimer happen in about 5% to 10% of children. The most common side effects are rashes, upset stomach, changes in blood tests that measure how children's livers are working, lower numbers of white cells (the cells that fight infection) in the children's blood, and lower numbers of platelets (the cells that help blood clot) in the children's blood. At every visit, we will be checking your child for these side effects. We will ask you about any illness that your child has had when you come to clinic, and we will look for side effects with blood tests. So far, there have been very few side effects with succimer, and they have gone away when the succimer was stopped. Few children have had to stop succimer because of side effects. If your child has severe side effects, we will stop the medicine.

The other half of the children in this study will get capsules that look exactly the same, including the beads inside, but have no succimer. These capsules will not remove lead from children's bodies, and have no side effects.

Since we do not know whether it is better for children like yours to get succimer or not, we will put the children into these two groups at random, like tossing a coin. You and the TLC doctor who takes care of your child will never know which group your child is in. In case of problems, there will be another doctor at the clinic who does know what group your child is in and will take the necessary actions.

It is important that you tell us if your child gets sick with a cold or other illness while taking the capsules, and we will give you phone numbers to use for calling us. We also ask you to write down in a medicine diary if your child gets sick with a cold or other illness while taking the TLC capsules. It is also important to tell us if your child is taking any other medicines while they are taking capsules. A doctor from the TLC study will help take care of any immediate need.

We will ask you to come back to the clinic in one week after your child starts taking capsules and we will check your child and do a blood test for lead and for any side effects. The blood is usually taken with a needle from the vein in the child's arm, and the

amount is between one and three teaspoons. The needle stick usually hurts, and sometimes leaves a bruise. To minimize this only experienced personnel will draw blood. We will look at the medicine diary with you to see how many of the capsules your child took, and we will ask you if your child was sick.

We will ask you to come back to the clinic again one month from now, and have the same things done. If the lead in your child's body has not gone down enough, then we will ask you to come back to clinic and give you enough capsules for another 26 day course to give to your child. We think that about half to three quarters of the children in the study will get a second course. The chance will be the same whether your child got the capsules with succimer or the capsules without. If your child gets a second course, then we will ask you to come in for blood tests and a check up at one week and one month after the course starts, and to keep a medicine diary, the same as the first course. A few children, about 10%, who still have too much lead will get a third course of capsules, which will be the same as the first two courses.

2. Blood lead results: You and the TLC doctor taking care of your child will not know the results of the blood lead tests done during the first six months after your child starts taking capsules, but another doctor will know in case there is a problem. If your child is still taking capsules after six months, then you will not know the results of the blood lead tests done during treatment, and for three months after your child is finished taking capsules. You may have the blood lead results after these treatment periods if you want them.

3. Followup visits and vitamins: Once your child finishes taking the capsules, we will ask you to come back about every three to four months for a blood lead test until you have been in the study for about three years. We will give you vitamins at these clinic checkup visits, and ask that you give one to your child every day. You will not need to keep a diary anymore, but we think it is important for your child to take the vitamins every day.

4. Thinking, reasoning, and development tests: We will test your child's thinking, reasoning and development three times: at six months, 18 months, and three years after he/she begins taking the capsules. These tests take about 2 hours or less in the younger children, and about 2 hours and 30 minutes in the oldest children. The tests have the child play with toys and mazes and solve simple problems. Most children enjoy these tests, but they have to be feeling well to do them. Sometimes the tests have to be re-scheduled if your child is sick or not feeling well.

After one year in the study, we will give a parent, usually the mother, a short version of an IQ test, which involves reading and solving problems and takes about 45 minutes. We will also ask the parent questions about the child's behavior. There are no risks from any of these tests.

5. Damage at home or moving to a different home: It is important for you to tell us if you move, or if a plumbing leak or anything else damages the walls or ceilings in your home, because we will need to come out and inspect and clean up as we did at the beginning of the study. If the doctor who sees the results of the blood lead tests finds that the amount of lead in your child's blood has gone up too much, we may want to come and inspect or clean your home again. Very rarely, a child's blood lead level might go up so high during the study that they might receive additional treatment outside of the study. If this happens, the child will get the usual care for children with higher lead levels, which may include succimer. We will refer your child for proper care. The TLC study will not pay for or provide that care.

Even if you agree now to do these things, you can stop any time for any reason. If you do stop, it will not change the regular medical care of your child, or change any other benefits outside the TLC study that your family gets. Even if you stop being in the study in the early part, we will still invite you to come in later for the blood tests and the tests of your child's thinking, reasoning and development.

Regular medical care for children like yours includes blood tests for lead. The Baltimore City Health Department is responsible for inspecting homes of children whose blood tests show that they have too much lead exposure. The results of your child's blood lead tests have been/will be reported to them. All of the inspections and clean-ups in the study are additions to what the city would do, and the city's actions will not be changed.

Children with amounts of lead in their bodies like your child's usually do not get medicine to help them get rid of the lead. Succimer is not recommended for children with amounts of lead in their bodies like yours unless they are in a study. Succimer has been approved for treating children who have more lead in their bodies than your child does.

The results of the study will help other children because better decisions will be made about their treatment. Your child will not benefit directly from the study's results, because they will not be ready in time to help us in treating your child. The benefits to your child are:

tests show that they have too much lead exposure. The results of your child's blood lead tests have been/will be reported to them. Whatever the city does will not be changed if your child is eligible for this study, or if you decide to be in the TLC study.

Not every child will be eligible for the TLC study. Most of the time, we can tell if a child is eligible by the second clinic appointment, in about one month, but sometimes it will take longer. If your child is eligible, then we will ask for your consent again before your child is given medicine. We will give you a copy of the consent form for the treatment part of the study to take home with you today.

The results of the TLC study will help doctors know how to treat other children like yours who have been exposed to lead. Your child will not benefit directly from the TLC study's results, because the results will not be ready in time to help treat your child.

The benefits to your child of letting us find out if they are eligible for the TLC study are that:

- We will look carefully at your home to identify lead hazards and tell you about it.
- If your house doesn't qualify, we will offer you any information we have about ways to relocate your family to housing that is known to be lead safe
- We will clean-up the lead if it looks like your child and house are eligible.
- We will give you vitamins and minerals for your child.
- We will have a doctor examine your child.
- We will check the amount of lead in your child's body carefully.

If you sign this form, I are willing to join the research proje escribed to you on the other side of this page. Your doctors, or the investigators, did explain the other kinds of treatment that are available to you and to others. You should ask the principal investigator listed below any questions you may have about this research study. You may ask him/her questions in the future if you do not understand something that is being done. The investigators (or doctors) will share with you any new findings that may develop while you are participating in this study.

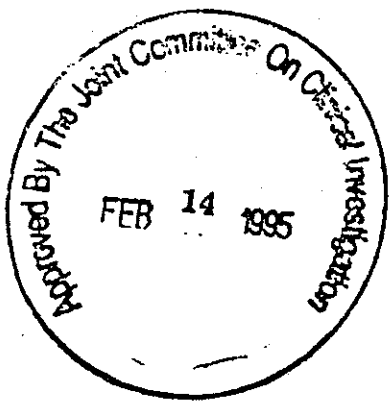
The records from this research study will be kept confidential and will not be given to anyone who is not helping on this study, unless you agree to have the records given out. If the study uses a new drug or device that is under the jurisdiction of the Food and Drug Administration (FDA), the FDA government officials may look at the relevant part of your medical records as part of their job to review new drug and device studies.

If you want to talk to anyone about this research study because you think you have not been treated fairly, or think you have been hurt by joining the study, or you have any other questions about the study, you should call the principal investigator, Dr. J.Julian Chisolm, at 550 9035, or call the Office of the Joint Committee on Clinical Investigation at 955-3008 or call The Francis Scott Key Medical Center Institutional Review Board for Human Research at 550-1853. Either the investigator or the people in the Committee office or IRB office will answer your questions and/or help you to find medical care for an injury you feel you have suffered. The Johns Hopkins University, The Johns Hopkins Hospital, The Francis Scott Key Medical Center, Kennedy Krieger Institute and the Federal Government do not have any program to provide compensation to you if you experience injury or other bad effects which are not the fault of the investigators.

You may withdraw from the research study at any time. Even if you do not want to join the study, or if you withdraw from it, you will still have the same quality of medical care available to you at Johns Hopkins or the Francis Scott Key Medical Center.

If you agree to join this study, please sign your name below.

NOT VALID WITHOUT THE COMMITTEE OR IRB STAMP OF CERTIFICATION



VOID ONE YEAR FROM ABOVE DATE
RPN NO. 92-11-19-01

Subject's signature
(Including children, when applicable)

Sharon Jackson
Signature of Parent or Guardian (when applicable)

Tracie W. Kirkland R.N. MS
Witness to Consent Procedures*

Janet Newmark MD
Signature of Investigator

June 21, 1995
Date

*Optional unless subject is illiterate, or unable to sign.

NOTE: Signed copies of this consent form **must** be a) retained on file by the Principal Investigator; b) deposited in the patient's medical record; and c) given to the patient.

Exhibit 12

The Johns Hopkins University School of Medicine
The Johns Hopkins Hospital

Joint Committee on Clinical Investigation

Please address reply to:
Administration 129 / School of Medicine
720 Rutland Avenue / Baltimore MD 21205-2196

(410) 955-3008
FAX (410) 955-4367

February 10, 1993

J. Julian Chisolm Jr. MD
Associate Professor, Pediatrics
3001 & 1/2 Biddle Street
Baltimore, Maryland 21213

RE: RPN 92-11-19-01, entitled "Toxicity of Lead in Children - Clinical Center"

Dear Dr. Chisolm:

The above-referenced protocol was approved by the JCCI on February 9, 1993. Enclosed is the standard approval letter.

The consent forms, however, can not be released until we have been notified of the IND number for the experimental drug. As soon as you receive the IND and let the JCCI know, the consent forms will be forwarded to you. The approval date will not change.

Sincerely yours,

Thomas R. Hendrix, M.D.
Chairman - JCCI
c/o 129 S/M Administration
School of Medicine

TRH:bbs

Enclosure

CONFIDENTIAL

Exhibit 13

In accord with the TLC study, Baltimore City's Department of Housing and Community Development provided property owners an opportunity to apply for a five-year forgivable loan of up to $7,500 for the purpose of reducing lead at a particular property. The loan was forgiven 20% per year for five years. Although Kennedy Krieger informed owners and landlords of the opportunity to take advantage of this loan program, it neither made the loans, made any decision regarding loan eligibility, disbursed funds, nor contracted for repair and maintenance activities.

At the point of formal enrollment in the study, each home was professionally cleaned in an effort to reduce exposure to lead house dust. All children were provided a vitamin mineral supplement (which, in addition to general health benefits, potentially decreased/slowed lead absorption in the event of further exposure). Either Succimer or the placebo was provided in appropriate doses and blood lead levels were followed. Detailed testing of children's cognitive development, neuropsychological function, and behavior was administered at baseline and at protocol-driven intervals during the study period.

The results of the TLC study were reported in the New England Journal of Medicine in May 2001. The NIEHS concluded that while children who had been given Succimer had more rapid drops in blood lead levels, any differences in test scores between that group and the placebo group were inconsistent and not statistically significant. Additionally, children given Succimer had an unexpectedly higher rate of injuries, a finding that remains unexplained. Based on this data, Succimer therapy (and chelation therapy in general) for children with blood lead levels below 45 micrograms per deciliter is not recommended. Succimer remains the recommended therapy for treatment of children with blood levels at or above 45 micrograms per deciliter.

[4] Each of the clinical centers worked with an IRB that was responsible for fulfilling the oversight role for that particular center. The IRB that oversaw the Kennedy Krieger Institute's participation in the study was the Joint Committee for Clinical Investigation (JCCI) of the Johns Hopkins Medical Institutions.

IN THE CIRCUIT COURT
FOR BALTIMORE CITY

QUYAISHA COLES, Minor,)
by Her Mother and Next Friend,)
VERONICA SCOTT,)
Plaintiff,) Case No.
v.) 24C01004337
KENNEDY KRIEGER INSTITUTE, INC.,)
et al.,)
Defendants.)

DEPOSITION OF CLARK H. McNUTT
Taken in behalf of the Plaintiff

October 8, 2003
VOLUME I
* * *

Q. Neither was supposed to be an abatement of lead paint hazards, though, correct?
MS. IVERSON: Objection, form.
BY MR. KAZMIERCZAK:
Q. Was either supposed to be an abatement of lead paint hazards?
A. No.
Q. Who was ERI's client for doing these interventions?
MS. IVERSON: What interventions?
MR. KAZMIERCZAK: Interventions that he's just talked about, I believe.
MS. IVERSON: I'm going to object because it's not been clear here. He's been referring to documents that are specific to 911 North Collington, and, yet, you're taking broadly in terms of some contract and generality.
I think if you can clarify the question, if whether he's speaking in generalities or whether he's speaking specifically to 911 North Collington that would be helpful.
BY MR. KAZMIERCZAK:
Q. Did Kennedy Krieger ever pay ERI directly for performing level one interventions?

MS. IVERSON: In what context?
MR. KAZMIERCZAK: In the context of the study.
MS. IVERSON: In the TLC study?
MR. KAZMIERCZAK: Yes.
THE WITNESS: Yes.
BY MR. KAZMIERCZAK:
Q. In the context of work performed by ERI in the Kennedy Krieger, TLC study who was --
MR. DAILY: If you can keep it up again, I'm sorry.
MR. KAZMIERCZAK: Sorry.
BY MR. KAZMIERCZAK:
Q. In the context of work performed by ERI in the TLC study who was ERI's client?
MS. IVERSON: Objection to form. Go ahead.
THE WITNESS: We invoiced Kennedy Krieger for all the work that we did.
BY MR. KAZMIERCZAK:
Q. Okay. So is my understanding correct that ERI had no discretion regarding the scope of environmental interventions to be performed?
MS. IVERSON: Objection, form. And, again, in what context?
MR. KAZMIERCZAK: Throughout the TLC study.

MS. IVERSON: In anything?
MR. KAZMIERCZAK: Well, let's back up, then. We'll do it this way.
BY MR. KAZMIERCZAK:
Q. Did ERI have any discretion at all regarding the scope of any environmental interventions performed to 911 North Collington?
MS. IVERSON: Before you answer the question can I ask you to break the question down? He's spoken now about a level one intervention, which is environmental cleaning. I think that is different from the earlier questions that he was asked about the specifications. So I think you're blending these two. Which one are you talking about?
MR. KAZMIERCZAK: Well, for a level one intervention.
MS. IVERSON: The cleaning?
MR. KAZMIERCZAK: The cleaning.
BY MR. KAZMIERCZAK:
Q. Did ERI have any discretion at all as to the scope of that intervention, if you will?
A. No.
Q. Whose discretion or whose direction were these performed according to?

MS. IVERSON: Objection.
THE WITNESS: Kennedy Krieger.
BY MR. KAZMIERCZAK:
Q. And ERI was doing this work at the behest of Kennedy Krieger?
A. Yes.
Q. Can you tell me what a level three intervention is or was?
MS. IVERSON: In the context of the TLC study?
MR. KAZMIERCZAK: Yes.
MS. IVERSON: Objection to foundation. Go ahead.
THE WITNESS: The TLC contract, it was three different levels of intervention on properties. It was level one, which we discussed earlier, a level two, and then a level three.
Each level of intervention had a price cap. I believe the level one was $1,750; the level two was $3,500; and the level three was 7,000 or 7,500. I may be wrong on those. They're close to that, but I can't remember.
The repair and maintenance and the TLC were the same thing, but there was a few hundred

IN THE CIRCUIT COURT
FOR BALTIMORE CITY

QUYAISHA COLES, Minor, by Her Mother and Next Friend, VERONICA SCOTT,	)	
Plaintiff,	)	Case No.
v.	)	24C01004337
KENNEDY KRIEGER INSTITUTE, INC., et al.,	)	
Defendants.	)	

DEPOSITION OF CLARK H. McNUTT
Taken in behalf of the Plaintiff

October 8, 2003
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* * *

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contract into the TLC contract.
Q. Okay. What was ERI's, I guess, job, for lack of a better word, to be with the TLC contract?
A. Our job was to perform the work that was in the written specifications.
Q. Who composed the written specifications?
MS. IVERSON: Wait a minute. As to what house? What are you talking about?
BY MR. KAZMIERCZAK:
Q. Well --
MS. IVERSON: I object to the form of the question because I don't think it's clear. It's very vague.
MR. KAZMIERCZAK: Okay.
THE WITNESS: They were field notes. The TLC contract used the same specifications as the repair and maintenance contract. And they were actually set up as macros with the abbreviations for those different treatment options.
And so what we would do is we receive field notes that were delineated by per room or area in a particular property, with those treatment option codes, which were directly tied to the written out specifications.

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So we would take those field notes and we would compose a written specification for that property. And those notes came from Kennedy Krieger.
BY MR. KAZMIERCZAK:
Q. I'll show you a document we're marking as Exhibit No. 2.
(Exhibit marked for identification: 2.)
BY MR. KAZMIERCZAK:
Q. If you can take a look at this packet of papers --
MS. IVERSON: May I see it before he answers questions about it?
MR. KAZMIERCZAK: Sure, absolutely. For the record, those are documents provided, I believe, by your client through discovery.
MS. IVERSON: It's a very lengthy number of pages. Are you marking the entire --
MR. KAZMIERCZAK: Yes.
MS. IVERSON: -- stapled packet as an exhibit?
MR. KAZMIERCZAK: Yes.
MR. DAILY: What are we marking as an exhibit?

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MS. IVERSON: Frank, there is an entire packet of information that is kind of a hodgepodge of different things.
The first page is receipt and acknowledgment for cleaning kit and lead education from the city of Baltimore signed by Veronica Scott on November 7, 1995.
Then there are some TLC documents. The first one is the form HOMELOG.O2, a home assessment log. There's one -- actually, I'm not sure if this is part of the same thing. That's one page.
Then there are some notes that may be part of that, one, two, three, four, five, six, or seven pages of that.
And then there's the diagram of the house at 911 North Collington, dated 10/13/95, and that's three pages long.
And then there is an environmental eligibility review form from September 20, 1995.
And then there's a housing status form from -- I'm not sure which date it is, but it has loan written up at the top of it for 911 North Collington.

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And then there is a unit cover sheet for 911 North Collington.
And then there are the pages that I suspect Mr. Kazmierczak is going to be asking Mr. McNutt about, which is 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 --
MR. DAILY: Thank you, Kelly. Thank you guys.
MS. IVERSON: I'm going to put this on the record since I'm almost through it. I think I counted 13 pages for that. And --
MR. KAZMIERCZAK: Did you get all of that, Frank?
MR. DAILY: I did. Thank you, John.
MS. IVERSON: The housing status form is repeats of the other one.
The entire thing is going to be marked as an exhibit. Perhaps just for ease of reference we can number the pages, so when he's referring to the page we can have a page number on it, since there's so many?
MR. KAZMIERCZAK: Sure. If you want to take a second I'll just put numbers on them, if that's okay with you?
MS. IVERSON: That's great, thanks.

Exhibit 16

12/07/94 10:52:22 IRB [IRB SEL TRAN INT RPT]

Protocol #	PI Last Name	PI First Name	Address
340028-129201	RUBIN	JUDITH	Room 132E, HH

Protocol Title: TOXICITY OF LEAD IN CHILDREN -- CLINICAL TRIAL

PEDIATRICS

Keyword #1	Keyword #2	Keyword #3	Keyword #4	Keyword#5	(410)-706-7864
LEAD	SUCCIMER	DEVELOPMENT	OUTCOME	TRIAL	

Meeting	Interim Rpt. Due	Annual Rpt. Due	PI Soc. Sec. #	Degree #1	Degree #2
12/04/92	05/19/95		085-34-0028	MD	MPH

CO-INVESTIGATOR #1: Last Name	First Name	CO-INVESTIGATOR #2: Last Name	First Name

School	Department	Effective Date	Risk
MEDICAL	MEDICINE	12/04/92	HIGH

<<<<<<<<<<<< RPN >>>>>>>>>>>>

DRUGS:
- Licensed Drugs/Reagents: Y
- Investigational New Drugs: Y — IND#: TO BE OBTAINED
- Sponsor: Y — Investigator: N

DEVICES:
- Investigational Devices: N — IDE#:

EXPOSURE:
- Radiation: N — Pregnant Women/Fetal Tissue: N
- Infectious/Biohazardous Agents: N — Children: Y

PROJECTS:
- Multi-Center Collaborative: Y — Funding by Public Health Service: Y
- Confidential Material: Y
- Location: PEDIATRIC AMBULATORY CENTER, WESTERN HEALTH BUILDING

SUBJECTS:
- Types: CHILDREN WITH ELEVATED BLOOD LEVELS
- Age Range: 10-36 MONTHS Males Only: N Females Only: N Males and Females: Y
- Source of Patient Population:

OUTPATIENTS

- Source of Normal Volunteer Population:

# of Subjects (First Year) 150 # of Subjects (Total Study) 150

CONFIDENTIAL

University of Maryland School of Medicine

Department of Epidemiology & Preventive Medicine
Baltimore MD 21201
410-706-2864
Fax: 410-706-8013

FAX TRANSMISSION COVER SHEET

Date: *January 2, 1996*

To: *Merrill Brophy*

Fax: *550-8365*

Re: *IRB response*

Sender: *Judith D. Rubin, MD, MPH*

YOU SHOULD RECEIVE 3 PAGE(S), INCLUDING THIS COVER SHEET. IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL 410-706-2864.

Hi Merrill-

Happy New Year!

Attached is the IRB letter and my response for your files.

Thanks.

Judy

CONFIDENTIAL

UNIVERSITY OF MARYLAND
AT BALTIMORE
INSTITUTIONAL REVIEW BOARD

Baltimore, MD
21201-1559

655 W. Baltimore St.
BRB 14-016

Date: 12/12/95

From: Institutional Review Board (Assurance Number M1174-01NR)

To: JUDITH RUBIN, MD,MPH
Dept: PEDIATRICS/EPIDEMIOLOGY
Address: ROOM 132E, HOWARD HALL

Re: "TREATMENT OF LEAD-EXPOSED CHILDREN (TLC) TRIAL"

The official record of this protocol includes the following information:
IRB Number: 1195011
Expiration: 12/08/98
PI: RUBIN, JUDITH

The Institutional Review Board met on December 8, 1995 and reviewed your protocol. However, the following information must be provided before final approval can be given. Please submit one copy of the requested information January 2, 1996 so that the IRB can evaluate your response at its next meeting.

- Although this trial is well designed and well justified, we are concerned that this trial is still ongoing after several years in operation. Since there is an untreated control group, we would like you to present us with data that would justify continuing the trial with an untreated group. Please provide us with preliminary data and data analysis that would suggest that there is no information yet available to state that succimer treatment is not effective in reducing low lead levels.

- We also would like you to submit any toxicity data collected at this or other study site so we can evaluate the risk section of your consent form.

If you have any questions, please contact the Office for Research Subjects by email (ORS@schmed01) or by telephone (410.706.5037).

Robert R. Conley, MD
Chairman, IRB

1 pt @ KKI
diarrhea → stopped drug → challenge → recurrence of diarrhea Did not unblend the pt.

email: ORS@schmed01.ab.umd.edu

CONFIDENTIAL

voice: (410) 706-5037

School of Medicine

UNIVERSITY OF MARYLAND
AT BALTIMORE

DEPARTMENT OF EPIDEMIOLOGY AND PREVENTIVE MEDICINE

January 2, 1996

CONFIDENTIAL

Robert R. Conley, M.D.
Chairman, IRB
14-016 BRB

Dear Dr. Conley:

Re: Toxicity of Lead-Exposed Children (TLC) Trial - IRB Number 1195011

I am writing in reply to the points raised in your letter of December 12. I have discussed the IRB concerns and outlined this response with the other TLC co-investigators at the Kennedy-Krieger Institute and Johns Hopkins School of Medicine.

Length of the trial. Following a one-year planning period, enrollment of study subjects began in August, 1994. Therefore, the length of the trial to date is just over 15 months. As outlined in the protocol, the major endpoint (outcome measure) is neurodevelopmental status 36 months after randomization. There is at present no new information that would preclude continuing the trial with an untreated group. Succimer continues to be labeled only for blood lead levels $\geq$ 45 micrograms/dl, higher than the range of blood leads in TLC subjects (considerably higher in most cases). Furthermore, there have been no controlled studies of succimer that confirm long-term benefit to patients.

Toxicity data. There have been no serious adverse events in the TLC trial thus far. Approximately 100 subjects have been randomized at the three Baltimore sites. Of these, only one child has been withdrawn from study drug because of side effects. In this case (a Kennedy-Krieger patient), the child developed diarrhea on drug; the drug was stopped and resumed a few days later, at which time the diarrhea recurred and so the drug was discontinued. This occurrence was not considered to be serious and did not result in unblinding of the child's treatment status. No serious adverse events related to drug administration have been reported to us from the other clinical centers.

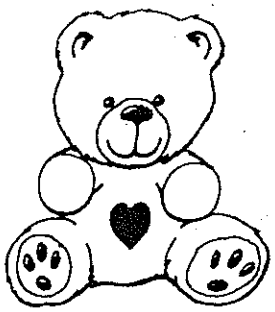
The status of the study was reviewed by the Data Safety Monitoring Committee in December 1995, at which time they decided to continue the trial. Please let me know if there are additional concerns about this study.

Yours truly,

Judith D. Rubin

Judith D. Rubin, M.D., M.P.H.
Associate Professor

660 West Redwood Street
Baltimore, Maryland 21201-1596
410 706 8013 FAX



T L C

Treatment of Lead-Exposed Children

September 28, 1995

Naline Bhargava, M.D.
St. Agnes Medical Center
3455 Wilkens Avenue
Baltimore, MD 21223

Dear Dr. Bhargava:

Thank you for referring to the Kennedy - Krieger Institute's clinical trial of the drug Succimer.

She has met criteria for inclusion into the study. She will be given either Succimer or a placebo in conjunction with residential lead clean-up and multivitamin with minerals supplement. The TLC trial will then follow him/her for three to four years with regularly scheduled blood lead monitoring and neurodevelopmental assessments.

Treatment with the study drug was begun on 09/27/95. Each course consists of 26 days of drug, with blood lead levels, complete blood count including neutrophils and serum chemistries sent to our independent physician reviewer and to our data center at Harvard University at day 7, day 28 and day 42. Results from this last visit determines if a second course of drug is required. No child will receive more than three courses of study drug.

Because of the double blind nature of this clinical trial we ask that you refrain from monitoring lead levels **during the treatment phase of the study,** for each participant. If you feel you must check levels, please do not inform the families or us of any results.

As soon as the child is in the follow-up phase of the TLC trial, we will again have lead and other results available to share with you and with the families. Children will be seen every three months for 24 months after treatment, and then every four months until subject age of 72 months or the end of the study. Once treatment is completed, children will be given multivitamins with minerals, and those children who were found to be iron deficient during the enrollment phase will resume iron therapy. In addition to determining lead levels at each

visit, families will be seen by a nurse and children will be examined by a pediatrician. Neurodevelopmental assessments will be repeated at periodic intervals.

We will notify you periodically of progress, and when study participation ends. Dr. J. Julian Chisolm, Jr. would be happy to answer any questions or respond to concerns. He may be reached at 550-9035.

Sincerely,

Merrill Brophy, Project Manager
Treatment of Lead Exposed Children
Clinical Trial

Kennedy Krieger Institute
A comprehensive resource for children with disabilities

LEAD-CLINIC

OPD PROGRESS NOTE:
Lead Poisoning
December 7, 1994

KKI NUMBER	05-20-06
PATIENT'S NAME	JACKSON-FEATHERSTONE, Shayonna
DOB	10/22/92
ADM DATE	
DISCH-DATE	
JHH NUMBER	259-30-85

DISPOSITION:

Refer to JHH/TAC Clinic for care of otitis immediately after this appointment. Clean with high phosphate detergents. Reduce milk intake to 24 ounces per day. Return to clinic on 2/8/95. This child is also referred to the TLC Program. If she joins, that takes precedence over return to this regular Kennedy Lead Clinic.

J. Julian Chisolm, Jr., M.D.

cc: Dr. Chisolm
PMP - TAC

Kennedy Krieger Institute
A comprehensive resource for children with disabilities

LEAD CLINIC

OPD PROGRESS NOTE:
Lead Poisoning
February 8, 1995

KKI NUMBER	05-20-06
PATIENT'S NAME	JACKSON-FEATHERSTONE, Shayonna
DOB	10/22/92
ADM DATE	
DISCH DATE	
JHH NUMBER	259-30-85

page one

Shayonna is brought for follow-up by her teenage mother, Sharon Jackson. She is referred from the JHH/TAC Clinic. Since March of 1994, mother and child have been living at 2418 E. Jefferson Street, (675-5042) 21205. The mother attends school. The child goes to a babysitter from 9:00 a.m. to 5:00 p.m. in the 600 block of N. Montford Avenue, 21205. The babysitter is Mary McKenzie (~~675-5042~~ 327-2308). About every other weekend the child stays with the paternal grandmother who lives out near the Alameda and Northern Parkway at 2825 Yorkwood Drive. This is a modern house and there is no scaling paint. The only scaling paint is that at E. Jefferson Street, where it appears that paint is peeling from all the woodwork. The home has never been inspected for lead. Mother states that they are cleaning with Thorofare brand detergent with phosphate. They wet mop the floors, windows, window wells every other day with this solution prepared as recommended in this clinic. The child often sucks on toys and sucks on her hands daily. She was seen mouthing both a toy and her fingers during the clinic visit. Calcium intake may be somewhat excessive. The child gets 32 oz. of WCM per day, one to two slices of cheese per day, ice cream daily, pudding almost daily and extra milk on her cereal so that in milk equivalents she may be getting close to 40 oz. per day. Mother is advised to cut the milk she drinks back to about 24 oz. per day. She gets liver twice a month. Other meats include roast, steak, turkey, chicken without the skin.

This child has been in good health since last seen. There are no known allergies, no current medication and no recent exposure to contagious childhood diseases. Immunizations are up to date.

PHYSICAL EXAMINATION:

This child is noted to have a PE tube in place in the right tympanic membrane. She is a tad obese. Otherwise, no significant abnormalities were noted.

Review of serial laboratory data show that during the past five months there has been no essential change in this child's blood lead concentration. Measurements have fluctuated between 18 and 21 μg Pb/dL whole blood. One wonders whether there is a whole lot of lead paint in this dwelling although when given the address one would certainly expect that.

005

Date	Notes and Signature
Rec'd 1.25.95	O - MH attempted at 2418 Jefferson St. Mother ill. Visit deferred until 1/26/95 at 3:30PM. Information left. Jenkins CHW
Rec'd 1.26.95	O - MH attempted & completed at 2418 Jefferson St c mother Sharon Jackson. NCV 3/95. Lived at present residence for 1 year. Flaking paint around windows, hole in wall (steps and peeling surface on wall between front windows. House inspected around Christmas by KKI. Awaiting call from Leroy Kirkland re: inspector. Family consist of Sharon & her mother Barbara Hunter & Theodore Cotton 1/18/92 (brother) & 2 children Keona 9/11/93 & Shayonna 10/20/92 (twins) Kr Kr. Keona has excessive hand to mouth activity. See Data base questionaire intake form for add'l information) At CDC CL III. Mod Risk F-H Hd & pamphlets given. Instructed to obstruct child's access to front wall 2° peeling paint & to cover hole on wall (steps (2) Referred env Insp 1-27-95 (3) IA 3/95 - Med flu — Jenkins CHW

Child's Name Featherstone, Keona

Birthdate 9/11/93 Medical Record # _____

Clinic JHHOPK3 TBC Contact Person _____

1150-10-83

BALTIMORE CITY HEALTH DEPARTMENT
LEAD PAINT POISONING PREVENTION PROGRAM

CLINICAL RECORD - SUPPLEMENTAL NARRATIVE SHEET

Page No. 1

dust samples. Both methods of collection have advantages and disadvantages which merit discussion during the planning phase. The lead content of vacuum dust samples can be reported in terms of lead-loading (μg Pb/m^2) and lead concentration (μg Pb/g). Wipe dust sample results are reported as lead loadings.

3.2.2.3 Plans to Decrease Exposure

For a number of reasons, our protocol is predicated upon assurance of "lead-safe" housing (defined below) for participating families. First, we have evidence that where there is ongoing residential lead exposure, children's PbB may actually increase while on succimer (see Figures 4 and 5). Secondly, the standard of care in Baltimore is to give succimer to children on an outpatient basis only if they are residing in "lead-safe" housing. Furthermore, the local standard of care includes intensive assistance to families in moving to "lead-safe" housing since they must be out of the house during abatements ordered by the Baltimore City Health Department. Lastly, we believe that the less intensive forms of dust-control alluded to in the NIEHS request for proposal are more likely to be successful in the better maintained types of housing defined herein as "lead safe."

This proposal includes a staff person to inspect the homes of potential subjects to determine if the dwelling meets study criteria for "lead-safe" housing. On-site inspection is important since histories obtained in the clinic may not be entirely reliable because the informant has not always been able to describe the condition of the property and the locations of scaling paint. If a house is found to meet pre-established enrollment criteria, then surface dust samples for lead analysis would be collected from floors, window sills and window wells which constitute household surfaces that young children often touch. These baseline results and other house assessment information would be used to guide the lead-exposure reduction activity in the home after enrollment.

We plan to achieve our goal of ensuring lead-safe housing by recruiting from among the following families with eligible children and by inspecting homes on-site in all cases prior to enrollment.

- Families already residing in modern housing, rehabilitated older housing, public housing, or well maintained older housing units;
- Families willing to relocate to such housing if available during the recruitment phase of the study.
- Families whose dwellings have already been abated or will be abated during the recruitment phase.

The specific criteria for lead safe housing and the housing assessment form(s) will be developed during the planning phase and tested during the pilot phase.

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Exhibit 23

graphite furnace atomic absorption spectrometry (GFAA) with Zeman background correction as found on a Perkin-Elmer instrument model 5100. Standard laboratory tests (SMA-12, CBC, routine urinalysis) will be performed at the clinical laboratories serve the JHH-HPLC and the UM-PAC. A figure in Appendix F summarizes performance of the KKI-TML in the Centers for Disease Control's external proficiency testing program for blood lead determinations. Performance data is for analysis by anodic stripping voltammetry during the period July 1989 to September 1992.

Safety Monitoring:

We expect that safety monitoring will be a joint effort between the clinical center and the Coordinating Center. At the clinical sites the focus of the clinical monitoring will be on side effects of drug therapy and of evidence of continued exposure to environmental lead. Should the need arise (e.g. evidence of significant drug toxicity or extreme elevations of blood lead) to break the code on an individual patient, the Coordinating Center will alone have access to the treatment allocation scheme (see above) and therefore will need to provide a safety officer available on a 24-hour basis in case of emergency.

The duplicate blood leads (analyzed at KKI-TML and the central study laboratory) and other selected laboratory tests specified above will facilitate clinical monitoring and enable prompt remediation of any adverse situations that occur. Individual treatment decisions may need to be made at the clinical center on an emergency basis (see below). It will be the responsibility of the Steering Committee to define stop points for the entire study and it will be the responsibility of the Coordinating Center to monitor for circumstances that could cause the trial to be stopped prematurely.

- **Removal from trial/breaking the code**

It is expected that some patients will experience increasing blood lead levels during the course of the trial. This could occur when a patient continues to experience exposure to one or more sources of environmental lead or when the endogenous lead burden is very high. The blood lead level at which chelation therapy is universally recommended is 45 µg/dL. Therefore, if a subject reaches or exceeds 40 µg/dL, chelation therapy may be instituted in accordance with our usual medical practice, i.e. in the in-patient setting to assure removal from further sources of environmental lead. This occurrence will also necessitate reinstitution of a search for the lead sources in the child's environment. It should not necessitate removal of the child from the trial for methodological reasons, as analysis by 'intention to treat' is the preferred mode of analysis for randomized clinical trials. However, it is important to recognize that such an occurrence may be perceived as an adverse outcome by the subject's family, resulting in voluntary withdrawal from the trial.

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Exhibit 25

IN THE CIRCUIT COURT
FOR BALTIMORE CITY

QUYAISHA COLES, Minor, by Her Mother and Next Friend, VERONICA SCOTT, Plaintiff,	)	Case No.
v.	)	24C01004337
KENNEDY KRIEGER INSTITUTE, INC., et al., Defendants.	)	

DEPOSITION OF CLARK H. McNUTT
Taken in behalf of the Plaintiff

October 8, 2003
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Q. Neither was supposed to be an abatement of lead paint hazards, though, correct?
MS. IVERSON: Objection, form.
BY MR. KAZMIERCZAK:
Q. Was either supposed to be an abatement of lead paint hazards?
A. No.
Q. Who was ERI's client for doing these interventions?
MS. IVERSON: What interventions?
MR. KAZMIERCZAK: Interventions that he's just talked about, I believe.
MS. IVERSON: I'm going to object because it's not been clear here. He's been referring to documents that are specific to 911 North Collington, and, yet, you're taking broadly in terms of some contract and generality.
I think if you can clarify the question, if whether he's speaking in generalities or whether he's speaking specifically to 911 North Collington that would be helpful.
BY MR. KAZMIERCZAK:
Q. Did Kennedy Krieger ever pay ERI directly for performing level one interventions?

MS. IVERSON: In what context?
MR. KAZMIERCZAK: In the context of the study.
MS. IVERSON: In the TLC study?
MR. KAZMIERCZAK: Yes.
THE WITNESS: Yes.
BY MR. KAZMIERCZAK:
Q. In the context of work performed by ERI in the Kennedy Krieger, TLC study who was --
MR. DAILY: If you can keep it up again, I'm sorry.
MR. KAZMIERCZAK: Sorry.
BY MR. KAZMIERCZAK:
Q. In the context of work performed by ERI in the TLC study who was ERI's client?
MS. IVERSON: Objection to form. Go ahead.
THE WITNESS: We invoiced Kennedy Krieger for all the work that we did.
BY MR. KAZMIERCZAK:
Q. Okay. So is my understanding correct that ERI had no discretion regarding the scope of environmental interventions to be performed?
MS. IVERSON: Objection, form. And, again, in what context?
MR. KAZMIERCZAK: Throughout the TLC study.

MS. IVERSON: In anything?
MR. KAZMIERCZAK: Well, let's back up, then. We'll do it this way.
BY MR. KAZMIERCZAK:
Q. Did ERI have any discretion at all regarding the scope of any environmental interventions performed to 911 North Collington?
MS. IVERSON: Before you answer the question can I ask you to break the question down? He's spoken now about a level one intervention, which is environmental cleaning. I think that is different from the earlier questions that he was asked about the specifications. So I think you're blending these two. Which one are you talking about?
MR. KAZMIERCZAK: Well, for a level one intervention.
MS. IVERSON: The cleaning?
MR. KAZMIERCZAK: The cleaning.
BY MR. KAZMIERCZAK:
Q. Did ERI have any discretion at all as to the scope of that intervention, if you will?
A. No.
Q. Whose discretion or whose direction were these performed according to?

MS. IVERSON: Objection.
THE WITNESS: Kennedy Krieger.
BY MR. KAZMIERCZAK:
Q. And ERI was doing this work at the behest of Kennedy Krieger?
A. Yes.
Q. Can you tell me what a level three intervention is or was?
MS. IVERSON: In the context of the TLC study?
MR. KAZMIERCZAK: Yes.
MS. IVERSON: Objection to foundation. Go ahead.
THE WITNESS: The TLC contract, it was three different levels of intervention on properties. It was level one, which we discussed earlier, a level two, and then a level three.
Each level of intervention had a price cap. I believe the level one was $1,750; the level two was $3,500; and the level three was 7,000 or 7,500. I may be wrong on those. They're close to that, but I can't remember.
The repair and maintenance and the TLC were the same thing, but there was a few hundred

dollars difference between each one.
MS. IVERSON: Objection, move to strike. Go ahead.
THE WITNESS: A level three intervention was designed to address the identified hazards in a property, and do that for under that price cap of $7,000 or $7,500.
The work that was involved in a level three was primarily window replacement, floor enclosure, door replacement, wall repair, or exterior paint stabilization. Level threes were always done on vacant properties.
BY MR. KAZMIERCZAK:
Q. Okay. Was a level three intervention designed to be a complete abatement of the lead paint hazards in the property?
A. No.
Q. Okay. And, same question, did ERI have any discretion regarding the scope of a level three intervention?
A. We didn't develop the specifications. Kennedy Krieger did, so....
Q. So it was Kennedy Krieger's scope of work and discretion, then?
MS. IVERSON: Objection, form and

foundation.
BY MR. KAZMIERCZAK:
Q. You can answer.
A. The work we did came from Kennedy Krieger. And Kennedy Krieger is the one that identified the components and the treatments in each property.
Q. Okay. It's my understanding that -- actually, strike that.
For the record, you've been provided with various documents that were provided in discovery, including health department records, Kennedy Krieger records, et cetera.
Is it correct to say that ERI performed a level one intervention at 911 North Collington?
MS. IVERSON: Objection.
THE WITNESS: ERI did do a level one treatment on 911 North Collington.
BY MR. KAZMIERCZAK:
Q. Do you know why ERI was contracted to do this work regarding 911 North Collington?
A. A level one was to clean lead dust, so that was our contract and our contractual obligation. So we performed our contractual obligation on that property.
Q. So it was because it was lead-based paint at

911 North Collington?
MS. IVERSON: Objection.
MR. DAILY: Guys, I'm sorry, I can't hear you.
MS. IVERSON: I just objected, Frank.
MR. DAILY: I heard the tail end so I couldn't quite make it out.
THE WITNESS: Are you able to hear me okay?
MR. DAILY: Is that you, Clark?
THE WITNESS: Yes, it is.
MR. DAILY: Sir, I can. The line is weird. It seems like it's electronically activated when there's sound, so it goes in and out. Sometimes voices naturally fade off, I miss the end or the beginning.
MS. IVERSON: Can we go off the record for a minute?
MR. KAZMIERCZAK: Sure.
(Discussion held off the record.)
(A break was taken from 1:18 to 1:39 p.m.)
BY MR. KAZMIERCZAK:
Q. Is it fair to say that ERI was also performing work at 911 North Collington because there was a child there with elevated lead blood levels?
A. I was aware that there was an EBL because there

was an abatement notice issued by the Baltimore City Health Department.
Q. Okay. So for 911 North Collington's level one cleaning, the scope of that work was set forth by the Kennedy Krieger through the TLC protocols?
MS. IVERSON: Objection.
THE WITNESS: That's correct.
BY MR. KAZMIERCZAK:
Q. Okay. Did that cleaning remove all of the lead paint hazards to children at 911 North Collington?
A. No.
Q. So lead paint hazards to children still remained there after the cleaning?
MS. IVERSON: Objection.
THE WITNESS: Yes.
BY MR. KAZMIERCZAK:
Q. Did you ever tell Kennedy Krieger, or make them aware that the cleaning left lead paint hazards to children?
A. By virtue of our written proposal it was identified that lead paint was left on the property, and that it needed to be monitored and maintained by others.

Arc Environmental, Inc.

Comprehensive Inspection and Consulting Services

Brownfield Redevelopment

Asbestos/ Lead-Based Paint

IAQ/Mold

Risk Assessment

Phase I ESAs

Design/Build

toring

Regulatory Compliance and Negotiation

USTs/ASTs

Site Characterization and Remediation

Hazardous Waste Sites (CERCLA/RCRA)

Building Assessments

Offices

Baltimore, MD

York, PA

Lead-based Paint Survey Report (Exterior Only)

PREPARED FOR

Evan K. Thalenberg, P.A.
216 East Lexington Street
Baltimore, MD 21202

August 29, 2005

Child: Shayonna Featherstone
Property Inspected: 2418 Jefferson Street

1311 Haubert Street • Baltimore, MD 21230 • tel 410.659.9971 • fax 410.962.1065

Inspection Summary

Inspection Site:	2418 Jefferson Street Baltimore, MD 21205
Inspection Date:	August 11, 2005
XRF Device:	Soitec MAP4
XRF Serial Number:	1279
Operator:	Chris White, MDE #7474
Company Accred. #:	MDE #4459

Lead-based paint was detected above the Maryland standard (> 0.7 mg/cm^2) on the following exterior components in this property:

Room	*Component(s)*
Front Exterior	wall
	window sill
	basement window sill

1. Overview

The purpose of this survey was to determine approximate levels of lead concentration from representative exterior building components throughout the property. The focus was to test chewable, friction, and impact surfaces in an effort to determine the potential of lead-based paint hazards that might exist in and around the dwelling. Although the sampling and reporting procedures used to inspect this property were consistent with the current HUD Chapter 7 Guidelines, it was not the objective of this inspection to test every painted component on the entire exterior of the property.

2. Instrumentation

2.1 Equipment

A MAP4 x-ray fluorescence ("XRF") spectrum analyzer, serial #1279, manufactured by Scitec Corporation, was utilized to perform this survey. This equipment has a Performance Characteristic sheet developed by HUD/EPA which defines the parameters for its use in the field. The MAP4 is able to classify sample readings at a 95% confidence rating at the Federal standard of 1.0 mg/cm^2.

2.2 Calibration Procedures

Calibration check readings serve to ensure that an XRF instrument remains within acceptable precision and accuracy levels throughout the entire inspection process. The following calibration check procedures and precision levels were used for this inspection:

Initial Calibration Check (completed before the inspection)
Three 15-second nominal time readings are taken on a wood block covered with the red NIST SRM #2579 (1.02 mg/cm^2). The average of the three readings must be 0.6 to 1.2 mg/cm^2 (inclusive).

Final Calibration Check (completed at the end of the inspection)
Repeat the process explained above.

The results from each set of calibration check tests are recorded at the bottom of the first "Lead-Based Paint Testing Data Sheet" that appears following this executive summary.

2.3 Substrate Correction

According to the HUD Performance Characteristic sheet for the Scitec MAP4 XRF equipment that was used to perform the inspection of this property, no substrate correction is required. Throughout the inspection process, only the "unlimited" mode was utilized by the technicians.

3. Reporting Notes

3.1 Determination of Paint Condition

The condition classification is based on a visual inspection of the paint film from which the reading was taken, or similar components in the same room from which the reading was taken. The description is assigned as a general condition of the paint surface that exists on the component that is being tested, and not necessarily of the specific spot at which the test is being conducted. The following is a guide in categorizing paint condition, based on the HUD Guidelines:

Intact: Paint film appears to have no surface deterioration and does not chalk, flake, or peel; no signs of cracking or blistering; no separation from the substrate.

Fair: The paint film is largely intact, but is cracked, worn, or chipping. Approximately 10% or less of the surface is deteriorated or defective.

Poor: More than 10% of the surface is peeling, chalking, flaking, blistering, or otherwise separated from the substrate. "Poor" paint conditions should be addressed as a top priority because the likelihood of these components generating leaded dust.

3.2 Classification of Readings

Each XRF test is classified as positive, negative, or inconclusive based on the following ranges according to the Performance Characteristic sheet for a Scitec MAP4 using the "unlimited" mode and in accordance with the Maryland standard of > 0.7 mg/cm^2:

Negative	**Positive**	**Inconclusive**
$\leq$ 0.7 mg/cm^2	$\geq$ 1.0 mg/cm^2	0.71 to 0.99 mg/cm^2

Please call Arc Environmental, Inc. should you have any questions about this report or have further concerns about the lead-based paint issues related to this property.

ARC ENVIRONMENTAL, INC.

Prepared By:

R. Shannon Cavaliere
Principal

Lead-Based Paint Testing Data Sheet

Client Name: Law Offices of Evan K. Thalenberg, P.A. Child: Shayonna Featherstone

Inspection Address: 2418 Jefferson Street, Baltimore MD 21205

Technician: Chris White Date: 8 / 11 / 05

Room	Wall	Component	Paint Condition	Result	P,N,I
Front Exterior	A	Wall	Fair	1.8	P
	A	Window Sill	Poor	8.0	P
	A	Basement Window Sill	Poor	1.5	P
	A	Basement Window Casing	Poor	0.4	N
		END OF DATA			
Arrived at Site, 2 story middle brick row home, vacant with door and lower level windows boarded, no access, windows appear to be replaced and components are wrapped in aluminum, soffit appears to be original and in poor condition, no access to rear					

Wall: A = a component tested on the closest wall parallel to the front door of the property. B,C, and D would be assigned in a clockwise fashion. Numbered digits are used if multiple components exist on the same wall (numbered left to right).

Component: D = door; DJ = door jamb; DC = door case; CL = ceiling; W = wall; WS = window sash; WIS = window sill; WC = window case; WW = window well; HR = handrail; BB = baseboard; S = shelf; SP = shelf support; C- = closet; P = post

Paint Condition: I = Intact; F = Fair; and P=Poor. A visual assessment of the paint film condition for a component tested or similar components in the same room but not tested.

Result: P= Positive; N= Negative; and I= Inconclusive

Initial Calibration Check: 1) 1.02 2) 1.08 3) 1.13 Average 1.08 (Pass) or Fail

Final Calibration Check: 1) 0.95 2) 1.12 3) 1.01 Average 1.03 (Pass) or Fail

IN THE CIRCUIT COURT
FOR BALTIMORE CITY

QUYAISHA COLES, Minor,)
by Her Mother and Next Friend,)
VERONICA SCOTT,)
Plaintiff,) Case No.
v.) 24C01004337
KENNEDY KRIEGER INSTITUTE, INC.,)
et al.,)
Defendants.)

DEPOSITION OF CLARK H. McNUTT
Taken in behalf of the Plaintiff

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(Discussion held off the record.)
MR. KAZMIERCZAK: For the record, I have just handwritten the page numbers in the upper right-hand corner in black pen. I came up with 35 pages.
BY MR. KAZMIERCZAK:
Q. Mr. McNutt, can you refer me, I guess, to the field notes? Can you identify whether or not they're in this part of this packet?
A. These drawings here, pages 11, 12, and 13, would come with the -- would come with this document here (indicating), pages 16 through 30.
I believe when we received this document there was a cover letter, also, requesting us to provide a proposal on our own letterhead using these notes and the diagrams.
So we would be presented with these floor plan drawings, which would be the footprint of the building showing the basement, the first and the second floors.
And then these field notes, this unit cover sheet, would tell us the level of intervention with the address and all. And then the field notes themselves would start with the front

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exterior, rear exterior, and then it would take you through the building just as if you were walking from the front to the back.
And each area would have a letter designation which were tied to the floor plans. And the treatment options for each component within a room would be identified through the code I was speaking about earlier, that abbreviated code.
So these forms here (indicating) all came from repair maintenance program. The cover letter was not, though. I was very familiar with the use of these because, actually, I helped develop them with Susan Kleinhammer at the beginning of the repair and maintenance contract.
Q. So Kennedy personnel would go out, compose these field notes, and send them to ERI in order to turn them into a proposal?
MS. IVERSON: Objection, form and foundation.
BY MR. KAZMIERCZAK:
Q. Who would compose the field notes?
A. Well, we would receive them from Kennedy Krieger, so. I think there's initial

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identification as to who did each one. And then we were familiar with the Kennedy Krieger field staff at the time, so...
Q. In these field notes, is it fair to say that they would be direction to ERI to what they wanted done to each particular property?
MS. IVERSON: Objection, form and foundation.
THE WITNESS: It identified room by room and area by area what the treatment was for each of the components that were to receive treatment.
BY MR. KAZMIERCZAK:
Q. Okay. I guess what I'm sort of getting at is that this was direction to ERI as to what Kennedy wanted done, correct?
MS. IVERSON: Objection.
BY MR. KAZMIERCZAK:
Q. Did ERI exercise its own discretion as to what should be done to each property?
A. No.
Q. So the discretion was Kennedy Krieger's as to what should be done?
MS. IVERSON: Objection, form, foundation.
THE WITNESS: Well, we didn't identify the

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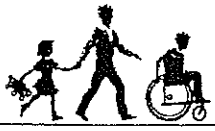
areas or the components. We were given these field sheets to put together a proposal on our own letterhead. They were Kennedy Krieger's specifications, Kennedy Krieger's field notes, so...
I think a lot of times we wouldn't even go out and see the properties, because all the dimensions and everything else were in these field notes, so...
Q. Can you tell me what a level one intervention is?
A. Level one is basically environmental cleaning.
Q. Okay.
A. And environmental cleanings were identified in these specifications, too. There was a lower level environmental cleaning, and then there was a more stringent application that was only utilized on vacant properties.
So in an occupied property all you could really do was cleaning with TSP and sealing some of the surfaces with floor wax, and whatnot.
In a vacant property you could paint the floors and do a lot more work. There was two types of environmental cleanings.

Exhibit 28



Kennedy Krieger Institute

A comprehensive resource for children with disabilities

January 25, 1993

Thomas R. Hendrix, M.D.
Chairman
Joint Committee on Clinical Investigation
Administration 129
Johns Hopkins University School of Medicine
720 Rutland Avenue
Baltimore MD 21205-2196

RE: RPN 92-11-19-01, entitled "Toxicity of Lead in Children - Clinical Center" and your letter of December 9, 1992

Dear Dr. Hendrix:

I am glad to respond to the questions set forth in you letter of December 9, 1992 and to provide some background for this multi-center study. Our application was submitted in response to an RFA issued by the National Institute for Environmental Health Sciences (NIEHS), in which they proposed a randomized, double-blind, placebo-controlled evaluation of a course of oral DMSA. They specify in the RFA that the outcome variable will be the child's neurodevelopmental status at four to five years of age. They invited proposals designed along the general outlines provided by them, with the understanding that the three proposals which they considered best would be funded and that the principal investigators for these three proposals would get together and agree to a single, common protocol. Therefore, the protocol which I submitted to you is not likely to be the final protocol. So much for the background. Now for the questions.

1. The current standard therapy for children with elevated blood lead levels is to give chelation therapy when the blood lead concentration exceeds 40-45 μg Pb/dL whole blood. When meso-2,3-dimercaptosuccinic acid (DMSA) is used at lower blood lead levels, it is considered investigational. In the NIEHS proposal, children with blood lead levels between 20 and 40 or 45 μg Pb/dL whole blood will be randomized to DMSA or a placebo. The proposal suggests that they receive a single course of oral DMSA. NIEHS would obtain the necessary IND from the FDA. Since NIEHS requires that this be an outpatient protocol, we have in our proposal specified safe housing for administration of the drug on an outpatient basis. Both DMSA-treated and placebo-treated subjects will have repeated housecleaning to suppress dust lead levels in the home. I know of no one who presently recommends treatment with chelation therapy at blood lead levels lower than 25 μg Pb/dL whole blood.

2. All subjects will be enrolled at either 12-30 months, or 18-36 months of age, and they will have repeated professional housecleaning until they are four or five years of

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age to suppress dust. We would not treat any children living in grossly substandard housing. Data from the prosepctive studies now in progress (Boston, Cincinnati, Port Pirie) indicate that cognitive outcome is best related to time-weighted lifetime average blood lead concentration. Thus, in the study proposed here, ability to lower this average will probably determine outcome. Those who receive DMSA will be compared with those who receive the placebo. In my view, the outcome of this study will not be determined by a single course of DMSA, but, rather, by the ability to suppress lead-bearing dust in the home over the long run and the degree and persistence of hand-to-mouth activity in the children. In short, the study involves children for whom chelation therapy with DMSA is not as yet approved by the FDA.

3. With regard to the question of side effects, I have now treated 60 children in a total of about 100 28-day courses of oral DMSA. In these children, I have not seen any significant elevations in the transaminases. We did have one child with an atopic history who developed giant urticaria when a second course was instituted. The only significant side effect that I have seen has been significant elevation in serum alkaline phosphatase. Measurement of isoenzymes indicates that the increase is due to alkaline phosphatase presumably derived from bone. There has been no evidence of liver dysfunction. This reaction has been reversible and has occurred in two patients on the study protocol. I am aware of its occurrence in two other children in the city of Baltimore not on my study protocol. The only significant reaction that I am aware of in adults occurred in a Danish worker who developed a fixed-drug eruption. I have observed neutropenia, but this has always been readily explained by a concurrent viral infection. I have treated two patients with sickle cell disease and six with G-6-PD deficiency, none of whom showed any untoward reaction. It would appear that the drug is remarkably free of serious side effects. The great increase in alkaline phosphatase activity (and I am talking about increases to 1500-4000 iu) is not readily explained.

I hope these responses will be adequate. Please let me know if there is any further information that you require. I await your reply before doing anything about the consent form.

Yours sincerely,

J. Julian Chisolm, Jr., M.D.
Director
Kennedy Krieger Institute Lead Program

JJC:crz

cc: G. Goldstein

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IN THE CIRCUIT COURT
FOR BALTIMORE CITY

QUYAISHA COLES, Minor,)
by Her Mother and Next Friend,)
VERONICA SCOTT,)
Plaintiff,) Case No.
v.) 24C01004337
KENNEDY KRIEGER INSTITUTE, INC.,)
et al.,)
Defendants.)

DEPOSITION OF CLARK H. McNUTT
Taken in behalf of the Plaintiff

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Enterprise was.

So I picked up that contract from the city, and we performed lead abatement/lead hazard reduction on some 75 properties for City Homes.

City Homes and Barry Manquits working with Kennedy Krieger at the time, and they were needing a contractor for what became the repair and maintenance program. And myself and our company -- I was no longer with MCS Environmental. I was now with the ERI, which was in 1991.

Through an invitation with Barry Manquits at City Homes and Nick Farr with Enterprise Foundation, I sat down with Dr. Mark Farfell and a number of the Kennedy Krieger people, and Susan Kleinhammer, and was asked to participate in this contract.

We developed specifications for that contract, and then we did different levels of intervention. Levels ones, twos, and threes on, I think it was 225 or 250 homes.

About two-thirds or three-quarters of the way through that contract the TLC program was going into place. And so we just kind of went from finishing up the repair and maintenance

Exhibit 33

IN THE CIRCUIT COURT
FOR BALTIMORE CITY

QUYAISHA COLES, Minor, by Her Mother and Next Friend, VERONICA SCOTT, Plaintiff,	)	Case No. 24C01004337
v.	)	
KENNEDY KRIEGER INSTITUTE, INC., et al., Defendants.	)	

DEPOSITION OF CLARK H. McNUTT
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disagree for reasons including but not limited to the fact that he has just indicated that there was some work. My understanding is, at least, there was some crossover between the studies which I think we're entitled to explore.

Furthermore, this case, at least my understanding of it, is this is sort of a lead case, if you will, for the purposes of discovery about these things.

We were trying to depose people in this generally to address, you know, how the study, in general -- hopefully that discovery will apply to cases and earlier stages, as well.

So, for that reason, I guess -- we're out here in Portland, Oregon. If he's knowledgeable about these things, you know.

MS. IVERSON: All of the cases that you have filed are cases that deal with the TLC study. There's nothing dealing with the R & M study, and not that it would be relevant here anyway.

And I'm not sure what you mean about "crossover," but they are two distinct studies.

The only study that is relevant at issue in

this case is the TLC study. And, therefore, it's the only study that is relevant to Mr. McNutt's testimony is any work that he may have worked with Kennedy Krieger involving the TLC study.

MR. KAZMIERCZAK: It's not just relevance, but it's also potential to lead to admissible evidence, which I think is a much broader standard.

You want to make your objection that's fine, I don't have any problem with that, but I would like to see what Mr. McNutt has to say.

BY MR. KAZMIERCZAK:

Q. The question which was way back was, can you tell me how ERI came to work with Kennedy Krieger in regard to the studies that you had mentioned?

MS. IVERSON: Objection as to pertains to a nonrelevant study.

THE WITNESS: In, I believe it was 1988, I was associated with another company, which was MCS Environmental, and we were doing asbestos abatement work at the time. And lead was just -- people were just beginning to talk about lead. So I did as much research as I

could on the subject.

And I had had a previous working experience with the Enterprise Foundation through company named Struever Brothers, Eccles & Rouse. And we did quite a few projects with them, so I knew a lot of people at the Enterprise Foundation.

I hooked up with a gentleman named Nick Farr, and asked for an introduction to -- which was City Homes, Barry Manquits (phonetic).

I later found out that City Homes was involved with a project through the city builders program, which is a training program through the city of Baltimore. And they were doing lead-based paint abatement on properties through this training program.

And the mayor, since the city was self-insured, the mayor did not want the potential liability, so they were looking for another environmental contractor to take over, I believe it was 75 homes in this particular grant that the Enterprise Foundation was involved with. I can't remember whether Fanny Mae was involved in it or not, but

Enterprise was.

So I picked up that contract from the city, and we performed lead abatement/lead hazard reduction on some 75 properties for City Homes.

City Homes and Barry Manquits working with Kennedy Krieger at the time, and they were needing a contractor for what became the repair and maintenance program. And myself and our company -- I was no longer with MCS Environmental. I was now with the ERI, which was in 1991.

Through an invitation with Barry Manquits at City Homes and Nick Farr with Enterprise Foundation, I sat down with Dr. Mark Farfell and a number of the Kennedy Krieger people, and Susan Kleinhammer, and was asked to participate in this contract.

We developed specifications for that contract, and then we did different levels of intervention. Levels ones, twos, and threes on, I think it was 225 or 250 homes.

About two-thirds or three-quarters of the way through that contract the TLC program was going into place. And so we just kind of went from finishing up the repair and maintenance

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al. *

Plaintiffs *

v. *

Case No. _____

KENNEDY KRIEGER INSTITUTE, INC., et al. *

Defendant. *

* * * * * * * * * * *

AFFIDAVIT OF CECILIA DAVOLI, M.D.
IN SUPPORT OF NOTICE OF REMOVAL

I, the undersigned, am over the age of eighteen, am competent to testify and have personal knowledge of the following:

1. I, Cecilia Davoli, M.D. am a physician currently licensed to practice medicine in the State of Maryland. My area of expertise is developmental pediatrics and I am Board Certified in pediatrics and neurodevelopmental disabilities. I am employed by the Kennedy Krieger Institute ("Kennedy Krieger") and am an Assistant Professor of Pediatrics at the Johns Hopkins University School of Medicine.

2. In the spring of 1993 I became involved with the National Institute of Environmental Health Sciences ("NIEHS") Study – Treatment of Lead-Exposed Children ("TLC"). My involvement was at Kennedy Krieger with J. Julian Chisolm, M.D. I served as a co-investigator for the portion of the TLC Study conducted at Kennedy Krieger.

3. In my role as co-investigator I have obtained first-hand knowledge regarding activities of the NIEHS and its officers as well as the CDC, related to the design and implementation of the TLC Study.

4. A group consisting of, among others, the NIEHS Project Officer and the Principal Investigators from the Clinical Centers, was charged with responsibility for virtually all aspects of the TLC Study, including, the design and implementation of the protocol, enrollment of Study participants, and follow-up. This group held regular meetings and/or conference calls in fulfillment of that responsibility. Also participating in those meetings and calls were various other individuals from NIEHS and the clinical centers who were involved with this Study. I was one such participant. Those meetings and calls were supervised by the NIEHS Project Officer, Dr. Walter Rogan. Dr. Rogan actively participated in the discussions, and guided the direction of the Steering Committee meetings to ensure that the TLC Study plans developed consistent with NIEHS objectives.

5. During the Steering Committee meetings, there was active discussion from all interested participants. However, the only way for a substantive TLC Study decision to be implemented and become part of the Study, was following review by NIEHS. Each and every decision of the Steering Committee was reviewed by Dr. Rogan prior to or during the process of its implementation. No decision could be final without review by Dr. Rogan and the NIEHS.

6. The NIEHS directly controlled and approved the information provided to the Study participants and their families as well as the information contained in the Informed Consent forms.

7. The NIEHS Project Officer and staff conducted periodic site visits at Kennedy Krieger. These visits were intended to: (1) ensure that Kennedy Krieger was conducting its portion of the Study consistent with the trial protocol; (2) review Study participant charts to ensure compliance with the United States Food and Drug Administration ("FDA") regulations for investigational new drugs ("IND"); (3) observe Kennedy Krieger's facilities; and (4) survey the residential houses involved in the Study.

8. NIEHS (Dr. Walter Rogan) held the IND exemption for the Study drug, Succimer. During one of the site visits, Dr. Rogan conducted a quiz to make certain that Kennedy Krieger staff involved in the TLC Study understood the nature of the drug, including its side effects, in order to ensure compliance with NIEHS and FDA reporting requirements.

9. In the TLC Study, the United States Centers for Disease Control and Prevention ("CDC") conducted the laboratory analysis of all blood lead samples from Study participants. Accordingly, it maintained oversight responsibility for all issues related to drawing blood at the Clinical Centers. The CDC established the protocol used by all Clinical Centers for drawing blood as well as for packaging the blood samples for shipment to the CDC laboratory in Atlanta, Georgia. Prior to the implementation of the TLC Study, the project manager for each clinical site was required to attend CDC training and was then expected to train personnel responsible for obtaining blood samples. This training provided instruction for compliance with the CDC protocol. The CDC conducted site visits to ensure that the Clinical Centers were complying with its blood drawing protocol. The CDC also provided certain of the equipment utilized in drawing the blood samples as well as all of the packaging materials.

10. In order to ensure uniform implementation of the TLC Study protocol, NIEHS required all Clinical Centers to participate in central training sessions to learn NIEHS approved techniques for measuring the height, weight, head circumference and blood pressure of Study participants. These were all values required to be obtained as part of the Study. Further, Central training was provided as to NIEHS approved methods for administering relevant psychometric testing, the results of which would be crucial to analyzing the outcome of the Study.

11. The Principal Investigator at Kennedy Krieger was required to seek approval form NIEHS in order to allocate funds for any purpose that deviated in any way from the contract drafted by NIEHS.

12. Kennedy Krieger was required to obtain IRB approval of the Informed Consent Form to be used in enrolling Study participants. After the local IRB utilized by Kennedy Krieger approved the form, Kennedy Krieger was required to submit that form to the NIEHS IRB for further review. The NIEHS IRB ultimately approved the Informed Consent Form used in the TLC Study.

13. Kennedy Krieger was obligated to follow, and did comply with, strict and comprehensive requirements pursuant to research involving human subjects, imposed by the federal government.

14. Based on my personal involvement and observation of virtually all aspects of the design and implementation of the TLC Study at Kennedy Krieger, there is no question that the federal government, through the NIEHS, FDA and CDC, retained and exercised a very detailed level of control over every aspect of the Study.

I HEREBY DECLARE UNDER THE PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Executed on: 19 April 2007

Cecilia Davoli, MD

Cecilia Davoli, M.D.

Exhibit 35

QUYAISHA COLES, MINOR, BY HER MOTHER AND NEXT FRIEND, VERONICA SCOTT,

Plaintiff

vs.

KENNEDY KRIEGER INSTITUTE, INC.,

Defendants

IN THE

CIRCUIT COURT

FOR

BALTIMORE CITY

24-C-01-004337

The deposition of CECEILIA DAVOLI, M.D. was held on Friday, November 21, 2003, commencing at 11:16 A.M., at the Law Offices of Goodell, DeVries, Leech & Gray, LLP, 20th Floor Commerce Place, One South Street, Baltimore, Maryland 21202, before William J. Counts, Notary Public.

APPEARANCES:

EVAN K. THALENBERG, ESQUIRE
On behalf of Plaintiff

DONALD DEVRIES, JR., ESQUIRE
On behalf of Defendants

ERICKA L. KLEIMAN, ESQUIRE
On behalf of Defendants

LARRISA N. MILLER, ESQUIRE
On behalf of Defendants

REPORTED BY: William J. Counts

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I would not necessarily completely agree with that statement in isolation.
Q Okay.
A If you are asking -- so I don't agree with it in isolation.
Q So what does it have to be read in context with?
A This is the consent form.
Q What if I show you the lead paint violation notice for this house. Will it help?
MR. DEVRIES: Objection. Let her answer the question.
A This is a consent form, I agree with that. This consent form has several parts. The first part of the consent form is a general summary of information about lead, and to the best of my recollection, that all of the consent -- this is for the TLC study -- and all of the consent forms in all four centers contain essentially the same language, and were written by a group of investigators from all four centers. And the language was reviewed by

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the IRB at Johns Hopkins for our particular center. And also this was a consent form that was approved by the NIEHS IRB. So in the context of the consent form and the purpose for which the consent form was written, in the context of this trial, then I do agree with the statement.
Q I am glad we cleared that up. Doctor, during the course of the Quyaisha Coles participation in this, who was her primary treating physician?
A Her primary care provider?
Q Yes.
A I honestly can't remember her primary care provider, her pediatrician.
Q Who was responsible for her care and treatment in regard to her elevated blood lead levels during the time that she was a participant in the TLC trials?
A Her primary care provider -- who was responsible for the care and treatment?
Q Who was responsible for her care and

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treatment during the time that she was in the TLC program? What doctor had primary responsibility for her health and well being as it related to her elevated blood lead levels?
A Well, that is difficult to answer with one answer. I can tell you she had a primary care provider. I can't remember who it was right at this second, who was responsible for her overall medical care, and that was her primary care provider. With -- within the context of the TLC study we were providing some care for the child, but I wouldn't describe it as primary treatment of the child.
Q Okay.
A She was participating in a study.
Q So she wasn't getting treatment, right?
A I wouldn't describe it as primary treatment. She was participating in a study, and we were following her and monitoring her within the context of this study, under the study protocol. But her primary medical care, we did not become her pediatrician, if that's what you are asking.

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Q Even for the elevated blood lead levels? Is that your position also? Let me ask you this. She was referred by Dr. Sedeke. Was Dr. Sedeke still responsible for the care and treatment of Quyaisha Coles in regard to elevated blood lead levels while she was in the TLC program?
A Dr. Sedeke was the primary care provider for this child. Dr. Sedeke had overall responsibilities for the medical care of the child in all respects, including the elevated blood lead level.
Q Throughout the time that Quyaisha Coles was in the TLC program, even though she had referred Quyaisha Coles to Kennedy Krieger?
MR. DEVRIES: I will object. There was no indication she referred the child to Kennedy Krieger prior. That's the assumption of your question.
Q Okay, assume that she referred Quyaisha Coles to Kennedy Krieger for her elevated blood lead levels.

QUYAISHA COLES, MINOR, BY HER MOTHER AND NEXT FRIEND, VERONICA SCOTT,	IN THE
Plaintiff	CIRCUIT COURT
vs.	FOR
KENNEDY KRIEGER INSTITUTE, INC.,	BALTIMORE CITY
Defendants	24-C-01-004337

The deposition of CECEILIA DAVOLI, M.D. was held on Friday, November 21, 2003, commencing at 11:16 A.M., at the Law Offices of Goodell, DeVries, Leech & Gray, LLP, 20th Floor Commerce Place, One South Street, Baltimore, Maryland 21202, before William J. Counts, Notary Public.

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On behalf of Plaintiff

DONALD DEVRIES, JR., ESQUIRE
On behalf of Defendants

ERICKA L. KLEIMAN, ESQUIRE
On behalf of Defendants

LARRISA N. MILLER, ESQUIRE
On behalf of Defendants

REPORTED BY: William J. Counts

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responsibility for ascertaining whether there was a problem?
A During -- this paragraph is about the blood being taken with a needle from the vein, and the needle usually hurts. To minimize only experienced personnel will draw the blood. And if anything unexpected happens during the course of having that blood drawn, a doctor from the study will take care of any immediate need.
Q Okay. On page five it says at the top, "The benefits to your child of letting us find out if they are eligible for the TLC study are that we will look carefully at your home to identify lead hazards and tell you about it."
The "we" in this case is Kennedy Krieger, isn't it?
A May I just think for a second?
Q Strike that before you answer that. How many of these meetings did you sit in on?
A Well, I can't give you an exact number.
Q Well, was it more than 20?

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A Visits in general, or this type of visit?
Q How many people did you sign up?
A My recollection, how many did I personally sign up?
Q How many of these meetings did you sit through approximately?
MR. DEVRIES: Regarding the consent form?
MR. THALENBERG: Yes.
A How many of these visits where a pre-enrollment consent form was signed?
Q Yes. How many did you sit through?
A I can't tell you. More than 20, but I can't give you another number.
Q Was it more than a thousand?
A No, sir.
Q More than a hundred?
A Possibly.
Q Did you receive training in how to conduct these meetings before you conducted them?
A Yes.
Q And you had input into preparation of this

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consent form, didn't you?
A Yes.
Q Okay. So one would assume when something is in here you know what it is supposed to mean, isn't that correct?
A That is correct. I was going to answer the question, but I was thinking.
Q Let me reask the question. The "we" in, "We will look carefully at your home to identify lead hazards and tell you about it," the "we" is Kennedy Krieger, isn't it?
A Well, not exactly. This was a standard consent form that was used in all of the four centers that were participating in the TLC study. So the "we" in general meant the environmental arm of the study, the people who were in the environmental arm of the study within each of the centers. So in the Baltimore center it would have been the employees who were within the -- who were doing the environmental arm of the TLC study. In general it meant an environmental worker from the

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TLC study. It wasn't necessarily Kennedy Krieger in the other centers.
Q I didn't ask you about the other centers. In your meeting with Veronica Scott, when you are reading this to Veronica Scott and it says, "We will look carefully at your home to identify lead hazards and tell you about it," in this context the "we" is Kennedy Krieger?
A In this particular form it would have been someone in the environmental arm of the TLC study, yes, who was employed by Kennedy Krieger.
Q When you are doing these meetings -- strike that. Do these take place in the clinic?
A When you say the word "meeting," are you referring to a clinic, this visit, this visit during which the trial pre-enrollment form is signed?
Q Right.
A Yes, this would have been a clinic visit, yes. And it would have taken place -- the Baltimore center was comprised of three clinical sites. One was at Kennedy Krieger Institute, one was at Johns

Exhibit 37

QUYAISHA COLES, MINOR, BY HER MOTHER AND NEXT FRIEND, VERONICA SCOTT,		IN THE
Plaintiff		CIRCUIT COURT
vs.		FOR
KENNEDY KRIEGER INSTITUTE, INC.,		BALTIMORE CITY
Defendants		24-C-01-004337

The deposition of CECEILIA DAVOLI, M.D. was held on Friday, November 21, 2003, commencing at 11:16 A.M., at the Law Offices of Goodell, DeVries, Leech & Gray, LLP, 20th Floor Commerce Place, One South Street, Baltimore, Maryland 21202, before William J. Counts, Notary Public.

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On behalf of Defendants

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On behalf of Defendants

LARRISA N. MILLER, ESQUIRE
On behalf of Defendants

REPORTED BY: William J. Counts

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Hopkins Hospital and one was at the University of Maryland. And I worked exclusively in the Kennedy Krieger Institute. However, occasionally there would be children from the other sites seen within that clinic. This particular meeting did occur within the Kennedy Krieger Institute.

Q When you were in the clinic did you customarily wear a white coat?

A It is my practice to wear a white coat when I am in the clinic. If you are asking me between 1994 -- excuse me, on this date 8/29/95, I don't know if I was wearing a white coat or not, but it is my general practice to wear a white coat.

Q Does it have your name stitched on it?

A Yes, sir.

Q Does it say "Dr." or "MD"?

A It says Cecilia Davoli, MD.

Q Usually you are wearing a white coat that says "Dr." on it is it fair to say?

A It says MD.

Q Medical doctor. Doctor, let's go to the

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next one. It says, "If your house doesn't qualify, we will offer you any information we have about ways to relocate your family to housing that is known to be lead safe."

"We," again in that context, is Kennedy Krieger, isn't it?

A It would have been, yes, people working within the TLC study that worked at Kennedy Krieger.

Q Did Kennedy Krieger have access to housing that was lead safe?

MR. DEVRIES: What do you mean by "access"?

Q Did they have a list of housing that was lead safe?

A Yes, we did have a list. It was a list -- my recollection is it was a list from the Coalition to End Childhood Lead Poisoning.

Q It also says in the next paragraph, "We will clean up the lead if it looks like your house and child are eligible."

Now if the house and child are

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eligible, then next the consent form is signed, the enrollment form, isn't that correct?

A Not at this visit. It would not have been --

Q No, the next visit. Isn't that true?

A I can't remember exactly. My recollection is -- can you tell me what the visit number was for this, when this one was signed?

Q When this one was signed or the next one?

A When this one was signed.

Q This was on August --

A No. What was the name of the visit, what was the code for the visit.

Q August 29th was the --

A Is there a V?

Q V1, all of that kind of stuff?

A Yes.

Q No. This one doesn't have that.

A So subsequent to this visit -- I can answer this in general.

Q In general.

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A It would be subsequent to this visit the enrollment form would be signed, but I cannot tell you for sure. I would have to look at the chart to see if there was a visit in between this visit and the visit where the enrollment form was signed. I just can't remember exactly.

Q But generally if the house and the child were deemed eligible, then the enrollment form is signed, is that correct?

A The enrollment form was a separate consent form. The parent would have to be interested in participating. It wasn't automatically signed after this form was signed. There would be some things that happened between the signing of this form and the signing of the enrollment form.

MS. KLEIMAN: If it helps the enrollment form is signed V2.

A So V2 would be when an enrollment consent is signed. There would be some type of visit between those two. That to my recollection would occur not in the clinic.

Exhibit 38

QUYAISHA COLES, MINOR, BY HER MOTHER AND NEXT FRIEND, VERONICA SCOTT,

Plaintiff

vs.

KENNEDY KRIEGER INSTITUTE, INC.,

Defendants

IN THE

CIRCUIT COURT

FOR

BALTIMORE CITY

24-C-01-004337

_____/

The deposition of CECEILIA DAVOLI, M.D. was held on Friday, November 21, 2003, commencing at 11:16 A.M., at the Law Offices of Goodell, DeVries, Leech & Gray, LLP, 20th Floor Commerce Place, One South Street, Baltimore, Maryland 21202, before William J. Counts, Notary Public.

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On behalf of Plaintiff

DONALD DEVRIES, JR., ESQUIRE
On behalf of Defendants

ERICKA L. KLEIMAN, ESQUIRE
On behalf of Defendants

LARRISA N. MILLER, ESQUIRE
On behalf of Defendants

REPORTED BY: William J. Counts

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Q So the "we" in this context refers to Kennedy Krieger personnel?
A I don't know if it refers specifically to Kennedy --
Q When you read this to Veronica Scott and you said, "We will have a doctor examine your child," you didn't mean that a doctor would come from Philadelphia to examine the child?
A No.
Q She would have reasonably assumed someone from Kennedy Krieger would examine her child?
A Yes, the doctor would be from Kennedy Krieger, I agree with that.
Q The last one is --
A I agree with that completely.
Q Doctor, the last one, "We will check the amount of lead in your child's body carefully." In this context as read by Veronica Scott, the "we" is Kennedy Krieger?
A Well, we would draw the blood, that is correct. We, Kennedy Krieger, will draw the blood.

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Q It says, "We will check the amount of lead in your child's body." Was there any other doctor in the room when you were reading this to Veronica Scott?
A Not to my recollection.
Q So you are the only doctor in the room, is that correct? So the "We will check the amount of lead in your child's body carefully," could actually be reasonably inferred to be you?
MR. DEVRIES: We can't assume what the person who is hearing this is thinking at the time.
MR. THALENBERG: I can.
MR. DEVRIES: She can talk about what she said.
A I am not trying to be difficult. This TLC consent form was a standardized consent form used in all four centers. And this was the consent form that was approved in all four centers, and additionally approved by NIEHS. So this "we" in the broad sense referred to all TLC study investigators.

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In the context of the visit with this individual child, the people that the parent and the child would have come into contact with, by virtue of being in the Baltimore center, would have been Baltimore study site investigators. So while I cannot completely agree that this "we" only refers to Kennedy Krieger Institute, I will agree that this child would have only been in contact with Baltimore study site investigators.
Q So one would reasonably infer from being read this that "We will check the amount of lead in your child's body carefully," that the "we" referred to Kennedy Krieger?
MR. DEVRIES: I object to what one would infer.
A I don't know what they inferred.
Q You didn't mean Kennedy Krieger when you said "we"? You meant Philadelphia?
A No, I did not say that, sir. I said that this -- the mother of this child and I were discussing what would happen within the Baltimore

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center. We never got into discussion of this "we" referring only to the Baltimore center.
Q You read this to her, "We will check the amount of lead in your child's body carefully." What do you think she would think when you read that to her?
A That she and I were discussing the baltimore, we were discussing with each other. You are asking me if "we" only refers to Kennedy Krieger, and I can't agree completely with that.
Q Let me ask you a couple more questions.
MR. DEVRIES: It's 10 after 5:00 you want to keep going?
MR. THALENBERG: Yes.
Q During this meeting did you tell Veronica Scott to move out of the house in which she lives?
A I don't really remember any details of what I specifically said to Veronica Scott during that visit.
Q Okay. But you don't remember telling her that, do you? Do you remember telling her "that you

Exhibit 39

QUYAISHA COLES, MINOR, BY HER MOTHER AND NEXT FRIEND, VERONICA SCOTT,	IN THE
Plaintiff	CIRCUIT COURT
vs.	FOR
KENNEDY KRIEGER INSTITUTE, INC.,	BALTIMORE CITY
Defendants	24-C-01-004337

The deposition of CECEILIA DAVOLI, M.D. was held on Friday, November 21, 2003, commencing at 11:16 A.M., at the Law Offices of Goodell, DeVries, Leech & Gray, LLP, 20th Floor Commerce Place, One South Street, Baltimore, Maryland 21202, before William J. Counts, Notary Public.

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On behalf of Defendants

REPORTED BY: William J. Counts

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Q Okay. But you don't remember telling her that, do you? Do you remember telling her "that you

Treatment of Lead-Exposed Children Trial

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September 21, 1994

and reflect well the national distribution of lead poisoning. The Harvard School of Public Health (Boston MA) will serve as the Data Coordinating Center, the Centers for Disease Control and Prevention (CDC, Atlanta GA), through its Nutritional Biochemistry Branch, will serve under an Intra-agency Agreement as the Central Laboratory for the Trial, and the Public Health Service Supply Service Center (Perry Point MD) will serve under an Intra-agency Agreement as the Drug Distribution Center.

Central policy for the Trial will be set by a Steering Committee composed of one representative from each of the above-mentioned organizations and the Project Officer (from NIEHS) who will serve *ex officio*, making a total of seven members. Each regular representative will have one vote. The NIEHS Project Officer will vote to resolve ties. The Committee will elect its own Chair. The Steering Committee will be ultimately responsible for the Trial protocol and manual of operations. It will review and approve all requests to undertake ancillary studies that involve TLC subjects or TLC data as well as all proposals for publications and presentations based on TLC subjects or TLC data. The power to control the budget of the Trial and of the individual contracts rests with NIEHS under the usual federal laws and regulations.

NIEHS has appointed a Data and Safety Monitoring Committee which will be advisory to the Institute. The Committee is composed of the following seven members:

Stephen Gehlbach, Amherst, MA (Chair)
Carol Angle, Omaha, NE
John Faison, Philadelphia, PA
Bernadette Gray-Little, Chapel Hill, NC
Sherman James, Ann Arbor, MI
Lemuel Moyé, Houston, TX
Herbert Needleman, Pittsburgh, PA

Membership was determined by the NIEHS and was limited to people without appointments at the Universities involved in implementing the Trial. Meetings of the Data and Safety Monitoring Committee will be arranged by the Data Coordinating Center. The Project Officer, the Principal Investigator from the Data Coordinating Center, and the Chair of the Steering Committee will commonly attend all or parts of these meetings, but the Data and Safety Monitoring Committee shall have the prerogative of working in executive session without these other individuals. The Data and Safety Monitoring Committee will review and approve the Trial protocol and will monitor the accumulating data and progress of the Trial at least annually. It is anticipated that ordinary recommendations from the Data and Safety Monitoring Committee will be made to the Project Officer, but unusually important findings or opinions of the Committee can be forwarded, at the Committee's discretion, to the Director of NIEHS or to other officials.

A Planning Committee composed of the Steering Committee members and other professional personnel at the various sites will meet as necessary and will be responsible, with assistance from the Data Coordinating Center staff, for writing the Trial protocol and for developing a manual of operations for the Trial. The planning committee will assist with arrangements for the comparable and coordinated implementation of the protocol at the various sites. Meetings of the entire or of partial membership of the Planning Committee may be called by the Steering Committee or by the Project Officer in consultation with the Principal Investigator from the Data Coordinating Center and the Chair of the Steering Committee. The Chair of the Steering Committee will also chair the Planning Committee. The protocol and manual of operations developed by the planning committee will be subject to amendment and approval by the Steering Committee and to approval by the Data and Safety Monitoring Committee.

The work of the Planning Committee will be facilitated by subcommittees with expertise in the several areas related to the Trial. These subcommittees may be established, altered, or abolished as

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Northern Division)

SHAYONNA FEATHERSTONE, et al.	*	
Plaintiffs,	*	
v.	*	Case No. 1:07-CV-1120
KENNEDY KRIEGER INSTITUTE, et al.,	*	
Defendants	*	

* *

DEFENDANTS PYTHAGORAS AND
ANNE L. PASSAS' ANSWER TO CROSS-CLAIM

Pythagoras Passas and Anne L. Passas, Defendants and Cross-Defendants, hereby Answer the Cross-Claim filed on behalf of Defendants Kennedy Krieger Institute, Inc., Cecilia Davoli, M.D., the Johns Hopkins University, The Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, M.D., Lewis C. Becker, M.D., David R. Cornblath, M.D., Paul Lietman, M.D., and Hayden G. Braine, M.D., and state as follows:

1. Defendants are without sufficient knowledge and information and cannot admit or deny the allegations contained in ¶1. The allegations in this paragraph are, therefore, denied.

2. Denied.

3. Denied.

4. Denied.

5. Denied.

Defendants deny that the Cross-Plaintiffs are entitled to the relief requested in Count I.

6. Denied.

7. Denied.

Defendants deny that the Cross-Plaintiffs are entitled to the relief requested in Count II.

General Defenses

Defendants reserve the right to rely upon any defenses available in law or in fact and reserve their right to amend their Answer to Cross-Claim.

Defendants also reserve the right to raise affirmative or negative defenses in response to the Cross-Claim.

Respectfully submitted,

ROLLINS, SMALKIN, RICHARDS & MACKIE

/s/
Ralph E. Wilson
(Federal Bar No. 04923)
401 N. Charles Street
Baltimore, Maryland 21201
(410) 727-2443

Attorneys for Defendants Pythagoras Passas
and Anne L. Passas

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 6th day of June, 2007, a copy of Defendants Pythagoras and Anne L. Passas' Answer to Cross-Claim, which was filed electronically on this date, was mailed, postage pre-paid to:

Evan K. Thalenberg, Esq.
Nicholas A. Szokoly, Esq.
LAW OFFICES OF EVAN K. THALENBERG, P.A.
216 East Lexington Street
Baltimore, MD 2120 2
Attorneys for Plaintiffs

Natalie Magdeburger, Esq.
Raymond L. Marshall, Esq.
WHITEFORD, TAYLOR & PRESTON, L.L.P.
210 West Pennsylvania Avenue
Towson, MD 21204-4515
Attorneys for The Johns Hopkins University, The Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, M.D., Lewis C. Becker, M.D., David R. Cornblath, M.D., Paul Lietman, M.D., and Hayden G. Braine, M.D., and Peter Lees, Ph.D.

Barry C. Goldstein, Esq.
Nicole A. McCarus
WARRANCH & BROWN, LLC
1301 York Road, Suite 300
Lutherville, MD 21093
Attorneys for Kennedy Krieger Institute, Inc., and Cecilia Davoli, M.D.

and

Helen Heath, Individually and t/a Lady "H" Enterprises
6732 Wilmont Drive
Gwynn Oak, MD 21207
Pro Se Defendant

/s/
Ralph E. Wilson

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al.	*	
Plaintiffs	*	
v.	*	
		Case No. 1:07-cv-01120
KENNEDY KRIEGER INSTITUTE, INC., et al.	*	
Defendants	*	

* * * * * * * * * * *

DEFENDANTS' REPLY TO PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS FOR FAILURE TO JOIN A RULE 19 PARTY, OR IN THE ALTERNATIVE, MOTION TO JOIN THE NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES AS A PARTY

Defendants, Kennedy Krieger Institute ("Kennedy Krieger") and Cecilia Davoli, M.D. (collectively referred to as "Kennedy Krieger Defendants"), by their undersigned counsel, hereby submit their Reply to Plaintiffs' Opposition to Defendants' Motion to Dismiss for Plaintiffs' Failure to Join a Rule 19 Party or, in the Alternative, Motion to Join the National Institute of Environmental Health Sciences as a Party ("NIEHS"), and state as follows:

I. INTRODUCTION

Without the NIEHS, there would have been no Treatment of Lead Exposed Children Study ("TLC Study"). The NIEHS was intimately involved in every aspect of the TLC Study from its conception, design, implementation and funding. Indeed, after the TLC Study was concluded, the NIEHS was the entity that took credit for the TLC Study and submitted articles for peer reviewed publication regarding the results of the TLC Study. In their Opposition to Defendants' Motion to Dismiss for Failure to Join a Rule 19

Party, or in the Alternative, Motion to Join the National Institute of Environmental Health Sciences as a Party ("Opposition"), Plaintiffs turn a blind eye to these obvious facts and, by implication, request that this Court do the same.

The NIEHS is an essential and, therefore, necessary party to this litigation. Without the NIEHS as a party to this suit, incomplete justice can be the only result, variant obligations may be imposed upon the parties, and the NIEHS may be irrevocably damaged in its ability to protect its interests. To ensure justice, this Court should grant Defendants' Motion to Dismiss or, in the Alternative, require Plaintiffs to Join the NIEHS as a party to this action.[1]

II. FACTUAL BACKGROUND

In an attempt to color this Court's view of the TLC study, Plaintiffs' Opposition is replete with mischaracterizations and misleading statements regarding the TLC Study and the parties and researchers involved. These statements are irrelevant to the issue before the Court at this time – namely, whether the NIEHS is a necessary party to this litigation. Therefore, the Defendants do not believe it necessary to address every misstatement at this time. Nonetheless, the Defendants are compelled to address some of these mischaracterizations to ensure that this Court does not assume these allegations are true.

[1] Plaintiffs allege that the Defendants are required to identify the United States Government as a Defendant in this case. At most, the Defendants' alleged failure to name the United States rather than the NIEHS is nothing more than a simple misnomer. Because the Defendants are not attempting to sue the NIEHS, and because it is abundantly clear that the Defendants are seeking to join the NIEHS, this simple misnomer does not mandate that Defendants' Motion be denied. *See e.g., Idaho AIDS Found., Inc. v. Idaho Hous. & Fin. Ass'n*, 422 F. Supp. 2d 1193 (9th Cir. 2006) (party defendant asserted that the United States Department of Housing and Urban Development should be joined pursuant to Rule 19 (a) (2), the Court did not consider whether HUD could be sued). The Defendants discuss the procedure for bringing suit against the NIEHS in Section III of their Reply.

A. Pursuant to federal statutes, the NIEHS sponsored, funded, and managed the TLC Study.

It is undisputed that the NIEHS contracted with Kennedy Krieger and other clinical centers in Philadelphia, Newark, Cincinnati and Columbus to implement the TLC Study. Indeed, the NIEHS did so pursuant to federal statute. Federal law makes clear that the general purpose of the NIEHS is to conduct and support research regarding factors in the environment that affect human health:

> The general purpose of the National Institute of Environmental Health Sciences (in this sub-part referred to as "the Institute") is the conduct and support of research, training, health information dissemination and other programs with respect to factors in the environment that affect human health, directly or indirectly.

42 U.S.C.A. § 2851.

In an effort to further this general purpose, Congress required the NIEHS to "conduct a comprehensive program to promote safe, effective, and affordable monitoring, detection, and abatement of lead-based paint and other lead exposure hazards." 15 U.S.C.A. § 2685 (a). Consequently, the NIEHS is required to conduct studies of lead exposure in children who have elevated blood lead levels:

> The Secretary of Health & Human Services (hereinafter in this sub-section referred to as "the Secretary"), acting through the Director of the Centers for Disease Control, ("CDC") and the Director of the National Institute of Environmental Health Sciences, shall jointly conduct the study of the sources of lead exposure in children who have elevated blood lead levels (or other indicators of elevated lead body burden), as defined by the Director of the Centers for Disease Control.

15 U.S.C.A. § 2685 (c) (emphasis added).

Given these directives, the NIEHS issued a Request for Proposal ("RFP") for development of the TLC Study, and the NIEHS accepted Kennedy Krieger's "proposal." The NIEHS drafted a contract and forwarded it to Kennedy Krieger for signature.[2] The NIEHS prepared the contract without any participation from Kennedy Krieger. *See* Exhibit 1 - Contract drafted by the NIEHS. This government contract served as the basis for the relationship between the NIEHS and Kennedy Krieger in conducting the TLC study. In the contract, the NIEHS identified, with great specificity, the tasks it required Kennedy Krieger to perform and Kennedy Krieger was expressly prohibited from acting outside the express scope of authority outlined in the contract. *Id.*

The goal of the TLC Study was to determine if treating children with blood lead levels in the range of 20 *ug*/dl - 45 *ug*/dl with succimer, a chelation agent, would reduce the amount of lead in their blood. The NIEHS **directed and sponsored** the TLC Study and authored its own publications about the TLC Study. *See* Exhibit 2 - *The Treatment of Lead-Exposed Children TLC Trial: Design and Recruitment For the Study and Effect of Oral Chelation on Growth and Development in Toddlers, Paediatric & Perinatal Epidemiology* 12, 313-33 (1998). The data coordinating center was at the Harvard School of Public Health, the central laboratory was at the CDC in Atlanta, and the central pharmacy was the Program Support Center of the United States Department of Health and Human Services in Perry Point, Maryland. *Id.* at p. 315. Moreover, in a press release located on the NIEHS website, the NIEHS acknowledged that it **managed** the TLC Study with the Harvard School of Public Health. *See* Exhibit 3 - Press Release by the NIEHS.

[2] This was a multi-center study and, accordingly, the NIEHS contracted with three other Clinical Centers to conduct the TLC study in addition to Kennedy Krieger. Those other sites were Cincinnati, Columbus, Philadelphia and New Jersey.

The NIEHS conceived, developed, funded, and oversaw the TLC Study. Walter J. Rogan, M.D. of the NIEHS, was the Project Officer and principal investigator for the TLC Study. As Project Officer, Dr. Rogan's role was to effectuate research pursuant to state and federal statute. Dr. Rogan's leadership in the TLC Study was so prominent that it is still highlighted on the NIEHS web site, and is described as follows: "Dr. Rogan was project officer and one of the principal investigators for the four-site, randomized, controlled clinical trial of oral chelation therapy to prevent lead-induced disorders of growth, behavior and cognitive development in toddlers." *See* the NIEHS web site at http://dir.niehs.nih.gov/direb/staff/rogan/hom.htm (emphasis added).

Other than Dr. Rogan, many others at the NIEHS were intimately involved with the TLC Study. In fact, the NIEHS Institutional Review Board approved the TLC Study. Moreover, other Institutional Review Boards, including the Harvard School of Public Health and the Centers for Disease Control and Prevention, approved the TLC Study. *See* Exhibit 4 - *The Effect of Chelation Therapy with Succimer on Neuropsychological Development in Children Exposed to Lead, N. Engl. J. Med. Vol. 344, No. 19, p. 1422 (May 10, 2001).* Given that the NIEHS funded, controlled and directed the TLC Study, it is improper for Plaintiffs to file suit against Kennedy Krieger, and not the NIEHS, which by its own admission, implemented the TLC Study.

B. The *Grimes* Decision is irrelevant to the TLC Study.

Plaintiffs place great reliance on *Grimes v. Kennedy Krieger Institute, Inc.*, 366 Md. 29, 782 A.2d 807 (2001). Plaintiffs' reliance upon *Grimes*, however, is misplaced because *Grimes* has nothing to do with the TLC Study. In *Grimes,* the Maryland Court of Appeals reviewed the decision of the Baltimore City Circuit Court granting summary

judgment in favor of Kennedy Krieger regarding the Repair and Maintenance Study ("R&M Study"), not the TLC Study. In granting summary judgment, the trial court ruled that Kennedy Krieger owed no duty to the minor plaintiffs. The decision was appealed and the Maryland Court of Appeals ruled that there was, in fact, a duty between Kennedy Krieger and the minor plaintiffs because of a "special relationship." The Court of Appeals reversed the grant of summary judgment in favor of Kennedy Krieger, and remanded the case to the trial court. **The Maryland Court of Appeals did not comment on, or make any reference to, the TLC Study.** Nevertheless, Plaintiffs devote a significant portion of their Opposition asserting that the *Grimes* decision is relevant to the TLC Study. To assert so is a blatant mischaracterization of the *Grimes* opinion.

Moreover, the Court in *Grimes* did not make any findings of fact relative to this case or to the TLC Study. In its opinion following a Motion for Reconsideration, the *Grimes* Court expressly stated that its opinion pertained to the trial court's grant of summary judgment and that every other issue regarding liability or damages remained open for further factual development:

> Although we discussed the various issues and arguments in considerable detail, the only conclusion that we reached as a matter of law was that, on the record currently before us, summary judgment was improperly granted – that sufficient evidence was presented in both cases which, was taken in the light most favorable to the plaintiffs and believed by a jury, would suffice to justify verdicts in favor of the plaintiffs....Every issue bearing on liability or damages remains open for further factual development, and any relevant evidence not otherwise precluded under our Rules of Evidence is admissible.

Grimes, 782 A.2d at 861, 366 Md. at 119 (emphasis added).

Indeed, the Court of Appeals specifically stated that the record before it was "not extensive," *Id.* at 50 n.12, and referred to the record as "sparse," *Id.* at 46-47. It is therefore incorrect and misleading for Plaintiffs to cite the *Grimes* opinion in support of "factual" propositions that have not been subjected to the adversarial process and/or decided by a finder of fact. To the extent that the Court of Appeals discussed factual issues, it was doing so in the context of summary judgment.

The Court of Appeals decision in *Grimes* was not, and is not, relevant to the TLC Study.

C. There Have Been Other TLC Study Cases Removed to Federal Court.

In their Opposition, Plaintiffs assert that the Defendants' contention that the federal court has subject matter jurisdiction is "newly adopted." *See* Plaintiffs' Opposition at p. 23. That statement is incorrect. In *Somers v. Kennedy Krieger Institute, Inc.*, Case No. L-02-CV-419 and *DeShields v. Kennedy Krieger Institute, Inc.*, Case No. L-02-CV-222, Plaintiffs' counsel filed suit against Kennedy Krieger with regard to its implementation of the TLC Study for the NIEHS. In response, Kennedy Krieger removed these cases to federal court pursuant to 28 U.S.C. §1442 (a) (1).

D. Keona and Shayonna Featherstone had elevated blood lead levels prior to being seen at the Kennedy Krieger Lead Clinic.

Plaintiffs' Opposition characterizes Keona and Shayonna Featherstone as healthy children prior to being seen at the Kennedy Krieger Lead Clinic.[3] This is wholly inaccurate.

[3] The Kennedy Krieger Lead Clinic evaluated and treated many children in Baltimore City who had elevated blood lead levels. Only a very small subset of all children seen at the Kennedy Krieger Lead Clinic became enrolled in the TLC Study.

Keona Featherstone was born on September 11, 1993. Prior to her initial presentation to the Kennedy Krieger Lead Clinic on May 17, 1995, Keona Featherstone already had elevated blood lead levels. On September 14, 1994, the Maryland Department of the Environment measured Keona Featherstone's blood lead level at 20 *ug/dl. See* Plaintiffs' Opposition at p. 15. On December 12, 1994, her blood lead level was 23 *ug/dl*, as measured by the Maryland Department of Health & Mental Hygiene. *Id.* On April 14, 1995, the Maryland Department of Health & Mental Hygiene measured her blood lead level at 20 *ug/dl*. *Id.* Therefore, Keona Featherstone had elevated blood lead levels for at least 8 months before she was evaluated at the Kennedy Krieger Lead Clinic and enrolled in the TLC Study.

Shayonna Featherstone was born on October 2, 1992. She resided with her family at 1504 E. Lanvale Street, Baltimore, Maryland until 1993. A Kennedy Krieger Lead Clinic note dated September 7, 1994, indicates that the property contained flaking paint on the walls and windows. *See* Exhibit 5 - Kennedy Krieger Lead Clinic Note dated September 7, 1994 at p. 2. The floors were noted to be in poor condition. *Id.* Also, flaking paint was noted on the outside windows. *Id.* From October 1993 through April 1994, the Featherstone family resided at 2406 E. Eager Street, Baltimore, Maryland. After April 1994, the Featherstone family resided at 2418 E. Jefferson Street, Baltimore, Maryland.

On July 22, 1994, the Baltimore City Health Department recorded Shayonna Featherstone's blood lead level as 32 *ug/dl*. *See* Plaintiffs' Opposition at p. 15. She was referred to the Johns Hopkins' TAC Clinic at that time, and later referred to the Kennedy

Krieger Lead Clinic. Like her sister, Keona, Shayonna Featherstone had elevated blood lead levels prior to her referral to the Kennedy Krieger Lead Clinic.

III. THE NIEHS MAY BE JOINED AS A PARTY PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 19.

Noticeably absent as a named Defendant from this lawsuit is the NIEHS.[4] Pursuant to the Federal Tort Claims Act ("FTCA"), the NIEHS, through the federal government, may be sued, and therefore may be joined to the instant action. As discussed herein, the NIEHS is a necessary and indispensable party with substantial interests in the subject matter of this litigation. For these reasons, Plaintiffs' failure to join the NIEHS as a party to this case requires that this lawsuit be dismissed, or in the alternative, that the NIEHS be joined as a party to this litigation.

A. The NIEHS, through the United States, is amenable to suit under the FTCA.

Plaintiffs argue that the Defendants' Motion should be dismissed because the NIEHS cannot be sued in its own name and Defendants have failed to properly identify the individuals to be joined. *See* Plaintiffs' Opposition at pp. 17-18, *citing In re Stat-Tech Secs. Litigation,* 905 F. Supp. 1416 (D. Colo. 1995). In *Stat-Tech*, a *pro se* defendant filed a motion to dismiss pursuant to Rule 19 but "[made] no attempt either to identify the individuals he claims should have been joined or to aver how their absence impedes his ability to protect his interests or subjects him to multiple or inconsistent liabilities." *Stat-Tech*, 905 F. Supp. at 1421. The court held that defendant failed to meet his burden under Rule 19. *Id.*

[4] The NIEHS operates a research facility in North Carolina as a subsidiary of the National Institutes of Health ("NIH"), itself a branch of the United States Department of Health and Human Services.

Stat-Tech is easily distinguishable from the instant case because the Defendants' Motion to Dismiss identifies the NIEHS, a federal agency, as a necessary party to be joined. The Motion discusses in detail the reasons why joinder should be required.

Moreover, Defendants' Motion should not be denied on the hyper technical argument that the NIEHS cannot be sued in its own name. In making this argument, Plaintiffs improperly view Defendants' Motion as a suit against the NIEHS. Defendants' Motion, however, only identifies the NIEHS as the party to be joined, setting forth the reasons why it should be joined. If this Court grants Defendants' Motion, then it will be Plaintiffs' duty to follow the proper procedures in order to pursue a claim against it and/or the United States. It is clear from Plaintiffs' Opposition that Plaintiffs are well aware that the NIEHS is a federal agency of the United States, and made arguments contending neither the NIEHS nor the United States should be sued. Consequently, Plaintiffs' "form over substance" argument has no legal effect upon Defendants' Motion.

Plaintiffs contend that federal agencies such as the NIEHS cannot be sued without suing the United States and without congressional consent. The Defendants disagree. *See Information Syst. & Networks Corp., v. The Dept. of Health and Human Services,* 970 F. Supp. 1 (D.D.C. 1997) (a contract dispute where plaintiffs named the NIEHS as a party defendant); *Idaho AIDS Foundation, Inc. v. Idaho Housing & Finance Assoc.*, 422 F. Supp. 2d 1193 (9th Cir. 2006) (where the federal Department of Housing and Urban Development (HUD) was ordered to be joined as a necessary party); *Boles v. Greeneville Housing Authority*, 468 F. 2d 476 (6th Cir. 1972) (where the court found that HUD was an indispensable party); *Bridges v. Blue Cross and Blue Shield Assoc.*, 889 F. Supp. 502

(D.D.C. 1995) (where the court ordered the federal Office of Personnel Management to be joined as a party defendant because it had substantial interest).

In a negligence case, a party seeking to proceed against the United States for negligent acts of a United States agency or of that agency's employees committed in the scope of their employment, must pursue such claims under the FTCA, 28 U.S.C. §§ 2671 *et. seq*. The FTCA provides:

> [t]he United States shall be liable, respecting the provisions of this title relating to tort claims, in the same manner and to the same extent as a private individual under like circumstances . . . With respect to any action under this chapter [ ] the United States shall be entitled to assert any defense based upon judicial or legislative immunity which otherwise would have been available to the employee of the United States whose act or omission gave rise to the claims, as well as any other defenses to which the United States is entitled.

28 U.S.C. § 2674. The FTCA sets forth prerequisites to filing suit against the United States. *See e.g.*, 28 U.S.C. § 2675. Those pre-requisites include complying with the time restrictions for bringing the action. *See* 28 U.S.C. § 2401; *Martin v. United States*, 436 F. Supp. 535 (S.D. Ca. 1977). Further, this Court has exclusive jurisdiction over FTCA claims. *See* 28 U.S.C. § 1346 (b). Additionally, the FTCA is an exclusive remedy. *See* 28 U.S.C. § 2679. Here, the proper vehicle for Plaintiffs to join the NIEHS is through the FTCA. Plaintiffs' failure to join the NIEHS is the result of Plaintiffs' own actions and these Defendants should not be prejudiced by Plaintiffs' failure to do so.[5]

[5] The FTCA exempts discretionary functions, and must satisfy a two-part test. *See United States v. Gaubert*, 499 U.S. 315 (1991) (citations omitted). Discretionary functions are ones that involve an element of judgment or choice. *Id.* at 322. Second, the discretionary function exception should protect only those administrative decisions grounded in policy. *Id.* As shown above, the NIEHS is mandated by federal statute to conduct research regarding the effects of lead exposure in children. When an agency is required to perform a function, as the NIEHS was required to do so here, then there is no element of choice involved. *See, e.g., Starrett v. United States*, 847 F.2d 539, 541-42 (9th Cir. 1988).

This case arises from allegations of tortious harm resulting from a contract between a federal agency (the NIEHS) and a federal contractor (Kennedy Krieger), acting within the scope of their contract. The involvement in the TLC Study by the NIEHS was mandated by federal statute. Therefore, the NIEHS is amenable to suit under the FTCA.

B. The NIEHS is a necessary and indispensable party pursuant to Rule 19.

The Court analyzes Rule 19 (a) and (b) in order to determine whether an absent party is necessary and indispensable for purposes of joinder. Rule 19 (a) and (b) provide:

> (a) person who is subject to service of process and whose joinder will not deprive the court of jurisdiction over the subject matter of the action shall be joined as a party in the action if (1) in the person's absence complete relief cannot be accorded among those already parties, or (2) the person claims an interest relating to the subject of the action and is so situated that the disposition of the action in the person's absence may (i) as a practical matter impair or impede the person's ability to protect that interest or (ii) leave any of the persons already parties subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by reason of the claimed interest. If the person has not been so joined, the court shall order that the person be made a party.
>
> (b) If a person as described in subdivision (a)(1)-(2) hereof cannot be made a party, the court shall determine whether in equity and good conscience the action should proceed among the parties before it, or should be dismissed, the absent person being thus regarded as indispensable.

The NIEHS is subject to both the necessary joinder analysis of Federal Rule 19 (a) and the indispensable joinder analysis of Federal Rule 19 (b).[6] Not only is the NIEHS necessary and indispensable on account of its own interests, but it is also so connected with the subject matter of this lawsuit that the NIEHS must be a party to this litigation for the proper protection of the already named Defendants whom judgment will necessarily and directly affect. A defendant cannot be required to litigate questions that primarily and

[6] Rule 19 (b) identifies four factors to be considered by the Court in determining when an action can proceed or whether it should be dismissed if a party is indispensible. The Defendants assume that the NIEHS, as a federal agency, can be joined, and therefore, a detailed analysis under Rule 19 (b) is not addressed in this Reply.

directly involve issues with third persons not before the court. *See* 30A C.J.S. Equity §142, at 113.

In addition, the absence of the NIEHS as a party Defendant will severely handicap Kennedy Krieger in asserting a defense to Plaintiffs' allegations, and substantial prejudice will be incurred. Kennedy Krieger has been sued as a result of performing the TLC Study, which was directed, controlled and managed by the NIEHS pursuant to federal statute. If the NIEHS had not requested that the TLC Study be performed, Kennedy Krieger would never have been involved in the Study and subsequently sued. It is imperative that the NIEHS be entitled to present the reasons why the NIEHS wanted the TLC Study performed, and, additionally, why the City of Baltimore was chosen as the TLC Study site. The Court cannot fashion an effective remedy without the NIEHS as a party.

Plaintiffs' suit attempts to force the Defendants to defend their actions without adding the NIEHS, which contracted with them and controlled the implementation of the TLC Study. This is fundamentally unfair to the Defendants. Both parties to a contract are necessary and indispensable parties involving actions taken pursuant to the contract.[7] *See Yashenko v. Harrah's NC Casino Co., LLC,* 446 F.3d 541 (4th Cir. 2006) (where the court ruled that both parties to a contract were necessary parties to the cause of action.) *See Palmer v. Koksing,* 2005 WL 1389177 (S.D.W.Va. 2005) (where the Court held that plaintiffs failed to join a necessary party, the United States Army Corp of Engineers), *Teamsters Local Union No. 171 v. Keal Driveaway Co.*, 173 F.3d 915, 918 (4th Cir. 1999)

[7] There is no prescribed formula for determining whether a party is indispensable since that matter can be determined only in the context of particular litigation. Provident Tradesmens Bank & Trust Co. v. Patterson, 390 U.S. 102 (1968). Therefore, a Court may not know whether a particular party is "indispensable," and it would be premature to find that the NIEHS is not a necessary party, without permitting the current parties to conduct discovery in this matter.

(*citing Delta Fin. Corp. v. Paul D. Comanduras & Assocs.*, 973 F.2d 301, 305-06 (4th Cir. 1992) (parties to a contract are necessary parties to a lawsuit based on that contract.)).

The NIEHS not only had input regarding the design of the TLC Study, but it funded and controlled the TLC Study. Kennedy Krieger was directed and controlled by the NIEHS. To establish this relationship, the NIEHS drafted a contract to be signed by Kennedy Krieger, which served as the basis for the relationship between the NIEHS and Kennedy Krieger in conducting the TLC Study.

Plaintiffs' main allegation in this case is that the Defendants breached a duty to the participants in the TLC Study. These allegations are directly based on Kennedy Krieger's contract with the NIEHS to implement the TLC Study.[8] Therefore, the Court's adjudication of this case on the merits will necessarily require it to interpret the nature, design and intent of the Study, including agreements between the NIEHS and Kennedy Krieger.

As the party charged with drafting the contract and negotiating the design and implementation of the Study, the NIEHS undoubtedly has a direct interest in the Court's determination of research obligations to which it was intimately involved. Kennedy Krieger did not have authority to deviate from its contract with the NIEHS, as the NIEHS exhibited intimate and detailed control over the TLC Study.[9] *See Ricci v. Massachusetts*

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[8] The contract states that a coordinating center, clinical centers, and the NIEHS staff, will participate in the design of the trial protocol and then recruit, evaluate, treat and follow-up patients according to trial protocol.

[9] A Project Officer from the NIEHS, Dr. Walter Rogan, served as a representative on the Steering Committee, which established central policy for the Study. The NIEHS also appointed a Data and Safety Monitoring Committee, which served as an advisory committee to the Institute. Membership was determined by the NIEHS, and the NIEHS officers attended all or parts of these meetings. The Data and Safety Monitoring Committee reviewed and approved the Study protocol and monitored the accumulating data and progress of the Study. Indeed, in "Commonly Asked Questions," an educational material distributed to the general public, the NIEHS is defined as the "central agency for the study." The "Project Office" was NIEHS, and the "Project Officer" was Dr. Rogan of the NIEHS. Dr. Rogan was a member of the Steering Committee, the Drug Management Subcommittee, and the Clinical Issues Subcommittee. Beth Ragan of the

Association for Retarded Citizens, Inc., 97 F.R.D. 737 (D. Mass. 1983) (court ordered the Dept. of Health and Human Services (HHS) be made a party to the case due to its ongoing and intimate involvement with, and monitoring of, the defendants).

There is no doubt that the NIEHS is a necessary and indispensable party.

i. Under Rule 19 (a)(1), complete relief in this case cannot be accorded among the existing parties without the addition of the NIEHS.

Plaintiffs argue that the NIEHS is not a necessary party to the instant litigation because joinder is not necessary to afford complete relief to Plaintiffs. The Defendants disagree.

Resolution of these claims undoubtedly involves an analysis of the actions of the NIEHS, which directed and implemented the TLC Study. It is likely that the fact finder will determine that the NIEHS, not the current Defendants, was responsible for the design and implementation of the TLC Study. In that instance, without the presence of the NIEHS as a named party, Plaintiffs would be denied appropriate and complete relief. *See Ethypharm S.A. France v. Bentley Pharmaceuticals, Inc.*, 388 F. Supp. 2d 426 (D. Del. 2005) (finding a subsidiary to be a necessary and indispensable party because of the possibility that already named defendant would be found not liable, leaving plaintiff with incomplete relief).

NIEHS was a Member of the Environmental Issues Subcommittee. In addition, Dr. Rogan reviewed and commented on the protocol for determining whether abnormal laboratory values indicated an Adverse Drug Experience (ADE). Following his review of the ADE definitions and reporting requirements, Dr. Rogan trained clinical staff on how to respond to ADEs that might arise pursuant to the TLC Study.

Dr. Rogan's published article regarding the TLC Study from the Pediatric and Perinatal Epidemiology Journal explains that the NIEHS created a web page directly associated with the NIEHS in which the details of the TLC Study structure, function, associate investigators, staff, affiliation, etc, were displayed.

Defendants strongly believe that the jury will find in their favor. Nonetheless, joining the NIEHS as a necessary party may serve to avoid multiple litigation, provide all parties with complete and effective relief in a single action, while simultaneously protecting an absent party from the possible prejudicial effect of deciding the case without it.

ii. Under Federal Rule 19 (a)(2)(i), the NIEHS has substantial interests in the subject matter of this action and failure to join the NIEHS will impair its interests.

The NIEHS is a necessary party pursuant to Rule 19 (a) for two reasons. First, permitting this action to go forward without the NIEHS would impair or impede its ability to protect a "claim[ed] ... interest relating to the subject of the action." Fed. R. Civ. P. 19(a) (2) (i). The NIEHS has substantial interests in the subject matter of this action, that being the professional mission and undertakings of the institution. The NIEHS has no way to protect those interests absent its role as a party to this lawsuit.

Moreover, the NIEHS has a direct interest in the performance of such studies, as it may affect future research endeavors that it will undertake pursuant to federal statute. Plaintiffs allege that the NIEHS has no continuing interest in the subject matter of this case because the Study has concluded and the results have been published. The Defendants disagree.

In cases seeking reformation, cancellation, rescission, or otherwise **challenging the validity of a contract**, "all parties to the contract probably will have a substantial interest in the outcome of the litigation and their joinder will be required." *See* Wright & Miller, *Federal Practice and Procedure*, § 1613 at 200-03 (2004 ed.) (citations omitted) (emphasis added). Here, there is a direct contract between the NIEHS and Kennedy

Krieger. As stated above, Plaintiffs' fundamental contention is that the TLC Study should not have been done in the first place because Plaintiffs believe that the TLC Study posed an unreasonable risk to the participants; this position is no different than a challenge to the validity of the NIEHS/Kennedy Krieger contract. NIEHS certainly has a substantiated interest in this litigation. Consequently, Plaintiffs must be required to join the NIEHS to this case.

The NIEHS, as its mission and purpose mandate, engages in federally-sponsored research involving environmental factors, such as lead exposure, in children. The NIEHS conducted the TLC Study in Newark, Philadelphia, Cincinnati and Columbus. Resolution of this case will undoubtedly have ramifications for other cases involving the NIEHS contracts for the TLC Study, and the NIEHS IRB approval of research. The NIEHS undoubtedly has an interest in this litigation.

The NIEHS possesses interests separate and distinct from those of the current Defendants. The ability of the NIEHS to protect its interests regarding research on lead-based paint and its effect on children has been, and will continue to be impeded if the NIEHS is not joined in this matter. Therefore, it must be a party to this action both to defend its actions in the TLC Study and other studies that it sponsors involving minors. The interests of the NIEHS are especially vulnerable in that if they are not vigorously asserted by counsel before the Court, the true nature and extent of these interests may not be explored until after they are irreparably prejudiced.

Moreover, in deciding whether the Defendants were negligent in their performance of the TLC Study, the Court will have to evaluate research requirements, and what conduct satisfies those requirements. Joinder of the NIEHS will provide the Court with maybe

otherwise unobtainable information regarding the TLC Study. *See Johnson v. Colts, Inc.*, 306 F. Supp. 1076, 1079 (D. Conn. 1969) (Court ordered Plaintiff to amend complaint where party to be joined would assist court in interpreting collective bargaining agreement negotiated by unions).

Plaintiffs argue that neither the NIEHS nor the United States have asserted any interest relating to the instant action and that "it defies reason to believe that the NIEHS was not aware of the *Grimes* opinion." However, it is illogical to assume that the NIEHS monitors all federal and state court filings across the country to determine whether it has an interest in the litigation. Rule 19 requires a party to existing litigation to request that a non-party be joined when appropriate. Rule 19 does not require non-parties to monitor litigation and request joinder. The NIEHS should be a litigant in this matter and have the opportunity to defend its interests and influence the outcome of this case.

iii. Under Federal Rule 19 (a)(2)(ii), the absence of the NIEHS as a party could lead to inconsistent obligations.

Permitting this suit to continue without the NIEHS could subject the parties to a substantial risk of incurring conflicting legal obligations. Fed. R. Civ. P. 19(a) (2) (ii). If this action is allowed to proceed, this Court may make rulings regarding the terms of the TLC Study protocols, parental consents, or the general appropriateness of the TLC Study. Another court in another jurisdiction may make entirely different rulings regarding the same issues involving the TLC Study. For example, this Court might find that it was inappropriate for parents or guardians to consent for minors to participate in the TLC Study. This would have the effect of halting Kennedy Krieger's research involving minors. Another court, in reviewing the TLC Study, might find that consent by a parent or

guardian for a minor to participate in a study is permissible and is required pursuant to Kennedy Krieger's mission to conduct research.[10]

The effect of these conflicting rulings would obviously lead to inconsistent obligations by Kennedy Krieger – where compliance with one judgment would conflict with the other. *See Owens-Illinois, Inc. v Meade*, 186 F.3d 435 (4th Cir. 1999) (holding that possibility that one court might compel arbitration while the other court might allow alternative judicial remedies to some of the plaintiffs warranted having one court adjudicate the entire case with all of the affected parties before it); *Teamsters,* 173 F. 3d at 915 (holding that continuing without unjoined party was impermissible because that party could file suit in another forum to protect its interests and subject joined party to conflicting legal judgments); *Schlumberger Industries, Inc. v. National Sur. Corp.,* 36 F.3d 1274 (4th Cir. 1994) (holding that the potential for factual "whipsaw" from two pending cases warranted having one court adjudicate the entire matter with all the parties before it).

iv. Efficient and facilitated discovery in this case cannot be accorded among the existing parties without the addition of the NIEHS.

One of the purposes of Federal Rule 19 is to provide for the full and complete adjudication of a dispute with a minimum of litigation effort, so that the interests of the plaintiff, defendants, and the public will be best served. *Cable TV Fund 14-A, Ltd. v. Property Owners Ass'n Chesapeake Ranch Estates, Inc.* 706 F. Supp. 422, 430 (D. Md. 1989).

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[10] Kennedy Krieger is an internationally recognized facility located in Baltimore, Maryland, dedicated to improving the lives of children and adolescents with pediatric developmental disabilities through patient care, special education, evaluation, **research**, rehabilitation, and professional training. In addition to the Kennedy Krieger School, the Institution's services include over 40 outpatient clinics, neurobehavioral, rehabilitative, and pediatric feeding disorder inpatient units, plus several home and community programs providing services to assist families. *See* Kennedy Krieger Institute web site at www.kennedykrieger.org/kki_2nd_inside.jsp?pid =1.

Discovery in this case will undoubtedly be hindered by the absence of the NIEHS as a party Defendant. Access to important documents such as: committee meeting minutes; IRB records; documents relating to the NIEHS and the IRB approval process; documents detailing the design and implementation of the TLC Study; and documents explaining the role of Kennedy Krieger, are essential to the matters at issue in this case. As a party Defendant, the NIEHS would facilitate access to such records and other tangible evidence and assist the Court in evaluating this complicated case. *See Johnson*, 306 F. Supp. at 1079.

In addition to facilitating access to a potentially widespread collection of relevant documents, the involvement of the NIEHS in the form of depositions and live testimony is mandatory to the understanding of the design and implementation of the TLC Study, and to the defense of this case. Also, there will be extensive testimony from numerous witnesses from the NIEHS regarding the detailed involvement and control that the NIEHS had over the Study. It would also provide a mechanism for the NIEHS to address the allegations arising from situations in which it was involved. Without being a party to this litigation, the NIEHS will be unable to defend itself regarding its actions.

For the reasons previously stated in Defendants' Motion to Dismiss, the NIEHS is an indispensable party to this litigation. If this Court disagrees, then Defendants request that this Court attempt to lessen their prejudice by allowing Defendants to depose representatives of the NIEHS and propound written discovery upon the NIEHS in order to obtain information it possesses regarding the TLC Study that it initiated and managed.[11]

[11] The Defendants strongly believe that the Court has subject matter jurisdiction over this matter. However, it is anticipated that Plaintiffs will file a Motion to Remand this case to state court. If that occurs, the Defendants respectfully request that the Court deny Plaintiffs' Motion since it would be exceedingly difficult,

IV. CONCLUSION

The NIEHS has substantial interests that merit its inclusion in this case as a necessary and indispensable party. Without the presence of the NIEHS as a party in this case, complete relief cannot be afforded among the existing parties and the NIEHS will be unable to protect its interests as they relate to the TLC Study. Because Plaintiffs have failed to name the NIEHS as a party, this matter should be dismissed. Alternatively, in the event that this Court does not grant dismissal of this matter, this Court should order Plaintiffs to amend their Complaint to join the NIEHS as a Defendant. This case cannot proceed in equity and good conscience without the presence of the NIEHS as a named party.

For all of the reasons stated, Defendants Kennedy Krieger Institute and Cecilia Davoli, M.D., respectfully request that this Court grant their Motion to Dismiss for Failure to Join a Rule 19 Party or, in the Alternative, Motion to Join the National Institute of Environmental Health Sciences as a party.

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if not impossible, to obtain documents from federal agencies and compel depositions of federal employees regarding the TLC Study while in state court.

Respectfully submitted,

/s/ Barry C. Goldstein
Barry C. Goldstein
(Federal Bar No. 24796)
Nicole A. McCarus
(Federal Bar No. 27971)
John T. Sly
(Federal Bar No. 26608)
Waranch & Brown, LLC
1301 York Road, Suite 300
Lutherville, Maryland 21093
(410) 821-3511 (Phone)
(410) 821-3501 (Fax)
Attorneys for Defendants
Kennedy Krieger Institute, Inc.
and Cecilia Davoli, M.D.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 18th day of June 2007, a copy of the foregoing Defendants' Reply to Plaintiffs' Opposition to Defendants' Motion to Dismiss for Failure to Join a Rule 19 Party or, in the Alternative, Motion to Join the National Institute of Health Sciences as a Party, was electronically filed and mailed, first class, postage prepaid, to:

Evan K. Thalenberg, Esquire
Evan K. Thalenberg, P.A.
216 E. Lexington Street
Baltimore, Maryland 21202
Attorney for Plaintiffs

Natalie Magdeburger, Esquire
Raymond Marshall, Esquire
Whiteford, Taylor & Preston, L.L.P.
210 W. Pennsylvania Avenue
Towson, Maryland 21204-4514
Attorneys for Defendants The Johns Hopkins University, The Institutional Review Board of The Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, M.D., Lewis C. Becker, M.D, David R. Cornblath, M.D., Paul Lietman, M.D., Hayden G. Braine, M.D. and Peter Lees, M.D.

Ralph Wilson, Esquire
Rollins, Smalkin, Richards & Mackie
401 N. Charles Street
Baltimore, Maryland 21201
Attorneys for Defendants Pythagoras and Anne Passas

Michael D. Vogelstein, Esquire
Law Offices of Michael D Vogelstein
201 N Charles St Ste 801
Baltimore, MD 21201
Attorneys for Defendants, Marc and Nancy Medin, N.A.C.I. Corporation, and Shenan Management

By U.S. Mail To:
Helen Heath, Individually and Trading As
Lady "H" Enterprises
6732 Wilmont Drive
Gwynn Oak, Maryland 21207
***Pro Se* Defendant**

By U.S. Mail To:
Timothy P. Knepp, Esquire
Law Office of Timothy P. Knepp
106 N. Marlyn Avenue
P. O. Box 34019
Essex, Maryland 21221
Attorneys for Defendants Pythagoras and Anne Passas

/s/ Barry C. Goldstein
Barry C. Goldstein

EXHIBIT 1

AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)

CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
01-ES-35362	SEE BLOCK 20C	59528

5. ISSUED BY — CODE

ional Institute of
Environmental Health Sciences
ontracts & Procurement Management Branch, OM
.O. Box 12874 (79 Alexander Dr., 4401 Bldg.)
esearch Triangle Park, NC 27709

6. ADMINISTERED BY (If other than Item 5) — CODE

OMB No. 0990-0115

ATTN: Thomas M. Hardee

7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, State and ZIP Code)

Kennedy Krieger Research Institute, Inc.
707 North Broadway
Baltimore, MD 21205

8. DELIVERY

☐ FOB ORIGIN ☒ OTHER (See below)

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: — ITEM

DE — FACILITY CODE

11. SHIP TO/MARK FOR — CODE

SEE ARTICLE C.3.c., ARTICLE G.2.

12. PAYMENT WILL BE MADE BY — CODE

SEE ARTICLE G.3.

. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:

☐ 10 U.S.C. 2304(c)( ) ☐ 41 U.S.C. 253(c)( )

14. ACCOUNTING AND APPROPRIATION DATA
DOC: N1ES35362A SOCC: 25.3T CAN: 3-8420886
EIN: 1-521524967-A1 PIN: A451

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	TITLE: "TOXICITY OF LEAD IN CHILDREN TRIAL -- CLINICAL CENTER"				
	NTRACT PERIOD OF PERFORMANCE: June 30, 1993 - June 29, 1998 (Sixty Months)				
	CONTRACT TYPE: Cost-Reimbursement, Completion Form				
	HUMAN SUBJECTS MULTIPLE PROJECT ASSURANCE NO.: M1011				
	CURRENT OBLIGATION:				$ 445,410

15G. TOTAL AMOUNT OF CONTRACT: BASIC: $5,765,029 INCLUDING OPTIONS: $5,951,305

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I — THE SCHEDULE	
X	A	SOLICITATION/CONTRACT FORM	
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	
X	D	PACKAGING AND MARKING	
X	E	INSPECTION AND ACCEPTANCE	
X	F	DELIVERIES OR PERFORMANCE	
X	G	CONTRACT ADMINISTRATION DATA	
X	H	SPECIAL CONTRACT REQUIREMENTS	
		PART II — CONTRACT CLAUSES	
X	I	CONTRACT CLAUSES	
		PART III — LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	J	LIST OF ATTACHMENTS	
		PART IV — REPRESENTATIONS AND INSTRUCTIONS	
X	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
	M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 2 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18. ☐ AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

19A. NAME AND TITLE OF SIGNER (Type or print)

Karen R. Cox
Research Administrator

20A. NAME OF CONTRACTING OFFICER

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY Karen R. Cox (Signature of person authorized to sign)	6/29/93	BY _____ (Signature of Contracting Officer)	

SECTION B

SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

"Toxicity of Lead in Children Trial -- Clinical Center"

ARTICLE B.2.a. ESTIMATED COST - BASIC CONTRACT (CLIN 0001)

a. The estimated cost of the work under this contract is $5,765,029.

b. Total funds currently available for payment and allotted to this contract are $445,410. For further provisions on funding, see the LIMITATION OF FUNDS clause incorporated herein.

c. It is estimated that the amount currently allotted will cover performance of the contract through June 29, 1994.

d. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

e. For general information only, the following schedule of incremental funding is provided:

Year 1	$ 445,410
Year 2	$1,864,556
Year 3	$1,157,636
Year 4	$1,123,879
Year 5	$1,173,548

f. Costs contributed/shared by the contractor shall not be charged to the Government under any other contract, grant, or cooperative agreement (including allocation to other grants, contracts, or cooperative agreements as part of an independent research and development program). The contractor shall report the organizations' share of the costs expended by category, on the Financial Report of Individual Project/ Contract NIH Form 2706, as referenced in SECTION G, ARTICLE G.4, Contract Financial Report. Costs applicable to this condition are salary rates in excess of $125,000 as precluded in accordance with Public Law (P.L.) 102-394 and as addressed in ARTICLE B.4.b. and ARTICLE H.12., and costs shared for the maintenance contracts as addressed in ARTICLE B.4.b.

ARTICLE B.2.b. ESTIMATED COST - OPTION No. 1, XRF (CLIN 0002)

a. The estimated cost of the work under this contract is $39,400.

b. Total funds currently available for payment and allotted to this contract are $_____. For further provisions on funding, see the LIMITATION OF FUNDS clause incorporated herein.

c. It is estimated that the amount currently allotted will cover performance of the contract through _____.

d. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.2.c. ESTIMATED COST - OPTION No. 2, Caldwell Testers (CLIN 0003)

a. The estimated cost of the work under this contract is $146,876.

b. Total funds currently available for payment and allotted to this contract are $_____. For further provisions on funding, see the LIMITATION OF FUNDS clause incorporated herein.

c. It is estimated that the amount currently allotted will cover performance of the contract through _____.

d. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the Clauses, ALLOWABLE COST AND PAYMENT, [and FIXED FEE (if applicable),] incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

(1) Acquisition, by purchase or lease, of any interest in real property;

(2) Special rearrangement or alteration of facilities;

(3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.); (See ARTICLE B.4)

(4) Travel to attend general scientific meetings; (See ARTICLE B.4)

(5) Foreign Travel;

(6) Patient Care Costs; (See ARTICLE B.4)

(7) Property classified as sensitive equipment, regardless of acquisition value (as defined in Appendix C of the 1990 HHS publication entitled Contractor's Guide for Control of Government Property);

(8) Capitalized non-expendable equipment (defined as both real and personal property having an acquisition cost of $1,000 or more with a life expectancy of more than two years). (See ARTICLE B.4)

b. Travel Costs

(1) Domestic Travel

(a) Total expenditures for domestic travel incurred in direct performance during the entire period of performance of this contract shall not exceed $30,765 including registration fees. Domestic travel expenditures incurred for any one year shall not exceed $10,000. The Contractor shall not incur costs in excess of the foregoing amounts without prior written approval of the Contracting Officer.

(b) The cost of travel by privately-owned automobile shall be reimbursed at the mileage rate prescribed by the contractor's established, generally applicable travel policy in lieu of actual cost, provided, however, that such reimbursement shall not exceed the otherwise allowable comparative cost of travel by common carrier. The initial rate applicable to this contract is $0.25/mile.

Reasonable actual costs of lodging and subsistence, or per diem in lieu of actual costs, shall be allowable to the extent that such actual costs or per diem amounts do not exceed the amounts or per diem rates prescribed by the contractor's established, generally applicable travel policy.

Any revision to the contractor's established, generally applicable travel policy submitted to the cognizant audit agency during the period of performance of this contract shall be effective, without formal modification to this contract, upon delivery to the contracting officer of notice describing such revised policy together with evidence of submission thereof to the cognizant audit agency.

(c) Government Contract Discounts for Air Fares, Hotel/Motel Accommodations, and Automobile Rentals

The Contractor may take advantage of Government contract discounts when performing travel authorized under this contract. The Contractor will be responsible for obtaining a copy of the Federal Travel Directory which lists the (GSA)

contractors offering discounts for air fares and automobile rentals, and the Federal Hotel/Motel Discount Directory which lists lodging accommodations. Information regarding yearly subscriptions for the Federal Travel Directory and the Federal Hotel/Motel Discount Directory may be obtained by contacting the Government Printing Office order desk at area code (202) 783-3238. Requests for subscriptions should be mailed to:

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

When using the Directories the Contractor should insure that the airlines, hotels/motels, or automobile rental firms listed in the appropriate directory offer Government rates. Next, if the Contractor elects to utilize Government contract discounts, the Contractor must write the Contracting Officer in advance, and request permission to use the GSA contractor. The Contracting Officer shall provide a specific authorization to use the Government fare which must be presented by the Contractor to the carrier with the payment for the flight.

Contract fare air carriers accepting payment only by Government Travel Order (GTR) may not be used since NIEHS does not issue GTRs to contractors.

Any savings achieved through the Contractor's use of Government travel discount programs shall accrue to the Government.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, authorization of the following items within the limits set forth is hereby granted.

a. Salary Rate Limitations

Pursuant to the conditions set forth in Public Law (P.L.) 102-394, ARTICLE H.12, the cost for reimbursement of salary rates currently in excess of the established limitation for the individuals named below shall be shared at a rate of 100% of the excess amount by Kennedy Research Institute or its subcontractors:

NAME	TITLE
J. Julian Chisolm, M.D.	Principle Investigator
Gary W. Goldstein, M.D.	Co-Principle Investigator
Martha B. Denckla, M.D.	Co-Principle Investigator

b. Subcontracts

(1) University of Maryland

A cost-reimbursable type subcontract with the University of Baltimore at Maryland to serve as a "mini-subcenter" in the recruitment of patients in the estimated cost of $599,499 is hereby authorized in accordance with FAR 44.201-2. The subcontract will provide for blood lead screening for lead toxicity of potential patients, identifying eligible recruits, and conducting follow-up blood monitoring throughout the course of the contract. Contracting Officer approval of the subcontract in accordance with FAR 44.203 will be granted upon receipt of a fully executed copy of the subcontract. The subcontract will contain the general clauses applicable to a non-profit educational institution.

(2) Johns Hopkins University School of Medicine

A cost-reimbursable type subcontract with the Johns Hopkins University School of Medicine to serve as a "mini-subcenter" in the recruitment of patients in the estimated cost of $593,962 is hereby authorized in accordance with FAR 44.201-2. The subcontract will provide for blood lead screening for lead toxicity of potential patients, identifying eligible recruits, and conducting follow-up blood monitoring throughout the course of the contract. Contracting Officer approval of the subcontract in accordance with FAR 44.203 will be granted upon receipt of a fully executed copy of the subcontract. The subcontract will contain the general clauses applicable to a non-profit educational institution.

c. Travel

Travel by the following individuals in the total amount of $30,761 for attendance at steering committee sessions, general scientific meetings, and project related training:

Principle Investigator
Co-Principle Investigators
Nurse Study Coordinator
Data Coordinator

d. Patient Care Costs

Patient care costs are provided through the subcontracts authorized under this contract. In accordance with the clause entitled "Research Patient Care Costs", NIH (RC)-11, the Contractor shall, through its subcontractors, make every reasonable effort to obtain third party payment where third party payors (including Government agencies) are authorized or under a legal obligation to pay all or a portion of the charges incurred under this contract for the appropriate types of procedures/tests. Only those charges not recoverable from third party

payors and which are consistent with the Terms and Conditions of the contract are chargeable to this contract.

e. Patient Travel

The contractor shall be responsible for all local travel associated with recruitment and retention of patients. The amount authorized to support this travel shall not exceed $228,500.

f. Patient Incentives

In order to recruit and retain sufficient numbers of children for participation in the study trial, the Contractor is authorized up to $48,700 for incentives approved by the IRB and protocol.

g. Clean-up

To ensure a safe environment of study patients, a maximum of $436,923 is authorized for lead dust clean-up. The Contractor shall not expend contract funds for lead abatement. (See ARTICLE H.14. for conditions applying to recovery of costs.)

h. Relocation

Relocation costs are authorized at a rate of $550 per relocation in cases where a patient must vacate the original primary residence. The total maximum allowable for relocation expenses is $13,750.

i. Cost Sharing

The following costs for equipment maintenance contracts shall be shared in the ratios indicated, with the Government's ratio being indicated first and the Contractor's ratio indicated second (Government/Contractor). The Contractor shall account for the charges by reporting the total costs incurred and the amount billed to the Government on NIH Form 2706, Financial Report of Individual Project/Contract.

Provider	Equipment Maintained	Estimated Cost	Share Ratio
Perkin Elmer Maintenance Plan	GFAA[1] model 25100PC and peripherals	$7,190/yr	10%/90%
ESA, Inc.	ASV[2] model 3010A	$1,000/yr	50%/50%

[1] GFAA (Graphite Furnace Atomic Absorption Spectrophotometer)
[2] ASV (Anodic Stripping Voltammeter)

j. Lease Arrangements

Authorization is hereby granted for lease of one (1) compact vehicle at the rate of $159 per month.

SECTION C

DESCRIPTION/SPECIFICATION/WORK STATEMENT

ARTICLE C.1. BACKGROUND

Precedents: Since 1980, NIEHS has supported a series of longitudinal studies of childhood lead poisoning. These studies have shown small deficits in the cognitive development of young children in association with levels of blood lead commonly found in the US. NIEHS has also supported clinical studies leading to the licensure of the drug succimer, an orally administered chelating drug now labelled for use in children with blood lead levels above 45 µg/dl, a level thought to indicate a high risk for symptomatic lead poisoning and above the levels that produce cognitive delay.

General Background: Cognitive delay in toddlers has been associated with maternal lead levels in the 10-20 µg/dl range, and delays in four year olds with similar lead concentrations when they themselves were 2 years old. The Centers for Disease Control and the American Academy of Pediatrics have revised downward the blood lead levels of concern in young children, and children with blood lead levels greater than 10 µg/dl are now thought to have unacceptable exposure to lead. There are, however, no data on whether treatment of children with chelating agents prevents the cognitive delay associated with these levels. There are about four million children who fulfill the new criteria for unacceptable exposure to lead. NIEHS believes that large numbers of children with blood lead levels below 45 µg/dl will be treated with succimer, and that a clinical trial of the use of succimer in the prevention of lead-associated cognitive delay in young children is both necessary and timely. The objective of this Contract is to conduct, analyze, and issue a report of a randomized, multi-center, placebo controlled trial of succimer in the prevention of lead-associated cognitive delay in young children. This Contract is for one (1) of three (3) or possibly four (4) Clinical Centers. A separate, companion contract, N01-ES-35360 has been awarded for the support of the Coordinating Center.

ARTICLE C.2. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the work set forth below, including recruitment, treatment, retention, and follow-up of children in a clinical trial. In doing so, the Contractor shall comply with all local, state, and Federal laws and regulations pertinent to the various aspects of the trial. The Contractor shall conduct performance predicated on the agreements and understandings reached through discussions and negotiations leading to award based on the following documents which are incorporated by reference:

(1) Original Proposal dated November 24, 1992
(2) Revised Proposal dated May 10, 1993

(3) Best and Final Offer dated June 4, 1993
(4) Clarifying Information dated June 13, 1993

If there is any inconsistency between the referenced documents and the work described in Paragraph a. of this ARTICLE, the terms and conditions of Paragraph a. of this ARTICLE shall control.

(BASIC CONTRACT)

The protocol and strategies for the trial will result from the deliberations of the Steering Committee during the planning phase. The Steering Committee, as initially constituted, shall consist of the PIs of the Clinical Centers, the PI of the Coordinating Center, and the NIEHS Project Officer. The PI of the central lab will be a member of the Steering Committee ex officio. The Manual of Operations and Final Protocol shall be incorporated by reference into this Statement of Work when they are completed by the Steering Committee and approved by the Data and Safety Monitoring Committee. The clean up protocol at each site will be incorporated by reference into this Statement of Work when completed by the Clinical Center PI and approved by the Project Officer. The Steering Committee may elect to alter its composition at any time after it has been constituted; it must notify the PO of plans to do so. The trial shall proceed as follows: 9-12 months for planning; about 1 year for patient enrollment and treatment; the remaining 3 years for follow-up. Each child will be followed to age 4 at a minimum; longer follow-up is desirable for those children randomized early. Most close out activities should be completed by the final (5th) year of the contract. The activities, none of which are currently anticipated, of any center beyond five years from the initial award except for work specified herein will depend on the issuance of a continuation RFP by the Institute and successful re-competition. The trial is of oral chelation therapy with the drug succimer in lead exposed children (blood leads of about 20 μg/dl to 45 μg/dl) of about 18 to 36 months of age. The endpoints are the scores on developmental tests; other endpoints of interest include evidence of drug efficacy and compliance, such as urine and blood lead levels; excretion of other ions like iron, zinc, and calcium; and nervous system, renal and hematopoietic function/toxicity.

The Clinical Center shall evaluate the children prior to randomization for iron, vitamin, or other nutrient deficiency, and treat such deficiencies. Clinical Center staff, as may be augmented by local/state health officials, shall evaluate children's homes, and, if necessary, their day care or other sites where they spend time, and provide clean-up according to trial protocol. The criteria by which homes will be evaluated and the clean-up protocol shall be decided during the planning phase, but clean-up will not be identical at each site, and will consist of means suited to the catchment area of each Clinical Center. The Steering Committee shall, among their other functions, appoint a Clean-Up subcommittee, whose function will be to coordinate the various clean-up activities. However, the ultimate decision about clean-up methods at each site rests with the PI of the site and the PO. Chelation challenge and XRF studies are separately budgeted options, which may be included at some of the Clinical Centers (see "Options"below.

In cooperation with the Coordinating Center, the other Clinical Centers, and NIEHS staff, the Clinical Center shall participate in the design of the trial protocol, and then recruit, evaluate, treat and follow-up patients according to trial protocol. The Clinical Center shall provide data to the Coordinating Center, and monitor for efficacy and adverse effects. The Clinical Center shall participate in the randomization according to trial protocol and document that randomization has occurred according to assignment; and collect, monitor and edit data. The Clinical Center principal investigator (PI) shall participate, along with the other Clinical Center PIs, the Coordinating Center PI, and NIEHS program staff, in the final analyses and write-up of the studies.

Patient population: For purposes of planning the study, the Clinical Center shall provide to the Steering Committee the source population from which the Clinical Center will draw patients eligible for the trial, including numbers, ages, racial composition, and regular sources of health care. For all Centers combined, NIEHS estimates that evaluating the drug treatment for an effect of 3 developmental quotient points will require that the trial have 786 evaluable children with complete data at an absolute minimum; each Clinical Center shall recruit enough children so that on the order of 333 children per center are randomized. Stratified or blocked sampling may be desirable.

Recruitment: For purposes of planning the study, the Clinical Center shall provide to the Steering Committee a description of any previous efforts at recruiting patients into clinical studies at the institution, and plans for recruitment into this one. If referred patients are to be the source, then the referral sources shall be discussed and the rates of referral estimated.

If the Clinical Center must screen their population (or otherwise deal with children who have no information on recent blood lead levels) then it the Clinical Center shall provide blood lead analyses in support of the screening program; however, the blood lead level determination that actually determines eligibility will be performed centrally for the study (see Laboratory section below.)

Eligibility: Children eligible for the trial should be about two years old and have blood lead levels between about 20 and 45 μg/dl at the time of randomization, i.e., on at least two occasions and after iron deficiency is treated. (See women and minority recruitment below.)

Data collection schedules: The Clinical Center shall schedule and see the children according to trial protocol.

Source identification and clean-up: The Clinical Center will evaluate and clean-up the children's homes and other sites as necessary according to trial protocol. The Clinical Center shall identify lead sources in the child's environment and decrease the exposure in those who need it. If clean-up efforts involve other institutions, such as health departments, then the Clinical Center shall coordinate plans for working with them. Each Clinical Center shall be responsible for preparing its own clean up efforts, in consultation with the Clean-up Subcommittee.

Each Clinical Center shall provide short term housing as it considers necessary.

Nutritional management: The Clinical Center shall evaluate the children for iron deficiency and treat it, and insure that all children meet RDAs for relevant micronutrients, such as zinc and calcium, according to trial protocol. It is possible that there may be a high prevalence of iron deficiency, deficiency of micronutrients such as zinc, and diets deficient in calcium or other nutrients. The Clinical Center shall be responsible for monitoring compliance with such supplementation according to trial protocol.

Laboratory Support: Laboratory activities in support of this project are in three parts: blood lead levels used to determine the possible eligibility of the children for the trial (screening); clinical testing of the children, for iron status, hematocrit, etc., and monitoring of blood lead or urine lead levels immediately prior to randomization and during and after therapy. Each Clinical Center shall be responsible for those blood lead level determinations necessary to go from their catchment population to about 350-400 children who are iron-replete and who meet the trial's blood lead level criteria.

Each Clinical Center shall perform clinical monitoring of children, and including any laboratory procedures necessary for safety monitoring because the children are being treated under an IND.

Drug therapy: The Clinical Centers shall treat the children according to trial protocol. The treatment regimen will be decided upon by the Steering Committee during the planning phase.

Safety and efficacy monitoring: The Clinical Centers have the primary responsibility for the monitoring of the safety of the children and monitoring the efficacy of the drug. The Clinical Center shall be responsible for safety monitoring, and shall implement a means of following compliance, blood lead and urine lead according to trial protocol. The Clinical Center shall schedule the follow-up and evaluation of children.

Developmental testing: The Clinical Centers shall perform developmental testing of the children according to trial protocol.

Retention: The Clinical Center is primarily responsible for the retention of the children in the trial. A high percentage is absolutely necessary for the trial to succeed. The Clinical Center shall implement plans for keeping families active in the study, including contact with other than immediate family members, newsletters, etc. according to trial protocol and as appropriate for their catchment areas.

Clinical Center involvement with the Coordinating Center: The initial activity of the selected Coordinating Center and Clinical Centers shall be the development of a common protocol and study manual of operations. The Clinical Center PI shall cooperate with both the other Clinical Centers and with the Coordinating Center in carrying out the trial.

NIEHS will serve in a coordination, advisory, and assistance role at this stage, will approve final study design, and arbitrate disagreements between centers. The Clinical Center shall work with the Coordinating Center, any other Clinical Centers, NIEHS, and outside experts as appropriate.

Records: The Clinical Center shall generate quality data on the events in all phases of the trial. The Clinical Center shall document data that it provides to the Coordinating Center, and handle all study forms or their electronic equivalent appropriately. The Clinical Center shall insure confidentiality and security of records. In general, clinical records dealing directly with the care of the children are the property of the Clinical Center and subject to whatever safeguards the Institution has. To the degree possible, the government will not have access to individually identifiable records, which will reside with the Clinical Centers. In the event that the government must take possession of individually identifiable records, then the provisions of the Privacy Act apply. In such case, the NIEHS System of Records (Federal Register, Vol. 58, No. 8, Jan. 11, 1991) will apply for routine uses.

Monitoring: Monitoring shall be done according to trial protocol. The Clinical Center shall monitor the children and provide data to the Coordinating Center. The Clinical Center shall respond promptly to all queries raised by the Coordinating Center, and provide accurate, high quality data.

Interim reporting: Primary responsibility for interim reports on the progress of the trial in general rests with the Coordinating Center; however, the Clinical Center shall provide all data necessary for the construction of interim reports at site visits, meetings of the Data and Safety Monitoring Committee, etc., as they pertain to the individual Clinical Centers.

Publication: Reports for publication are the primary responsibility of the publications subcommittee; the Clinical Center's PI or a designee must be prepared to serve on that Committee. The initial design and main results papers of the study will be prepared by the subcommittee and appear under the name of the study, depending on the journal selected and journal policy. During the main analyses of the study, any publications proposed by a single Clinical Center from its own data must be seen and approved by the Steering Committee.

IND: NIEHS plans to sponsor the IND applications, but substantial cooperation will be needed from the Clinical Centers. The Clinical Center(s) shall provide all necessary support to NIEHS for the IND application.

Women and minority enrollment: Both boys and girls will be eligible. Encouragement of minority participation shall be part of the Clinical Centers' responsibilities.

Pilot: The decision as to whether to have a pilot study , and which institution will function as the pilot if there is one, will be made by the Steering Committee.

Treatment allocation: The Clinical Center shall randomize children into drug and placebo arms according to trial protocol.

Data handling: The Clinical Center shall be responsible for obtaining and transmitting data to the Coordinating Center under the trial protocol, including such aspects as programming, editing, and data transfer. Training in data entry shall be provided by the Coordinating Center.

Training: In addition to the general training provided by the Coordinating Center, the Clinical Center shall provide necessary training to and/or certification of study personnel at their site in home inspection, home clean up, nutritional evaluation and supplementation of children, developmental testing, and the other activities of the trial.

Study manual: The construction of the overall study manual will primarily be a responsibility of the Coordinating Center, but the Clinical Centers' staff will be the primary source for material on home evaluation, clean up, nutritional supplementation, management, and testing of the children.

Close out: The respective Clinical Centers shall be responsible for the orderly close-out of the trial at their sites, including active follow-up of patients, return of extra drugs or other materials to the Coordinating Center, and the establishment of a registry to enable later follow-up of the children. The Clinical Center shall deal with any questions arising about the conduct of the trial after publications have appeared.

(OPTION)

The following elements are not a requirement of the basic contract, but included as options which may be exercised in accordance with ARTICLE H.7., Options.

OPTIONAL - XRF and Chelation Challenge

NIEHS has not determined, at the time of the award of the basic contracts, whether or not to support XRF studies or chelation challenge studies. Clinical Centers taking this option have provided proposals and accompanying budgets. Before NIEHS decides to fund these options, it will request that the Steering Committee propose a coordinated protocol for XRF and/or chelation challenge studies. The cost of these studies shall not exceed, at each site, the amount budgeted for such studies in the Best and Final offer. If NIEHS approves an XRF or chelation challenge protocol and opts to fund it, the protocol will be included by reference in this requirement.

ARTICLE C.3. REPORTING REQUIREMENTS

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below:

a. Technical Reports

Type of Report	Description
Semi-annual Report* (1st year only)	Report describing progress in planning, recruitment, community activity, screening, etc. Emphasis on material not covered in Steering committee meetings.
Quarterly Progress Report* (subsequent years)	(1) Tabular material with numbers of families contacted and screened, or referrals; eligibles, numbers randomized, treated, and followed. Activities planned and executed during reporting period. Activities planned for next reporting period. Report of difficulties encountered which may affect further progress (2) Narrative describing study activities, with emphasis on those activities not covered in the Steering committee meetings.

b. Racial/Ethnic Enrollment Reports

Planned Enrollment Report	Summary of study population in terms of planned sample size and inclusion of participants by ethnic minorities (use table that follows).
Actual Enrollment Report	Summary of the number of participants actually enrolled according to designated racial/ethnic categories (use table that follows).

American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total

During the last portion of the planning phase (year 1), the programmer and study manager (2 people) will also be required to make three (3) trips for training. Three (3) trips for programmer and study manager for training will be required in the second year, and one (1) trip per year each for programmer and study manager for continued training in the third and fourth years of the contract. The destination for all training trips will be Research Triangle Park, North Carolina.

Two (2) trips per year in years 1-5 of the contract shall be made to scientific meetings of direct pertinence to the project.

Contractor shall support local travel for project staff.

The contractor shall be responsible for all local travel associated with recruitment and retention of patients.

SECTION D

PACKAGING, MARKING, AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

ARTICLE D.1. PACKAGING

The Contractor shall comply with special packaging requirements which may be identified in the protocol.

ARTICLE D.2. MARKING

All reports and other documents and materials to be delivered under this contract shall be submitted with a letter of transmittal identifying the contract number, project title, type of report or document, etc.

ARTICLE D.3. SHIPPING

All reports, documents, and other materials to be delivered under this contract shall be submitted to the addressee(s) in ARTICLE C.3.c.

SECTION E

INSPECTION AND ACCEPTANCE

ARTICLE E.1. INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this ARTICLE, Dr. Walter J. Rogan is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at the National Institute of Environmental Health Sciences, Division of Intramural Research, Research Triangle Park, NC. Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer, or the duly authorized representative.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

Number	Title
52.246-8	Inspection of Research and Development -- Cost-Reimbursement (APR 1984)

ARTICLE E.2. PROTOCOL ACCEPTANCE

Notification of the formal acceptance of the protocol shall be provided in writing by the Project Officer and endorsed by the Contracting Officer.

Failure of the contractor to recognize fully the cooperative nature of this project during any time of performance and failure of the contractor to abide by the approved shared protocol may result in Termination (either for convenience or default) in accordance with the Termination Clause (FAR 52.249-5).

SECTION F

DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The Period of Performance of this Contract shall be for a period of sixty (60) months, beginning June 30, 1993 and continuing through June 29, 1998. The Period of Performance encompasses the completion of all technical effort as described in Section C., ARTICLE C.2. and submission of all reports as specified in Section C., ARTICLE C.3.

ARTICLE F.2. DELIVERIES

a. Satisfactory performance of this contract shall be deemed to occur upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

(1) The items specified below as described in SECTION C, ARTICLE C.3. shall be delivered f.o.b. destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APR 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING, AND SHIPPING, if included, of this contract]:

Item	Description	Quantity	Delivery Schedule
(a)	Biannual Report		
(b)	Quarterly Progress Report		
(c)	Planned Enrollment Report		(See ARTICLE C.3.c.)
(d)	Actual Enrollment Report		
(e)	Final Report		

The above items shall be addressed and delivered to:

Addressee	Deliverable Item No.	Quantity
	(See ARTICLE 3.d)	

ARTICLE F.3. STOP WORK ORDER

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER I) CLAUSE:

52.212-13, STOP WORK ORDER (AUG 1989) - ALTERNATE I (APR 1984)

SECTION G

CONTRACT ADMINISTRATION DATA

ARTICLE G.1. REFERENCES TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

All references to the Secretary, Department of Health, Education and Welfare, HEW, HEWPR, HEW forms, etc., shall be changed to Secretary, Department of Health and Human Services, HHS, HHSAR, etc., as appropriate.

ARTICLE G.2. PROJECT OFFICER/ALTERNATE PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

Project Officer

Dr. Walter J. Rogan
Acting Clinical Director
National Institute of Environmental Health Sciences
Division of Intramural Research
P.O. Box 12233, Mail Drop A3-05
Research Triangle Park, NC 27709
Telephone No.: (919) 541-4578

Alternate Project Officer

Ms. Beth Ragan
National Institute of Environmental Health Sciences
Division of Intramural Research
P.O. Box 12233, Mail Drop A3-05
Research Triangle Park, NC 27709
Telephone No.: (919) 541-2767

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Alternate Project Officer is responsible for conducting the actions of the Project Officer as set forth in the above paragraph in the absence or other unavailability of the Project Officer. The authority of the Alternate Project Officer will not extend beyond those circumstances where the Project Officer is unable or unavailable to conduct the express limited responsibilities as set forth in this Contract and in the Project Officer's Appointment Letter.

**** For all other costs specifically approved under ARTICLE B.4., Advance Understandings, include separate cost information as an attachment.

ARTICLE G.5. FINAL PROTOCOL AND MANUAL OF OPERATIONS

The final Protocol and final Manual of Operations and all Project Officer approved revisions to those documents shall be automatically incorporated into this contract's Statement of Work.

The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor of any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.3. INVOICE SUBMISSION -- LETTER OF CREDIT (Payee Identification Number [PIN])

Advance payments will be provided pursuant to HHSAR Clause No. 352.232-73, entitled METHOD OF PAYMENT--LETTER OF CREDIT (APR 1984), which is incorporated in this contract by reference. The PIN is A451. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, are attached and made a part of this contract for the submission of completion and/or final invoices. The invoice instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper" invoice, pursuant to FAR 32.9. The completion and/or final invoice shall be submitted concurrently as follows:

(1) An original and two copies to the following office:

National Institutes of Health
Division of Financial Management
Contracts Section, FAAB
Building 31, Room B1B05A
9000 Rockville Pike
Bethesda, Maryland 20892

(2) Three copies to the following approving officer:

National Institute of Environmental Health Sciences
Attn: Contracting Officer
Contracts & Procurement Management Branch, OM
79 T.W. Alexander Drive, 4401 Building
P.O. Box 12874
Research Triangle Park, North Carolina 27709

(3) Inquiries regarding letter of credit payments should be directed to the office administering advance payments designated in HHSAR Clause No. 352.232-73 entitled, METHOD OF PAYMENT--LETTER OF CREDIT (APR 1984) at the following address:

Department of Health and Human Services/OASH/OM/ORM
Division of Payment Management
P.O. Box 6021
Rockville, Maryland 20852

Telephone: (301) 443-1350

ARTICLE G.4, CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Form NIH 2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the NIH Instructions, Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the thirtieth (30th) working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph d. below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. The first financial report shall cover the period consisting of the first full calendar month/first full calendar three months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a monthly/quarterly basis.

c. If the final payment of this contract is to be made on the basis of a desk audit, the Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This article does not supersede the record retention requirements in FAR Part 4.7.

d. The following expenditure categories shall be reported:

Direct Labor
Fringe Benefits
Project Management
    Travel
Clinical Management
Lead Dust Management
QA/QC
Lab Analysis
Data Collection
Psychometrics
Indirect Costs
Subcontracts
    Univ. of Maryland @ Baltimore
    Johns Hopkins Univ. School of Medicine
Total Estimated Cost

* For Direct Labor, itemize the effort contributed by each individual on an attachment to Form 2706.

** For Costs recovered through 3rd party payers such as insurance carriers, landlords, et.al., indicate the costs recovered and subsequently credited to the contract

*** For costs shared for maintenance contracts, include the total amount charged by the service organization and the amount billed as the Government's portion.

ARTICLE G.5. FINAL PROTOCOL AND MANUAL OF OPERATIONS

The final Protocol and final Manual of Operations and all Project Officer approved revisions to those documents shall be automatically incorporated into this contract's Statement of Work.

SECTION H

SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. KEY PERSONNEL

a. Pursuant to the Key Personnel clause incorporated in this contract, by reference in Part II, Section I, the following individual(s) [is/are] considered to be essential to the work being performed hereunder:

NAME	TITLE
J. Julian Chisolm, M.D.	Principle Investigator
Gary W. Goldstein, M.D.	Co-Principle Investigator

b. When "key personnel" have been identified in this contract, it has been determined that such named personnel are necessary for the successful performance of this contract; and the Contractor agrees to assign such persons to the performance of the work under this contract, and shall not reassign or remove any of them without the consent of the Contracting Officer in accordance with the procedure outlined in d. below.

c. In addition, during the first ninety (90) days of performance, the Contractor shall make no substitutions of key personnel unless the substitution is necessitated by illness, death, or termination of employment. The Contractor shall notify the Contracting Officer within 15 calendar days after the occurrence of any of these events and provide the information required by Paragraph d. below. After the initial ninety (90) day period, the Contractor shall submit the information required by paragraph d. to the Contracting Officer at least 15 days prior to making any permanent substitutions.

d. The Contractor shall provide a detailed explanation of the circumstances necessitating the proposed substitutions, complete resumes for the proposed substitutes and any additional information requested by the Contracting Officer. Proposed substitutes shall have substantially equal abilities and qualifications to those of the persons being replaced. The Contracting Officer will notify the Contractor within 15 calendar days after receipt of all required information of the decision on substitutions. This article will be modified to reflect any approved changes of key personnel.

ARTICLE H.2. CRITICAL PERSONNEL

Positions designated as critical to the performance of this contract are set forth below. Whenever the Contractor anticipates changes to any personnel in these critical positions, the Contractor shall notify the Contracting Officer, providing detailed explanation of the circumstances necessitating the change(s), proposed substitution(s), resumes for the proposed substitute(s),

and any additional information requested by the Contracting Officer for review.

There are no critical personnel designated under this Contract

ARTICLE H.3. HUMAN SUBJECTS

The research involving human subjects required under this Contract shall not be conducted without the prior written joint approval of the Project Officer and Contracting Officer (See SECTION E. ARTICLE E.3.). As a condition for receiving such approval, the Contractor shall have provided to the Contracting Officer a properly completed Optional Form 310,"Protection of Human Subject Assurance Identification/Certification/Declaration", certifying Institutional Review Board (IRB) review and approval of the protocol. The appropriate human subjects multiple project assurance number applicable to this Contract is M1011.

ARTICLE H.4. HUMAN MATERIALS

No material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans. The acquisition and supply of all human specimen material (including fetal material) used under this contract will be obtained by the Contractor in full compliance with applicable State and local laws and the provisions of the Uniform Anatomical Gift Act in the United States and that no inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.5. PRIVACY ACT

This Contract requires the Contractor to do one or more of the following: design, develop or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violations of the Act may involve the imposition of criminal penalties. In compliance with the requirements of this Act, the Contractor shall utilize the NIEHS existing system of records, identified in the Federal Register, Volume 56, Number 8, January 11, 1991 under System of Records Number 09-25-0134.

ARTICLE H.6. GOVERNMENT PROPERTY

a. In addition to the requirements of the Clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor shall comply with the provisions of the DHHS Publication Contractor's Guide for Control of Government Property, dated 1990, which is incorporated by reference. Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations,

inventory, and reporting requirements under the contract. A copy of this publication is available from the Contract Property Administrator. This contract's Contract Property Administrator is:

Mike Zindell
Research Contracts Property Administrator
Research Contracts Property Administration
National Institutes of Health
Building 13, Room 2E-65
9000 Rockville Pike
Bethesda, MD 20892

Telephone: (301) 496-6466

ARTICLE H.7. CONTRACTOR-ACQUIRED GOVERNMENT PROPERTY - SCHEDULE I-A

Pursuant to the Clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor is hereby authorized to acquire the property listed in the attached Schedule I-A for use in direct performance of the contract. This contract is for scientific research and is with a nonprofit institution whose primary purpose is the conduct of scientific research. Therefore, pursuant to subparagraph (c)(2) of the Clause, GOVERNMENT PROPERTY, title to equipment having an acquisition cost of less than $5,000 shall vest in the Contractor and title to equipment having an acquisition cost of $5,000 or more purchased with funds made available under the contract shall vest in the Contractor subject to the provisions of the Clause, GOVERNMENT PROPERTY; provided that the Government may direct transfer of the title to the Government or to a third party within twelve months after completion or termination of the contract. The transfer of title to such equipment to the Government or to a third party shall not be the basis for any claim against the Government by the Contractor.

Schedule I-A

There is currently no property identified for this Contract

ARTICLE H.8. GOVERNMENT FURNISHED PROPERTY - SCHEDULE II-B

Pursuant to the Clause, GOVERNMENT PROPERTY, incorporated in this contract, the Government [agrees to furnish/has furnished] to the Contractor for use in direct performance of the contract, the items listed in Schedule II-B below:

Schedule II-B

1. Drugs to be administered during trial
2. Placebo to be administered during trial
3. Laboratory determinations of blood lead levels

ARTICLE H.9. OPTIONS

a. Unless the Government exercises its option(s) pursuant to paragraph b. and/or c. of this article, the contract consists only of the statement of work as defined in Sections C and F of this contract.

b. The Government may, by unilateral modification, exercise an option within six (6) months after contract award for XRF Studies. Preliminary written notice of its intent to exercise the options will be provided at least sixty (60) days in advance. The preliminary notice does not commit the Government to exercise the option.

c. The Government may, by unilateral modification, exercise an option within twelve (12) months after contract award for Caldwell Testing. Preliminary written notice of its intent to exercise the options will be provided at least sixty (60) days in advance. The preliminary notice does not commit the Government to exercise the option.

ARTICLE H.10. SAFETY AND/OR HEALTH STANDARDS

The Government is not legally responsible for accidents, illnesses, or claims arising out of any work undertaken as a result of this Contract. The Contractor shall take the steps necessary to ensure compliance with all pertinent local, state, and Federal statues relating to occupational health, safety, and environmental protection associated with this Contract. In accordance with PHSAR 352.223-70 incorporated by reference under PART II, all work under this contract shall be conducted in accordance with the following general standards, as appropriate:

1. Standards issued pursuant to the National Occupation Safety and Health Act of 1970 (Title 29, Code of Federal Regulations [CFR])

2. Standards issued pursuant to the Atomic Energy Act of 1954 (42 USC 2021)

3. Standards issued pursuant to the U.S. Environmental Protection Agency, Title 40 CFR, as amended

4. Standards issued pursuant to the Department of Transportation Hazardous Materials regulations (Title 49 CFR parts 72, 171-180)

The Clinical Center shall report by telephone or FAX services adverse reactions, serious unanticipated side effects, etc. to the Coordinating Center, to the NIEHS Project Officer and Contracting Officer, and to the Chairman of the Data Safety Monitoring Board, within one (1) work day. The notification shall be confirmed by the Contractor in writing.

ARTICLE H.11. CONFIDENTIALITY OF INFORMATION

Approval of the Project Officer will be required prior to publishing any data arising from contract studies. Information which will be derived from this project may require special consideration with regard to the timing of its disclosure in order to protect the interests of the Government and the public.

In consideration of this the clause HHSAR 352.224-70, CONFIDENTIALITY OF INFORMATION (APR 1984) is incorporated in this contract under PART II, SECTION I, ARTICLE I.3.b. Department of Health and Human Services Acquisition Regulations (HHSAR) (48 CFR Chapter 3) Clauses.

It is understood that this is a multi-center study and that a single center may not publish its own data until after multi-center publication or two (2) years following termination of the project, whichever comes first. Then a single Clinical Center may publish scientific papers from its own data. During the main analysis of the study, copies of any such papers shall be provided to the Steering Committee for review and comment forty-five (45) days prior to submission for publication or presentation.

ARTICLE H.12. SUBCONTRACTING PROVISIONS

a. Small Business and Small Disadvantaged Business Subcontracting Plan

(1) The Small Business and Small Disadvantaged Business Subcontracting Plan, undated, is attached hereto and made a part of this contract.

(2) The failure of any Contractor or Subcontractor to comply in good faith with the Clause entitled "Utilization of Small Business Concerns and Small Disadvantaged Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages - Small Business Subcontracting Plan."

b. Subcontracting Reports

(1) The Contractor shall submit the original and 2 copies of Subcontracting Report for Individual Contracts, SF-294 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30
October 30

The Report shall be sent to the following address:

National Institute of Environmental Health Sciences
Attn: Contracting Officer
Contracts & Procurement Management Branch, OM
79 T.W. Alexander Drive, 4401 Building
P.O. Box 12874
Research Triangle Park, North Carolina 27709

If difficulties are encountered in attaining established subcontracting goals, the Contractor or Subcontractor shall explain why and include their "good faith" efforts in Item 18, Remarks, in the SF-294.

(2) The Contractor shall submit 1 copy of Summary Subcontract Report, SF-295 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. The Summary Subcontract Report shall be submitted annually on October 30.

The first report shall be submitted after the first full year of this contract in addition to any fractional part of the year in which this contract became effective. This Report shall be mailed to the following address:

Office of Small and Disadvantaged Business Utilization
Department of Health and Human Services
Room 517-D
200 Independence Avenue, S.W.
Washington, D.C. 20201

ARTICLE H.13. SALARY RATE LIMITATION IN FISCAL YEAR 1993

Pursuant to Public Law (P.L.) 102-394, no NIH Fiscal Year 1993 (October 1, 1992 - September 30, 1993) funds may be used to pay the direct salary of an individual through this contract at a rate in excess of $125,000 per year (direct salary is exclusive of overhead, fringe benefits and general and administrative expenses). The $125,000 per year salary limit also applies to individuals proposed under subcontracts. If this is a multi-year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate exceeds any salary rate ceiling established in future HHS appropriations acts. P.L. 102-394 states in pertinent part:

"None of the funds appropriated in this title for the National Institutes of Health and the Substance and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of $125,000 per year."

ARTICLE H.14. RECOVERY OF COSTS

During performance of this Contract, where contract funds are expended to discharge performance of certain functions such as residential lead hazard clean-up, temporary housing, patient care, etc. which may in turn be reimbursed by parties bearing a legal obligation to have borne such costs originally, such costs shall be recovered from the appropriate sources and applied as a credit to the Contract.

The Contractor shall keep an accurate account of all payments received from recipients of third party payments or other payors when such charges have been previously billed to the Government, or for other costs recovered in

PART II - CONTRACT CLAUSES

SECTION I

CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSABLE TYPE CONTRACT WITH NON-PROFIT INSTITUTIONS OTHER THAN EDUCATIONAL INSTITUTIONS

FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (JUN 1988)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

FAR Clause No.	Title and Date
52.203-1	Officials Not to Benefit (APR 1984)
52.203-3	Gratuities (APR 1984)
52.203-5	Covenant Against Contingent Fees (APR 1984)
52.203-7	Anti-Kickback Procedures (OCT 1988)
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (SEP 1990)
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (JAN 1990) (Over $100,000)
52.209-6	Protecting the Government's Interests when Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (NOV 1992)
52.215-1	Examination of Records by Comptroller General (FEB 1993)
52.215-2	Audit-Negotiation (FEB 1993)
52.215-22	Price Reduction for Defective Cost or Pricing Data (JAN 1991) (over $100,000)
52.215-24	Subcontractor Cost or Pricing Data (DEC 1991) (over $100,000)
52.215-26	Integrity of Unit Prices (APR 1991)

52.215-31	Waiver of Facilities Capital Cost of Money (SEP 1987)
52.215-33	Order of Precedence (JAN 1986)
52.215-39	Reversion or Adjustment of Plans for Postretirement Benefits Other Than Pensions (PRB) (JUL 1991)
52.216-7	Allowable Cost and Payment (JUL 1991) NOTE: For contracts with hospitals, in paragraph (a) the words "Subpart 31.2 of the Federal Acquisition Regulation (FAR)" are deleted and the words "45 CFR part 74 appendix E" are substituted in lieu thereof. For contracts with nonprofit organizations exempted from OMB Circular A-122, in paragraph (a), the words "Subpart 31.2" are deleted and the words "Subpart 31.7" are substituted in lieu thereof.
52.216-11	Cost Contract - No Fee (APR 1984)
52.217-5	Evaluation of Options (JUL 1990)
52.219-8	Utilization of Small Business Concerns and Small Disadvantaged Business Concerns (FEB 1990)
52.219-9	Small Business and Small Disadvantaged Business Subcontracting Plan (over $500,000) (JAN 1991)
52.219-13	Utilization of Women-Owned Small Businesses (AUG 1986)
52.219-16	Liquidated Damages - Small Business Subcontracting Plan (over $500,000) (AUG 1989)
52.220-1	Preference for Labor Surplus Area Concerns (APR 1984)
52.220-3	Utilization of Labor Surplus Area Concerns (APR 1984)
52.222-2	Payment for Overtime Premium (JUL 1990) (over $100,000) NOTE: The amount to be inserted in paragraph (a) is "zero" unless specified otherwise elsewhere in this contract.
52.222-3	Convict Labor (APR 1984)

52.222-26	Equal Opportunity (APR 1984)
52.222-28	Equal Opportunity Preaward Clearance of Subcontracts ($1,000,000 or more) (APR 1984)
52.222-35	Affirmative Action for Special Disabled and Vietnam Era Veterans (APR 1984)
52.222-36	Affirmative Action for Handicapped Workers (APR 1984)
52.222-37	Employment Reports on Special Disabled Veterans and Veterans Era (JAN 1988)
52.223-2	Clean Air and Water (Over $100,000) (APR 1984)
52.223-6	Drug Free Workplace (JUL 1990)
52.224-1	Privacy Act Notification (APR 1984)
52.224-4	Privacy Act (APR 1984)
52.225-11	Restrictions on Certain Foreign Purchases (MAY 1992)
52.227-1	Authorization and Consent (APR 1984) Alternate I (APR 1984)
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement (APR 1984)
52.227-11	Patent Rights - Retention by the Contractor (Short Form) (JUN 1989)

NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.

The office designated to represent the Contracting Officer in administering this clause is:

Extramural Inventions Reports Office, OER
National Institutes of Health
Building 31, Room 5B41
9000 Rockville Pike
Bethesda, MD 20892

Telephone: (301) 402-0850

	Correspondence with respect to the patent clause shall be directed to the above address with a copy to the Contracting Officer.
52.227-16	Additional Data Requirements - (JUN 1987)
52.232-9	Limitation on Withholding of Payment (APR 1984)
52.232-20	Limitation of Funds (APR 1984)
52.232-23	Assignment of Claims (JAN 1986)
52.232-25	Prompt Payment (APR 1989) NOTE: In the second sentence of Paragraph (b)(2), the words "30th day" are inserted.
52.232-28	Electronic Funds Transfer Payment Methods (APR 1989) NOTE: The office designated to receive information in paragraph (c) is: National Institutes of Health Division of Financial Management Chief, Contracts Section, FAAB Building 31, Room B1B05A 9000 Rockville Pike Bethesda, Maryland 20892
52.233-1	Disputes (DEC 1991)
52.233-3	Protest After Award (AUG 1989) - Alternate I (JUN 1985)
52.242-1	Notice of Intent to Disallow Costs (APR 1984)
52.242-13	Bankruptcy (APR 1991)
52.243-2	Changes - Cost Reimbursement (AUG 1987) Alternate V - (APR 1984)
52.243-7	Notification of Changes (APR 1984) * Insert 15 days in each blank
52.244-2	Subcontracts (Cost-Reimbursement and Letter Contracts) (JUL 1985)
52.244-5	Competition in Subcontracting (APR 1984)
52.245-5	Government Property (Cost-Reimbursement, Time-and-Material, or Labor-Hour Contract) (JAN 1986) Alternate I. (JUL 1985)

52.246-23	Limitation of Liability (APR 1984)
52.249-5	Termination for Convenience of the Government (Educational and Other Nonprofit Institutions) (APR 1984)
52.253-1	Computer Generated Forms (APR 1984)

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR Clause No.	Title and Date
352.202-1	Definitions (APR 1984) -- Alternate I (APR 1984)
352.228-7	Insurance - Liability to Third Persons (DEC 1991)
352.232-9	Withholding of Contract Payments (APR 1984)
352.233-70	Litigation and Claims (APR 1984)
352.242-71	Final Decisions on Audit Findings (APR 1984)
352.270-5	Key Personnel (APR 1984)
352.270-6	Publications and Publicity (JUL 1991)
352.270-7	Paperwork Reduction Act (APR 1984)

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS, DELETIONS, AND MODIFICATIONS OF CLAUSES

1. HHSAR Clause 352.217-72, Additional Cost Principles (OCT 1990), is hereby deleted in its entirety

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following by reference, with the same force and effect as if they were given in full text. Upon request, the contracting officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

1. FAR 52.220-4, Labor Surplus Area Subcontracting Program (APR 1984)

2. FAR 52.227-14, Rights in Data - General (JUN 1987), Alternate V (JUN 1987)

3. FAR 52.227-16, Additional Data Requirements (JUN 1987)

4. FAR 52.227-17, Rights in Data - Special Works (JUN 1987)

5. FAR 52.230-2, Cost Accounting Standards (SEP 1987)

6. FAR 52.230-4, Administration of Cost Accounting Standards (SEP 1987)

7. FAR 52.230-5, Disclosure and Consistency of Cost Accounting Practices (SEP 1987)

8. FAR 52.251-1, Government Supply Sources (APR 1984)

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATIONS/PUBLIC HEALTH SERVICE ACQUISITION REGULATIONS (HHSAR) (PHSAR) (48 CFR CHAPTER 3) CLAUSES:

This contract incorporates the following clauses by reference with the same force and effect as if they were given in full text. Upon request, the contracting officer will make their full text available.

1. HHSAR 352.224-70, Confidentiality of Information (APR 1984)

2. HHSAR 352.270-1, Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities (APR 1984)

3. PHSAR 352.223-70, Safety and Health (APR 1984)
NOTE: The codes, standards and criteria required by paragraph (a) are set forth under Section H.

4. PHSAR 352.280-1, Protection of Human Subjects (OCT 1986)

c. CONTRACT CLAUSES INCORPORATED IN FULL TEXT

The following clauses are attached and made a part of this contract:

(1) NIH(RC)-1 Invoice/Financing Request Instructions for the NIH Cost-Reimbursement Type Contracts (6/18/92)

(2) NIH(RC)-7, Procurement of Certain Equipment (APR 1984) (OMB Bulletin 81-16)

(3) NIH(RC)-11, Research Patient Care Costs, (4/1/84)

ARTICLE I.4. FAR CLAUSE 52.203-9, REQUIREMENT FOR CERTIFICATE OF PROCUREMENT INTEGRITY - MODIFICATION (NOV 1990)

(a) Definitions. The definitions set forth in FAR 3.104-4 are hereby incorporated in this clause.

(b) The Contractor agrees that it will execute the certification set forth in paragraph (c) of this clause when requested by the Contracting Officer in connection with the execution of any modification of this contract.

(c) Certification. As required in paragraph (b) of this clause, the officer or employee responsible for the modification proposal shall execute the following certification:

CERTIFICATE OF PROCUREMENT INTEGRITY - MODIFICATION (NOV 1990)

(1) I, _____ [Name of certifier] am the officer or employee responsible for the preparation of this modification proposal and hereby certify that, to the best of my knowledge and belief, with the exception of any information described in this certification, I have no information concerning a violation or possible violation of subsection 27(a), (b), (d), or (f) of the Office of Federal Procurement Policy Act, as amended* (41 U.S.C. 423), (hereinafter referred to as "the Act"), as implemented in the FAR, occurring during the conduct of this procurement (contract and modification number).

(2) As required by subsection 27(e)(1)(B) of the Act, I further certify that to the best of my knowledge and belief, each officer, employee, agent, representative, and consultant of _____ [Name of Offeror] who has participated personally and substantially in the preparation or submission of this proposal has certified that he or she is familiar with, and will comply with, the requirements of subsection 27(a) of the Act, as implemented in the FAR, and will report immediately to me any information concerning a violation or possible violation of subsections 27(a), (b), (d), or (f) of the Act, as implemented in the FAR, pertaining to this procurement.

(3) Violations or possible violations: (Continue on plain bond paper if necessary and label Certificate of Procurement Integrity - Modification (Continuation Sheet), ENTER "NONE" IF NONE EXISTS) _____

_____

_____

_____

_____

[Signature of the officer or employee responsible for the modification proposal and date]

_____

[Typed name of the officer or employee responsible for the modification proposal]

*Subsections 27(a), (b), and (d) are effective on December 1, 1990. Subsection 27(f) is effective on June 1, 1991.

THIS CERTIFICATION CONCERNS A MATTER WITHIN THE JURISDICTION OF AN AGENCY OF THE UNITED STATES AND THE MAKING OF A FALSE, FICTITIOUS, OR FRAUDULENT CERTIFICATION MAY RENDER THE MAKER SUBJECT TO PROSECUTION UNDER TITLE 18, UNITED STATES CODE, SECTION 1001.

(End of certification)

(d) In making the certification in paragraph (2) of the certificate, the officer or employee of the competing Contractor responsible for the offer or bid, may rely upon a one-time certification from each individual required to submit a certification to the competing Contractor, supplemented by periodic training. These certifications shall be obtained at the earliest possible date after an individual required to certify begins employment or association with the contractor. If a contractor decides to rely on a certification executed prior to the suspension of section 27 (i.e., prior to December 1, 1989), the Contractor shall ensure that an individual who has so certified is notified that section 27 has been reinstated. These certifications shall be maintained by the Contractor for a period of 6 years from the date a certifying employee's employment with the company ends or, for an agency, representative, or consultant, 6 years from the date such individual ceases to act on behalf of the contractor.

(e) The certification required by paragraph (c) of this clause is a material representation of fact upon which reliance will be placed in executing this modification.

PART III

LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Small Business and Small Disadvantaged Business Subcontracting Plan, undated, 6 pages

2. NIH 2706, Financial Report of Individual Project/Contract, 2 pages

3. NIH Instructions, Instructions for Completing Form NIH 2706, dated 5/92, 2 pages

4. Standard Form SF-LLL, Disclosure of Lobbying Activities, 1/90, 3 pages

5. NIH(RC)-1 Invoice/Financing Request Instructions for the NIH Cost-Reimbursement Type Contracts (6/18/92), 6 pages

6. NIH(RC)-7, Procurement of Certain Equipment (APR 1984) (OMB Bulletin 81-16), 1 page

7. NIH(RC)-11, Research Patient Care Costs, (4/1/84), 1 page

8. Optional Form 310, Protection Of Human Subjects Assurance of Identification/Certification/Declaration, dated 9-92, 1 page

9. Authorization to Use GSA Supply Sources, NIH Form 1705, 1 page

PART IV

REPRESENTATIONS AND INSTRUCTIONS

SECTION K

REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS OR QUOTERS

The following documents are incorporated by reference in this contract:

1. Representations and Certifications dated November 20, 1992.

2. Kennedy Krieger Research Institute Initial Proposal dated November 23, 1992; Revised Proposal dated May 12, 1993; Best and Final Offer dated June 4, 1993; and Clarifying Information dated June 18 - 25, 1993.

Attachment 1

KENNEDY KRIEGER RESEARCH INSTITUTE

1. Contract Number: NO1-ES-92-31

Contract Period: 07/01/93 - 06/30/98

Title: TOXICITY OF LEAD IN CHILDREN

Description: A placebo controlled trial of succimer in the prevention of lead-associated cognitive delay in young children

2. Contractor Name: Kennedy Krieger Research Institute

3. Individual Completing this Plan:
Neuman, Micheal, CPA
Assistant VP/Controller
Kennedy Krieger Institute
Baltimore, MD 21205
(410) 550 - 9472

4. Percentage Goals:

It is the policy of the Kennedy Krieger Research Institute (KKRI) that Small Business and Small Disadvantaged Business concerns be given the maximum practical opportunity to compete for the requirements of materials, equipment and services consistent with the efficient performance of this Research Project.

The KKRI establishes the following percentage goals for the proposed contract:

	Prime Contract	Percent	External Purchases	Percent
Total Estimated Dollars	$ 2,867,080	100%	$ 970,176	100%
Small Business	659,178	23.0%	659,178	67.9%
Small Disadvantaged	74,390	2.6%	74,390	7.7%

5. Comment on Goals and Subcontract Possibilities with Small businesses and Small Disadvantaged Businesses:

The percentage totals were determined by examining the total subcontracting possibilities inherent in this Research Project, and by estimating the likely Small Business and Small Disadvantaged Business utilization based on historical trends.

The KKRI will continue its attempts to find qualified Small Business and Small Disadvantaged Business Subcontractors to assist it in fulfilling its obligations under this contract.

6. Subcontracting Plan Administration:

The following individuals are designated to administer the subcontracting under this research project:

Project Manager (TBN.)
Toxicity of Lead in Children - DSMA Clinical Trial

The following KKRI procurement personnel have assisted in developing this Subcontracting Plan, and will continue to provide services and information to maximize Small Business and Small Disadvantaged Business utilization:

Gamache, Thomas, BA
Manager, Purchasing Department
Kennedy Krieger Institute
Baltimore, MD 21205
(410) 550 - 9472

Project Manager (TBN.)
Toxicity of Lead in Children - DSMA Clinical Trial

The duties of the Project Manager and Director of Purchasing with respect to Small Business concerns include the following:

(a) Identify qualified Small Business and Small Disadvantaged Business concerns as potential suppliers for KKRI requirements.

(b) Coordinate with the KKRI buyers to ensure that Small Business and Small Disadvantaged Business Concerns are considered fairly as subcontractors and supplies.

(c) Maintain appropriate records.

(d) Prepare and submit required reports.

(e) Keep abreast of current requirements, recent literature and forthcoming seminars in the field.

7. The KKRI Efforts to Assure Small Business and Small Disadvantaged Businesses Have Maximum Practical Opportunity:

The President of the KKRI has designated the Purchasing Department to carry the lead responsibility for implementing the KKRI's Small Business and Small Disadvantaged Business policy, and has confirmed the Institute's intent to take greater initiatives to encourage Small Business and Small Disadvantaged Business involvement in the procurement process. These actions are an appropriate extension of the Institute's fundamental policy of Equal Opportunity. Each individual faculty and staff member will be informed of this intent.

The Institute's efforts in this program include:

(a) Maintain directories and company brochures of Small Business and Small Disadvantaged Business Concern, keeping the KKRI

procurement staff aware of current directories and new information.

(b) Circulate company brochures to the KKRI faculty and staff.

(c) Attend Small Business and Small Disadvantaged Business Fairs and Expositions and Seminars as appropriate.

(d) Make various levels of KKRI Management, including program managers and staff members responsible for initiating procurement actions, aware of the Institute's responsibilities toward Small Business and Small Disadvantaged Business concerns.

(e) Make site visits as appropriate to Small Business and Small Disadvantaged Businesses.

(f) Receive visits from Small Businesses and Small Disadvantaged Businesses as appropriate.

(g) Include Small Businesses and Small Disadvantaged Businesses on bidder's lists where appropriate.

(h) Include appropriate instructions in the Institute's Administrative Manuals, and insert items in the Administrative Bulletin.

(i) Advise Small Business and Small Disadvantaged Business officials on problems before these result in loss of a subcontract or loss of future business opportunity.

(j) Monitor the United States Code, the Code of Federal Regulations, and the Federal Register for the purpose of keeping apprised of all applicable statutes and implementing regulations.

8. Records Maintained:

To demonstrate compliance with the procedures and goals set forth in this Plan, the following types of records will be maintained:

(a) Records showing solicitation of and awards to Small Businesses and Small Disadvantaged businesses.

(b) Summary records of buyer's bids, showing Small Business and Small Disadvantaged Business solicitations.

(c) Catalogs and brochures from Small Businesses and Small Disadvantaged Businesses.

(d) Documentation regarding site visits to Small Businesses and Small Disadvantaged Businesses.

(e) Documentation regarding site visits by Small businesses and Small Disadvantaged Businesses to the KKRI.

(f) Directories of Small Businesses and Small Disadvantaged Businesses.

(g) Computerized reports of Small Business and Small Disadvantaged Business utilization.

9. Statement of Assurances

The Kennedy Krieger Research Institute certifies that the appropriate clauses required by the General Provisions of this prime contract will be included in all subcontracts which offer further subcontracting opportunities, and that as the Prime Contractor we will require all subcontractors (except Small Business Concerns) who may received subcontracts in excess of $500,000 in case of a subcontract for all other contracts, to adopt a plan similar to this plan. Further , the Institute will submit such periodic reports as required and cooperate in any studies or surveys as may be required and in every way as required under the Solicitation Provisions outlined under Subpart 52.219.9 of the Federal Acquisition Regulations.

Neuman, Micheal, CPA
Assistant VP/Controller

KENNEDY KRIEGER RESEARCH INSTITUTE

POLICY OF COMPLIANCE WITH PUBLIC LAW 95-507

It is the policy of the Kennedy Krieger Research Institute that Small Business and Small Disadvantaged Business concerns be given the maximum practical opportunity to compete for the requirements of material, equipment and services consistent with the efficient performance of individual research projects.

The Institute establishes percentage goals for each proposed contract. These goals are determined by examining the total subcontracting possibilities inherent in each research project, and buy estimating the likely Small Business and Small Disadvantaged Business utilization based on historical trends.

The Institute continues to attempt to find qualified Small Business and Small Disadvantaged Business Subcontractors to assist it in fulfilling its obligations under the contracts.

In order to assure the Small Business and Disadvantaged Businesses have maximum practical opportunity, the University maintains catalogs, directories and brochures of Small Business and Small Disadvantaged Business concerns and circulates them among appropriate University Faculty and Staff. In addition to attending business fairs, expositions, and seminars, the University also advises and counsels business concerns regarding procurement procedures and placement on bidder's lists where appropriate.

The United States Code, the Code of Federal Regulations, and the Federal Register are regularly monitored for the purpose of keeping apprised of all applicable statues and implementing regulations.

Records showing solicitations of bids and bid awards are maintained to demonstrate compliance with the procedures and goals set forth for each subcontracting plan. Documentation of site visits made to Small and Small Disadvantaged Businesses in addition to computerized utilization reports are kept on file.

The President of the Institute has designated the Purchasing Department to carry the lead responsibility for implementing the Institute's Small Business and Small Disadvantaged Business policy, and had confirmed the Institute's intent to take greater initiatives to encourage Small Business and Small Disadvantaged Business involvement in the procurement process. These actions are an appropriate extension of the Institutes's fundamental policy and Equal Opportunity.

KENNEDY KRIEGER INSTITUTE
SMALL BUSINESS PLAN
SUMMARY OF EXTERNAL EXPENSES

PURCHASE/SERVICE	CONTEMPLATED SUPPLIER	BUSINESS CLASSIFICATION	
PROJECT MANAGEMENT			
SUPPLIES			
OFFICE SUPPLIES	LUCAS BROTHERS	LARGE	$19,615
PHOTOCOPYING SUPPLIES	LUCAS BROTHERS	LARGE	5,230
OTHER			
POSTAGE	U.S.P.S.	LARGE	9,133
SHIPPING	FEDERAL EXPRESS	LARGE	6,474
TELEPHONE	BELL ATLANTIC	LARGE	57,881
ADVERTISING	DAVIS ADVERTISING	SMALL	1,800
BOOKS & MANUALS	VARIOUS	LARGE	1,000
TYPING AND CLERICAL SERVICES	CAREERS, USA	SDB	8,602
TRAVEL	REIMBURSEABLE	LARGE	21,185
	BON VOYAGE TRAVEL	SDB	9,579
CLINICAL MANAGEMENT			
CLINICAL SUPPLIES	VWR	LARGE	6,592
PATIENT TRANSPORTATION	YELLOW CAB CO.	SMALL	228,005
VITAMINS	EDWARDS AND ANTHONY	SDB	56,209
LEAD DUST MANGEMENT			
CONSULTANTS	VARIOUS	LARGE	1,000
RANDOM DUST SAMPLES	IN-HOUSE	LARGE	28,035
HOUSE INTERVENTIONS	VARIOUS	SMALL	408,888
RELOCATION	EASTERN MOVING AND STORAGE	SMALL	13,750
QUALITY CONTROL			
STANDARD REFERENCE MATERIALS	VWR	LARGE	7,912
LABORATORY ANALYSIS			
ELECTRODE/ELECTRODE COMPARTMENT	VWR	LARGE	3,300
MAINTENANCE CONTRACTS	CHESAPEAKE LEASING	SMALL	6,735
DATA COLLECTION - FIELD			
PARTICIPATION INCENTIVES	VARIOUS	LARGE	48,700
VEHICLES	VARIOUS	LARGE	15,894
PSYCHOMETRICS			
TESTING MATERIALS	VARIOUS	LARGE	5,836

TOTAL - LARGE BUSINESS	$234,804
TOTAL - SMALL BUSINESS	$659,178
TOTAL - SDB	$74,390
TOTAL - COMBINED	$970,174

...nal Institutes of Health

Financial Report of Individual Project/Contract

Complete this form in accordance with accompanying instructions.

Toxicity Lead in Ch...ren's Trial -- Clinical C...ter Program

NO1-ES-35362

0990-0134
0990-0131

Reporting Period

(YEAR 1)

Contractor's Name and Address

Kennedy Krieger Research Institute, Inc.
707 North Broadway
Baltimore, MD 21205

Expenditure Category	Percentage of Effort/Hours		Cumulative Incurred Cost at End of Prior Period	Incurred Cost--Current Period	Cumulative Cost to Date (D + E)	Estimated Cost to Complete	Estimated Cost at Completion (F + G)	Funded Contract Amount	Variance (Over or Under) (I + H)
	Funded	Actual							
A	B	C	D	E	F	G	H	I	J
Direct Labor								$156,012	
Fringe Benefits								42,124	
Project Management								15,086	
Travel								9,950	
Clinical Management								-0-	
Lead Dust Management								1,000	
QA/QC								286	
Lab Analysis								-0-	
Data Collection								1,854	
Psychometrics								-0-	
Indirect Costs								126,735	
Subcontracts									
University of Maryland - Baltimore								47,777	
Johns Hopkins University School of Medicine								44,586	
Total Estimated Costs								445,410	

NIH 2706 (5/92) *(Formerly HHS 646)*

Attachment 2

Case 1:07-cv-01120-WMN Document 32-1 Filed 06/18/07 Page 47 of 62

nal Institutes of Health

Financial Report of Individual Project/Contract

Complete this form in accordance with accompanying instructions.

Toxicity Lead in C ren's Trial -- Clinical Center Program

NO1-ES-35362

0990-0134
0990-0131

Reporting Period

(TOTAL ESTIMATED COSTS)

Contractor's Name and Address
Kennedy Krieger Research Institute, Inc.
707 North Broadway
Baltimore, MD 21205

Expenditure Category	Percentage of Effort/Hours		Cumulative Incurred Cost at End of Prior Period	Incurred Cost--Current Period	Cumulative Cost to Date (D + E)	Estimated Cost to Complete	Estimated Cost at Completion (F + G)	Funded Contract Amount	Variance (Over or Under) (I + H)
	Funded	Actual							
A	B	C	D	E	F	G	H	I	J
Direct Labor								$1,493,627	
Fringe Benefits								403,277	
Project Management								109,755	
Travel								30,765	
Clinical Management								290,806	
Lead Dust Management								451,673	
QA/QC								7,912	
Lab Analysis								9,836	
Data Collection								64,594	
Psychometrics								4,836	
Indirect Costs								1,605,564	
Subcontracts									
University of Maryland - Baltimore								699,794	
Johns Hopkins University School of Medicine								592,591	
Total Estimated Costs								5,765,029	

NIH 2706 (5/92) *(Formerly HHS 646)*

Case 1:07-cv-01120-WMN Document 32-1 Filed 06/18/07 Page 48 of 62

Instructions for Completing Form NIH 2706— "Financial Report of Individual Project/Contract"

GENERAL INFORMATION

Purpose. Form NIH 2706 is designed to: (1) provide a management tool for use by NIH in monitoring the application of financial and personnel resources to NIH contracts, (2) provide contractors with financial and personnel management data which is usable in their management processes, (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel, and (4) obtain contractor's analyses of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

(a) **Scope.** The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

(b) **Number of Copies and Mailing Address.** An original and two (2) copies of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than the 30th working day after the end of the period reported.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate Form NIH 2706, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing Form NIH 2706. For the purpose of establishing expenditure categories in Column A the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) **Personnel—Professional.** Included are the senior level and all other personnel whose total annual salary rates are $50,000 or more. It should include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel—Other.** This will be listed as one amount unless otherwise required by the contract.

(3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property.** Nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See the DHHS "Contractor's Guide for Control of Government Property."

(5) **Supplies.** Includes the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care.** Costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) **Outpatient Care.** Costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) **Travel.** Includes all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify

Attachment 4

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB
0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action:	2. Status of Federal Action:	3. Report Type:
☐ a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	☐ a. bid/offer/application b. initial award c. post-award	☐ a. initial filing b. material change For Material Change Only: year _____ quarter _____ date of last report _____

4. Name and Address of Reporting Entity:	5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime:
☐ Prime ☐ Subawardee Tier _____, *if known*: Congressional District, *if known*:	Congressional District, *if known*:
6. Federal Department/Agency:	7. Federal Program Name/Description: CFDA Number, *if applicable*: _____
8. Federal Action Number, *if known*:	9. Award Amount, *if known*: $
10. a. Name and Address of Lobbying Entity *(if individual, last name, first name, MI)*:	b. Individuals Performing Services *(including address if different from No. 10a)* *(last name, first name, MI)*:

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

11. Amount of Payment *(check all that apply)*:	13. Type of Payment *(check all that apply)*:
$ _____ ☐ actual ☐ planned	☐ a. retainer ☐ b. one-time fee ☐ c. commission ☐ d. contingent fee ☐ e. deferred ☐ f. other; specify: _____
12. Form of Payment *(check all that apply)*: ☐ a. cash ☐ b. in-kind; specify: nature _____ value _____	

14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for Payment Indicated in Item 11:

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

15. Continuation Sheet(s) SF-LLL-A attached: ☐ Yes ☐ No

16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Signature: _____

Print Name: _____

Title: _____

Telephone No.: _____ Date: _____

Federal Use Only:

Authorized for Local Reproduction
Standard Form - LLL

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee", then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).

11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material change report, enter the cumulative amount of payment made or planned to be made.

12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.

13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.

14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.

15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.

16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

DISCLOSURE OF LOBBYING ACTIVITIES
CONTINUATION SHEET

Approved by OM
0348-0046

Reporting Entity: _____ Page _____ of _____

•U.S. G.P.O. 1990-260-706:00012

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Standard Form - LLL-A

INVOICE/FINANCING REQUEST INSTRUCTIONS FOR NIH COST-REIMBURSEMENT TYPE CONTRACTS

General: The contractor shall submit claims for reimbursement in the manner and format described herein and as illustrated in the sample invoice/financing request.

Format: Standard Form 1034, "Public Voucher for Purchases and Services Other Than Personal;" and Standard Form 1035, "Public Voucher for Purchases and Services Other Than Personal-- Continuation Sheet," or reproduced copies of such forms marked ORIGINAL should be used to submit claims for reimbursement. In lieu of SF-1034 and SF-1035, claims may be submitted on the payee's letter-head or self-designed form provided that it contains the information shown on the sample invoice/financing request.

Number of Copies: As indicated in the Invoice Submission clause in the contract.

Frequency: Invoices/financing requests submitted in accordance with the payment clause shall be submitted monthly unless otherwise authorized by the contracting officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include: (1) Costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the amount and month(s) in which such costs were incurred shall be cited.

Contractor's Fiscal Year: Invoices/financing requests shall be prepared in such a manner that costs claimed can be identified with the contractor's fiscal year.

Currency: All NIH contracts are expressed in United States dollars. Where expenditures are made in a currency other than United States dollars, billings on the contract shall be expressed, and reimbursement by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the contracting officer's approval which are not set forth in an advance understanding in the contract shall be so identified and reference the Contracting Officer's Authorization (COA) number.

Invoice/Financing Request Identification: Each invoice/financing request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request** — These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice** — The completion invoice is a final invoice which is submitted promptly upon completion of the work, but no later than one year from the contract completion date. The completion invoice should be submitted when all costs (except for finalization of indirect cost rates) have been assigned to the contract and all performance provisions have been completed.

(c) **Final Invoice** — A revised final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., final indirect cost rates and resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the explanatory notes below. These notes are keyed to the entries on the sample invoice/financing request.

(a) **Payor's Name and Address** — The paying office and address, identified in the Invoice Submission clause of the contract, shall be entered on all copies of the invoice/financing request.

(b) **Invoice/Financing Request Number** — Insert the appropriate serial number of the invoice/financing request.

(c) **Date Invoice/Financing Request Prepared** — Insert the date the invoice/financing request is prepared.

(d) **Contract Number and Date** — Insert the contract number and the date of the contract.

(e) **Payee's Name and Address** — Show the Contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) **Total Estimated Cost of Contract** — Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

(g) **Total Fixed-Fee** — Insert the total fixed-fee (where applicable).

(h) **Billing Period** — Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(i) **Amount Billed for Current Period** — Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the period.

(j) **Cumulative Amount from Inception to Date of this Billing** — Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

(k) **Direct Costs** — Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor** — This consists of salaries and wages paid (or accrued) for direct performance of the contract.

(2) **Fringe Benefits** — This represents fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.

(3) **Accountable Personal Property** — This category of cost includes permanent research equipment and general purpose equipment having a unit acquisition cost of $1000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS *Contractor's Guide for Control of Government Property.*) Show permanent research equipment separate from general purpose equipment. Prepare and attach Form HHS-565, "Report of Accountable Property," in accordance with the following instructions:

List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

(A) The item number for the specific piece of equipment listed in the Property Schedule;

(B) The Contracting Officer's Authorization letter and number, if the equipment is not covered by the Property Schedule, or;

(C) Be preceded by an asterisk (*) if the equipment is below the approval level.

Further itemization of invoices/financing requests shall only be required for items having specific limitations set forth in the contract.

(4) **Materials and Supplies** — This category includes equipment with unit costs of less than $1000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

(5) **Premium Pay** — This is remuneration in excess of the basic hourly rate.

(6) **Consultant Fee** — Fees paid to consultants. Identify consultant by name or category as set forth in the contract's advance understanding or in the COA letter, as well as the effort (i.e., number of hours, days, etc.) and rate being billed.

(7) **Travel** — Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel should be billed separately from domestic travel.

(8) **Subcontract Costs** — List subcontractor(s) by name and amount billed.

(9) **Other** — List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000 list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element should be listed separately.

(l) **Cost of Money (COM)** — Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(m) **Indirect Costs--Overhead** — Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(n) **Fixed-Fee Earned** — If the contract provides for a fixed-fee, it must be claimed as provided for by the contract. Cite the formula or method of computation.

(o) **Total Amounts Claimed** — Insert the total amounts claimed for the current and cumulative periods.

(p) **Adjustments** — This includes amounts conceded by the contractor, outstanding suspensions, and disapprovals subject to appeal.

(q) **Grand Totals**

The Contracting Officer may require the Contractor to submit detailed support for costs claimed on one or more interim invoices/financing requests.

SAMPLE INVOICE/FINANCING REQUEST

(a) Payor's Name and Address
NATIONAL INSTITUTES OF HEALTH
Division of Financial Management
Contracts Section, FAAB
Building 31, Room B1B05A
Bethesda, Maryland 20892

(b) Invoice/Financing Request No. _____

(c) Date Invoice Prepared _____

(d) Contract No. and Date _____

(e) Payee's Name and Address
ABC CORPORATION
100 Main Street
Anywhere, U.S.A. zip code

(f) Total Estimated Cost of Contract _____

(g) Total Fixed Fee _____

Attention: Name, Title, and Phone Number of Official to Whom Payment is Sent

(h) This invoice/financing request represents reimbursable costs from Aug. 1, 1982 through Aug. 31, 1982

	(i) Amount Billed for Current Period	(j) Cumulative Amount From Inception to Date of this Billing
(k) Direct Costs		
(1) Direct Labor	$ 3,400	$ 6,800
(2) Fringe Benefits	600	1,200
(3) Accountable Personal Property (Attach Form HHS-565)		
Permanent Research	3,000	8,000
General Purpose	2,000	
(4) Materials and Supplies	2,000	4,000
(5) Premium Pay	100	150
(6) Consultant Fee-Dr. Jones 1 day @ 100 (COA #3)	100	100
(7) Travel (Domestic)	200	200
(Foreign)	200	200
(8) Subcontract Costs	-0-	-0-
(9) Other	-0-	-0-
Total Direct Costs	$11,600	$20,650
(l) Cost of Money (Factor) of (Appropriate Base)	2,400	3,600
(m) Indirect Costs -- Overhead _____% of Direct Labor or Other Base (Formula)	4,000	6,000
(n) Fixed-Fee Earned (Formula)	700	1,400
(o) Total Amount Claimed	$18,700	$31,650
(p) Adjustments Outstanding Suspensions		(1,700)
(q) Grand Totals	$18,700	$29,950

"I certify that all payments requested are for appropriate purposes and in accordance with the contract."

_____ _____
Name of Official) (Title)

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SAMPLE INVOICE/FINANCING REQUEST ALTERNATE

(a) Payor's Name and Address
NATIONAL INSTITUTES OF HEALTH
Division of Financial Management
Contracts Section, FAAB
Building 31, Room B1B05A
Bethesda, MD 20892

(e) Payee's Name and Address
ABC CORPORATION
100 Main Street
Anywhere, USA zip code

Attn:
Name, Title, & Phone Number of
Official to Whom Payment is Sent

(b) Invoice/Financing Request No. _____

(c) Date Invoice Prepared _____

(d) Contract No. . . . _____

Date . . . . . _____

(f) Total Estimated Cost _____

(g) Total Fixed Fee . . _____

(h) This invoice/financing request represents reimbursable costs for the period from _____ to _____

Expenditure Category* A	Incurred Cost Current B	Incurred Cost Cumulative C	Cost at Completion D	Amount Funded E	Variance F
(k) Direct Costs:					
(1) Direct Labor					
(2) Fringe Benefits					
(3) Accountable Property (attach HHS-565)					
(4) Materials & Supplies					
(5) Premium Pay					
(6) Consultant Fees					
(7) Travel					
(8) Subcontracts					
(9) Other					
Total Direct Costs					
(l) Cost of Money					
(m) Overhead					
G&A					
(n) Fixed Fee					
(o) Total Amount Claimed					
(p) Adjustments					
(q) Grand Totals					

I certify that all payments are for appropriate purposes and in accordance with the contract.

_____ _____
(Name of Official) (Title)

* Attach details as specified in the contract

NIH(RC)-1
REV. 6/18/92

Insert this clause in all cost-reimbursement RFPs and contracts. Modify for use in fixed-price contracts.

PROCUREMENT OF CERTAIN EQUIPMENT

Notwithstanding any other clause in this contract, the contractor will not be reimbursed for the purchase, lease, or rental of any item of equipment listed in the following Federal Supply Groups, regardless of the dollar value, without the prior written approval of the contracting officer.

67 - Photographic Equipment
69 - Training Aids and Devices
70 - General Purpose ADP Equipment, Software, Supplies and Support (Excluding 7045-ADP Supplies and Support Equipment)
71 - Furniture
72 - Household and Commercial Furnishings and Appliances
74 - Office Machines and Visible Record Equipment
77 - Musical Instruments, Phonographs, and Hometype Radios
78 - Recreational and Athletic Equipment

When equipment in these Federal Supply Groups is requested by the contractor and determined essential by the contracting officer, the Government will endeavor to fulfill the requirement with equipment available from its excess personal property sources, provided the request is made under a cost-reimbursement contract. Extensions or renewals of approved existing leases or rentals for equipment in these Federal Supply Groups are excluded from the provisions of this article.

Research Patient Care Costs

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicar reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs. Patient care rates or amounts shall be established by the Secretary of HHS or his duly authorized representative.

(c) Prior to submitting an invoice for patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for patient care.

(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

Approved for use through 7/31/84

Protection of Human Subjects
Assurance Identification/Certification/Declaration
(Common Federal Rule)

POLICY: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the common rule. See Section 101(b) the common rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the common rule.

Institutions with an assurance of compliance that covers the research to be conducted on file with the Department, Agency, or the Department of Health and Human Services (HHS) should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency. Institutions which do not have such an assurance must submit an assurance and certification of IRB review and approval within 30 days of a written request from the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Application or Proposal Identification No. *(If known)*
☐ ORIGINAL ☐ FOLLOWUP ☐ EXEMPTION	☐ GRANT ☐ CONTRACT ☐ FELLOWSHIP ☐ COOPERATIVE AGREEMENT ☐ OTHER: _____	

4. Title of Application or Activity	5. Name of Principal Investigator, Program Director, Fellow, or Other

6. Assurance Status of this Project *(Respond to one of the following)*

☐ This Assurance, on file with the Department of Health and Human Services, covers this activity:

Assurance identification no. M-_____ IRB identification no. _____

☐ This Assurance, on file with *(agency/dept.)* _____, covers this activity.

Assurance identification no. _____ IRB identification no. _____ *(If applicable)*

☐ No assurance has been filed for this project. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

☐ *Exemption Status:* Human subjects are involved, but this activity qualifies for exemption under Section 101 (b), paragraph _____.

7. Certification of IRB Review *(Respond to one of the following IF you have an Assurance on file)*

☐ This activity has been reviewed and approved by the IRB in accordance with the common rule and any other governing regulations or subparts on

(date) _____ by: ☐ Full IRB Review or ☐ Expedited Review.

☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.		10. Name and Address of Institution
11. Phone No. *(with area code)*	12. Fax No. *(with area code)*	
13. Name of Official		14. Title
15. Signature		16. Date

Authorized for local reproduction

OPTIONAL FORM 310 (9-[illegible])
Sponsored by HHS/PHS/[illegible]

AUTHORIZATION TO USE GSA SUPPLY SOURCES

CONTRACTOR: (Name and Address)	CONTRACT NUMBER	S. A. NUMBER
Kennedy Krieger Research Institute, Inc. 707 North Broadway Baltimore, MD 21205	NO1-ES-35362 CONTRACT AMOUNT $5,765,029 EFFECTIVE DATE Jun3 30, 1993	EXPIRATION DATE June 29, 1998
ADDRESS WHERE MAIL, FREIGHT AND BILLING DOCUMENTS ARE TO BE DIRECTED (If different from the above)		FEDSTRIP ADDRESS ACTIVITY CODE

REGULATIONS: The Contractor is authorized to purchase supplies and equipment for this Cost-Reimbursement Type Contract from GSA Supply Sources pursuant to the following:

48 CFR 51.1, Contractor Use of Government Supply Sources;
41 CFR 101-26.2, Federal Requisitioning System;
41 CFR 101-26.3, Procurement of GSA Stock Items;
41 CFR 101-26.4, Purchase of Items from Federal Supply Schedule Contracts

TITLE: Title to property acquired by the Contractor under this authorization shall vest as set forth in the provisions of this contract. (See 48 CFR 51.106.)

LEASE OR RENTAL: Equipment ordered on a lease or rental basis under Federal Supply Schedule Contracts will be used solely in the performance of this contract.

FURNISHING INFORMATION TO CONTRACTORS: When a Regional Office of the Federal Supply Service, FSS, [illegible], is notified by the FSS Central Office that it has assigned a FEDSTRIP activity address code to a cost-reimbursement contractor of an agency, the FSS Regional Office will provide initial copies of the GSA Supply Catalog and FEDSTRIP Operating Guide and other necessary information. The Regional Office will also assist the contractor to prepare initial FEDSTRIP requisitions and complete GSA Form 457, FSS Publications Mailing List Application, so that current copies of required publications are received automatically from GSA.

PAYMENT FOR GSA SHIPMENTS: GSA will not forward bills to contractors for supplies until after the supplies have been shipped by GSA. Receipt of billing is considered to be sufficient evidence of delivery to establish contractor liability and to provide a basis for payment. Accordingly contractors are to make payments promptly upon receipt of billings (see 48 CFR 51.105).

PLACING ORDERS: The Contractor shall place orders in accordance with 41 CFR 101-26.2, 101-26.3, and 101-26.4. The Federal Standard Requisitioning and Issue Procedure (FEDSTRIP) shall be used when requisitioning items required by 41 CFR 101-26.2, and the above FEDSTRIP Address Activity Code shall be included in orders.

LIMITATIONS:

SIGNATURE OF CONTRACTING OFFICER	TYPED NAME (Contracting Officer)	DATE
Thomas M. Hardee	Thomas M. Hardee	June 25, 1993

NIH 1705 (Rev. 3/84)

'We must prevent exposure in the first place'

Drug Treatment of Lead-exposed Children Does not Improve Psychological Test Scores

Using a lead-lowering drug to reverse the IQ damage associated with the lead exposure is ineffective, the National Institute of Environmental Health Sciences announced today.

Walter Rogan, M.D. of NIEHS, and colleagues from the Treatment of Lead-exposed Children Trial (TLC) reported the results in *The New England Journal of Medicine* (May 10). The TLC study showed that, as expected, drug treatment with succimer lowered blood lead faster than placebo. Treating lead-exposed two-year-olds, however, did not improve scores on psychological, behavioral and IQ tests when the children were followed until age 5 years.

Succimer remains as the only drug given by mouth labelled for treating children with high blood lead levels. But the hope behind the study was that otherwise symptom-free children exposed to just enough lead to have affected their psychological, behavioral and intelligence tests, might be aided.

NIEHS Director Kenneth Olden, Ph.D., said, "For more than twenty years, NIEHS has sponsored much of the research showing that lead at these levels was harmful to children's brain function, and that succimer lowered blood lead. We had hopes that the treatment would prevent or reduce lead-induced damage in these children, who are mostly poor, African-American, and living in deteriorated housing in big cities. The results of the trial show clearly that treatment after the fact does not undo the damage among 5 year olds. We must prevent these children from being exposed in the first place."

TLC was sponsored by NIEHS and the Office of Research on Minority Health, both of the National Institutes of Health, and the Center for Environmental Health of the Centers for Disease Control and Prevention. McNeil Consumer Products, who produced succimer as Chemet when the study began, provided succimer and placebo. Chemet is now owned by Sanofi-Synthelabo, New York, New York.

TLC was carried out at four urban teaching hospitals:

- The Kennedy Krieger Institute in Baltimore, Md.,
- The University of Cincinnati in Cincinnati, Ohio,
- The University of Medicine and Dentistry of New Jersey, working with children in Newark, and
- Children's Hospital, Philadelphia, Pa.

The program was managed from NIEHS and the Harvard School of Public Health.

For the study, the Centers for Disease Control and Prevention measured blood lead and the Public Health Service Supply Service Center in Perry Point, Md., provided pharmacy services.

In the early 1990s, when the study was started, it was known that children exposed to more lead had lower scores on IQ tests and that succimer could lower lead levels in blood. It was not known whether using it prevented or reduced the effects of lead on test scores. About 780 children were enrolled between 1994 and 1997. Half were given succimer and half an identical capsule without active drug.

In addition, all the children's homes were cleaned of lead dust, they were given a mineral supplement, and their blood lead was followed. Detailed testing of their cognitive development, neuropsychological function, and behavior was done at three years of follow up. This is a time when the children are old enough to be given sophisticated tests (they were then about 5 years old) and it is the age at which there is the strongest evidence for an effect of lead.

While the children given succimer had more rapid drops in their blood lead, the differences in tests scores were small, inconsistent, and not statistically significant, the investigators said. The study was large enough to have detected an improved IQ score of less than 3 points, and no such improvement was seen.

Side effects were relatively infrequent in both groups, but the children given succimer had an unexpectedly higher rate of injuries, which is so far unexplained.

Based on these data, Rogan said, there is little reason to recommend chelation for children with exposures below the current recommendation of 45 µg/dL. Children generally have no symptoms below that level. Succimer remains the recommended therapy for outpatient treatment of children above that level.

The children who participated in TLC are being followed for an additional two years to see if some benefit emerges. In an Australian study, children whose blood leads fell faster without treatment when they were two years old had better IQ test scores when they were seven years old, and 7 year old children attend school and read and so can be tested more extensively.

Although lead poisoning in the US has declined dramatically since the removal of lead from gasoline, in 1998 about 8% of screened children still had blood lead levels that CDC defined as elevated, and about 1% of screened children had a blood lead level high enough to have been eligible for the TLC trial. Lead poisoning is concentrating now among poor children who are eligible for Medicaid and live in deteriorating, inner city housing.

For more information, see the TLC website at http://dir.niehs.nih.gov/direb/tlc1/home.htm.

For general questions about TLC : Dr. Walter Rogan, NIEHS, 919 541 4578, rogan@niehs.nih.gov

For questions about the specific clinical centers' activities:

Baltimore: Merrill Brophy, Kennedy Krieger Institute 410 866 0612 brophy@kennedykrieger.org

Cincinnati: Dr. Robert Bornschein, University of Cincinnati 513 558 0996 robert.bornschein@uc.edu

Or Dr. Kim Dietrich University of Cincinnati 513 558 5816 dietrikn@uc.edu

Newark: Dr. Richard Wedeen, Veterans' Administration New Jersey Health Care System, East Orange, 973 676 1000 x17877 wedeen@umdnj.edu

Or Dr. George Rhoads, UMDNJ Piscataway, 732 445 0195 rhoads@umdnj.edu

Philadelphia: Dr. Donald Schwarz, Children's Hospital 215 590 1462 schwarz@email.chop.edu

Jackson-Featherstone, Shayonna
10/22/92
05.20.06

KENNEDY KRIEGER CHILDREN'S HOSPITAL
LEAD POISONING PREVENTION PROGRAM INTAKE INTERVIEW

REFERRAL SOURCE Sue Porter, CNP / TAC

ADDRESS Park 307

PHONE 955-3055

23 mos BF

Informant Sharon Jackson Primary Caretaker? Yes [X] No [ ] Name of Primary Caretaker Mom

HOUSING

1. Address 2418 E Jefferson, 21205 From 4/94 To present Age of House 7 old. Code ___

Condition: Excellent [ ] Good [ ] Fair [X] Poor [ ] Other ___ Mo. Rent $360 Mo. Mort. $~~200~~ Incl H&E? Yes [ ] No [X]

Walls: Painted [X] Panelled [ ] Papered [ ] Plastered [X] Other ___

Flaking paint inside Yes [X] No [ ] Where LR, DR window sill, walls & frame

Plumbing Condition: Excellent [ ] Good [X] Fair [ ] Poor [ ] Other good drainage + pressure

Condition of Floors: Excellent [ ] Good [X] Fair [ ] Poor [ ] Other carpet LR & DR tile - kitchen, some bathrooms. steps - carpet Linoleum bedroom & BR.

Describe yard: Grass [ ] Cement [X] Grass/Cement [ ] Dirt [ ] Other ___

Fences Silver chain not painted Railings steel Garage/Shed No Porch steel porch back yard block. & rear

Flaking paint outside? Yes [X] No [ ] Where old. Windows - & front of house

Replacement windows? Yes [ ] No [X] Where ___

Demolition or construction in area? Yes [ ] No [X] Where/Describe ___

Nearby industry? Yes [ ] No [X] Where/Describe ___ Highway? Yes [ ] No [ ] Edison Hwy

Lead Inspected? Yes [ ] No [X] Date ___ Result ___ Reinspected? Yes [ ] No [ ] Date ___

Source of Heat: Radiators [X] Forced hot air [ ] Gas [ ] Other Oil - painted radiators Fireplace [ ] Woodstove [ ]

2. Address 2406 E Eager St 21205 From Oct 1995 To 4/94 Age of House ___

2 story apartment house owner by Grandad

Condition: Excellent [X] Good [ ] Fair [ ] Poor [ ] Other ___ Mo. Rent $___ Mo. Mort. $? Incl H&E? Yes [ ] No [X]

Walls: Painted [X] Panelled [ ] Papered [ ] Plastered [ ] Other Dirty wall

Flaking paint inside Yes [ ] No [X] Where ___

Plumbing Condition: Excellent [X] Good [ ] Fair [ ] Poor [ ] Other ___

Condition of Floors: Excellent [X] Good [ ] Fair [ ] Poor [ ] Other Kitchen tile (is new) LR DR carpet. wood steps (cement + carpet basement)

Describe yard: Grass [ ] Cement [X] Grass/Cement [ ] Dirt [ ] Other ___

Fences Silver chain Railings No Garage/Shed No Porch No

Flaking paint outside? Yes [ ] No [X] Where ___

Replacement windows? Yes [X] No [ ] Where Storm windows

Demolition or construction in area? Yes [ ] No [X] Where/Describe ___

Nearby industry? Yes [ ] No [X] Where/Describe ___ Highway? Yes [X] No [ ] Edison Hwy

Lead Inspected? Yes [ ] No [X] Date ___ Result ___ Reinspected? Yes [ ] No [ ] Date ___

Source of Heat: Radiators [ ] Forced hot air [ ] Gas [X] Other Vents Fireplace [ ] Woodstove [ ]

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ad Poisoning Prevention Program Intake Interview
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Address 1504 E. Lanvale St. 21213 From 1985? To Oct 1993 Age of House old
Condition: Excellent [ ] Good [ ] Fair [ ] Poor [X] Other shack Lived c mom mom paid. Mo. Rent $___ Mo. Mort. $___ Incl H&E? Yes [ ] No [ ]

Walls: Painted [X] Panelled [ ] Papered [ ] Plastered [X] Other ___

Flaking paint inside Yes [X] No [ ] Where walls windows - sill some levels

Plumbing Condition: Excellent [ ] Good [ ] Fair [ ] Poor [X] Other tub stopped up toilet overflows

Condition of Floors: Excellent [ ] Good [ ] Fair [ ] Poor [X] Other LR + DR carpet. Kitchen linoleum - coming up at door
wood - splinters + cracks

Describe yard: Grass [ ] Cement [ ] Grass/Cement [X] Dirt [X] Other ___

Fences silver chain rusty Railings no Garage/Shed no wood painted Porch NO

Flaking paint outside? Yes [X] No [X] Where windows peeling

Replacement windows? Yes [ ] No [X] Where old

Demolition or construction in area? Yes [ ] No [X] Where/Describe ___

Nearby industry? Yes [ ] No [X] Where/Describe ___ Highway? Yes [ ] No [ ] N. Ave ~~ave~~ ~~ave~~ ~~ave~~

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Lead Poisoning Prevention Program Intake Interview
Page 3

SUPPLEMENTAL HOUSING (continued)

3. Does child attend school? Yes [ ] No [ ] Name of school N/A

Address _____ Grade _____

used to ① Edin Street. 1500 block - ? Phone#

4. Is a babysitter used? ~~Yes [ ] No [ ]~~ How often _____ Telephone No _____

Name _____ Address _____ Age _____

used to ② 1703 Caroline St - Delores Weatherby ? phone #

HAND-TO-MOUTH ACTIVITY

Has the child ever chewed on: Paper? Yes [X] No [ ] Wallpaper? Yes [ ] No [X] Plaster Yes [ ] No [ ] Paint? Yes [X] No [ ]

Dirt? Yes [ ] No [X] Toys? Yes [X] No [ ] Woodwork? Yes [ ] No [X] Other Spittle hole in wall (when work in next apt's hand in it sticks on hand)

Is ongoing Yes [X] No [ ] When did the child stop? _____

Does the child suck thumb? Yes [X] No [ ] Fingers? Yes [ ] No [X] Bite nails? Yes [ ] No [X]

Interviewer observations pt eating potato chips Mom said pt chewed on intake she got p blood draw

DIET

Appetite Good [X] Poor [ ] Other _____ WIC certified Yes [X] No [ ] Milk intake 32 ounces/day

Milk type: Whole [X] 2% [ ] Skim [ ] By: Bottle [ ] Cup [ ] Other _____

Milk products cheese - almost ~~q~~ day yogurt, ice cream - a lot

c.l Milk intolerance symptoms? Yes [ ] No [X] Does child eat eggs? Yes [X] 6/week No [ ] _____

cnsw hates fish Meats? Yes [X] No [ ] Types pork chops chicken - will try, but picks skin 1 X month Liver? Yes [X] No [ ] Braunschweiger? Yes [ ] No [X]

Green vegetables? Yes [X] No [ ] broccoli, string beans ground beef - spag. meat loaf Yellow vegetables corn - ~~no~~

Citrus or fruit juices? Yes [X] No [ ] grape juice, orange juice Fruits? Yes [X] No [ ] bananas, grapes

Snacks? potato chips, candy, cookies

Fried foods? Yes [X] No [ ] yes Fat trimmed from meat? Yes [ ] No [X] Fatback used? Yes [ ] No [ ] sometimes

Other (e.g. favorite foods) _____

BEHAVIOR AND SYMPTOMS

Anorexia ? Yes [ ] No [X] Constipation? Yes [ ] No [X] Irritability? Yes [ ] No [X]

Behavior changes? Yes [ ] No [X] _____ Sleep changes? Yes [ ] No [X] _____

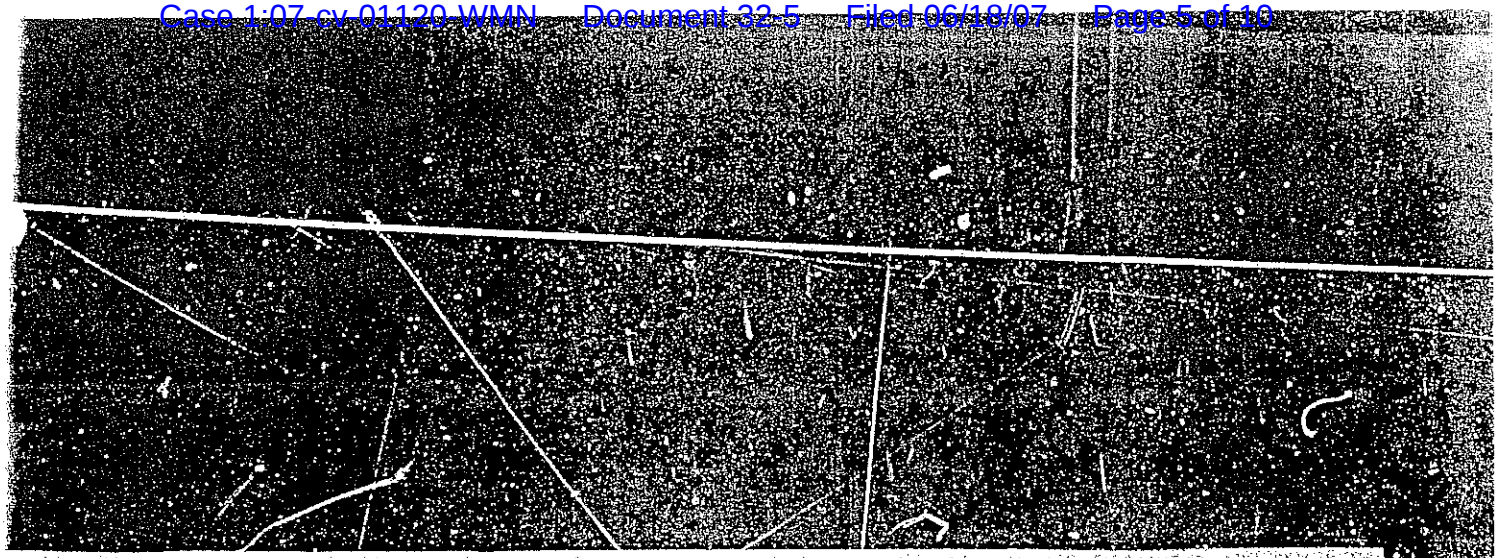
Interviewer observations: pt fussy at times also sat quietly on nurse's lap, mom's lap + played with toys for a while.

SOCIAL HISTORY

Income source ($/month) $ 551/month AFDC Food stamps ($/month) 400? /month

Family members: Barbara Hunter (maternal) Grandmom 38 yr Quin-Nette Hall - Aunt - 31 yr. Shawn Jackson - Mom - 17 yr. Theodore Cotton - 12 yr - ~~brother~~ uncle, Shayanna - pt 1 1/12 yr. Keonna Featherstone - 1 yr sister

00395



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Page 4

SOCIAL HISTORY (continued)

Is mother pregnant? Yes [ ] No [X] Was she present during deleading? Yes [ ] No [ ] N/A

Who works? 1) _____ Where? _____

Occupation: NO Possible lead exposure? Yes [ ] No [ ]

Where are clothes washed? _____ Changed: _____

2) _____ Where? _____

Occupation: _____ Possible lead exposure? Yes [ ] No [ ]

Where are clothes washed? _____ Changed: _____

PAST MEDICAL HISTORY

Health during pregnancy: good Where delivered: JHH

How delivered: FT SVD Breathed and cried: Yes [X] No [ ] Birth Weight: 8 lbs 7½ oz

Problems: Yes [ ] No [X] _____

When did mother go home? 2 nights When did baby go home? with mom

Developmental History

Rolled Over: 4 months Sat up: 5 months

Crawled: 7-8 months Walked: 12 months

Talked: Words: Dada 5 months Phrases: 12 months Sentences: N/A Pronouns: N/A

Other: Boppy and that

Immunizations up to date? Yes [X] No [ ] As reported from where? clinic

Current medications? None [X] _____ Routinely given? Yes [ ] No [ ]

Known allergies? None [X] _____ Recent exposure to childhood diseases? Yes [ ] No [X]

Relevant medical history ear infections tubes

Reliability of informant good

COMMENTS

00396

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LEAD CLINIC

INITIAL OPD NOTE:
Lead Poisoning
September 7, 1994

KKI NUMBER	05-20-06
PATIENT'S NAME	JACKSON-FEATHERSTONE, Shayonna
DOB	10/22/92
ADM DATE	
DISCH DATE	
JHH NUMBER	259-30-85

Shayonna Jackson-Featherstone is a 23 month old black female with an elevated blood lead level who is referred for an initial evaluation at KKI Lead Clinic today. She was referred due to a blood lead level of 32 µg/dL on 07/22/94.

REFERRAL SOURCE:

Sue Porter, CPNP
TAC Clinic
Park 307
Johns Hopkins Hospital
Telephone #955-0355

INFORMANT:

Mother, Sharon Jackson.

HOUSING:

From April, 1994 to the present, the family has lived in an old two-story rowhouse at 2418 E. Jefferson, Baltimore, MD 21205. This house is in fair condition. Rent is $360 dollars per month which does not include heat and electricity. The walls are painted and plastered. There is flaking paint inside the house in the living and dining rooms, on the window sills, wells and frames. The plumbing is in good condition with good drainage and water pressure. The floors are in good condition. There is carpeting in the living and dining rooms. The kitchen has ceramic tile on the floor which is broken in some areas. The steps are made of wood. There is linoleum in the bedroom and bathroom. The yard contains cement. There is an unpainted silver chain-linked fence in the yard. There is a steel black porch in the yard with a steel railing. It does not have peeling paint on it. There is flaking paint outside the house on the old windows and the front of the house. There are no replacement windows in the house. There is no nearby industry, demolition or construction in the area. There is a garage behind the house on Port Street where people work on their cars. The nearest major road is Edison Highway. The house has not been inspected for lead. The source of heat is oil radiators. The radiators are painted and mother does not think they have peeling paint on them.

From October, 1993 to April, 1994 the family lived in a two-story rowhouse at 2406 E. Eager Street, Baltimore, MD 21205. This home is owned by the grandfather. It is in excellent condition. Mother is unsure of the monthly mortgage payment. The walls are painted and covered with drywall. There is no flaking paint inside the house. The plumbing is in excellent condition. The floors are in excellent

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condition. There is tile in the kitchen and bathroom and there is carpeting in the living and dining rooms. The steps are made of wood. The basement contains cement and carpeting. The yard contains cement. There is no porch, railing, garage, or shed outside. There is a silver chain-linked fence outside the home. There is no flaking paint on the outside of the house. The house does have replacement windows and storm windows. There is no nearby industry, demolition, or construction in the area. The nearest major road is Edison Highway. The house has not been inspected for lead. The source of heat is gas vents.

From 1985 to October, 1993 the family lived in an old house at 1504 E. Lanvale Street. Mother describes this house as a "shack." She was living there with her mother, who paid the expenses. The walls were painted and plastered. There was flaking paint inside the house on the windows, walls, window sills, frames and window wells. The plumbing was in poor condition. The tub was stopped up and the toilet overflowed. The floors were in poor condition. The wooden floors had many splinters and cracks. There was carpeting in the living room and dining room. The linoleum in the kitchen was coming up off the floor. The yard contained grass, cement and dirt. There was a silver, rusty chain-linked fence in the yard. There was a wooden shed in the yard that had peeling paint on it. There was no porch or railing outside the house. There was flaking paint outside the house on the windows. There were no replacement windows in the house. There was no nearby industry, demolition or construction in the area. The nearest major roads were Harford Road and North Avenue. The house was not inspected for lead. Source of heat was gas vents.

ABATEMENT INFORMATION:

Before Shayonna was born, the house at 2406 Eager Street was remodeled by the grandfather approximately 6-10 years ago. Mother is not sure how the house was deleaded. Grandfather did the clean-up in the house. Mother does not know any other details about the abatement.

ADDITIONAL INFORMATION:

Mother sweeps, wet mops and wipes the counters everyday. She uses bleach, Comet and Pine Sol to clean the house. She does not own a vacuum cleaner. Shayonna plays all over the inside of the house. There are no pets inside the home. She does not have a painted crib.

SUPPLEMENTAL HOUSING:

Shayonna spends the night sometimes or a few hours during the day with her father, Kenyon Featherstone in his home off of Northern Parkway.

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She usually visits him 2-3 times a week. His telephone number is 532-8163. His home is in excellent condition. She also spends sometime with her father in a townhouse at 1216 E. Lanvale Street. This too is in good condition. She does not currently attend school. She used to go to a babysitter in the 1500 block of Eden Street. She also used to go to a babysitter at 1703 Caroline Street. This was the home of Delores Weatherby.

HAND-TO-MOUTH ACTIVITY:

Shayonna has been observed to chew on paper, plaster, paint, and toys. When you walk in the door of the current home, there is a small hole in the wall where Shayonna likes to put her hand in the hole and then suck on her hand. She has been observed to suck her thumb, but not her fingers. She does not bite her nails.

DIET:

Shayonna has a good appetite. She is WIC-certified. She drinks 32 ounces per day of whole milk. She eats cheese, yogurt and ice cream. She has no symptoms of milk intolerance. She eats six eggs a week. She eats a variety of meats including chicken, pork chops, and liver. She also eat fish, ground beef, meatloaf and spaghetti. She does not eat braunschweiger. She eats a variety of green vegetables and eats corn. She eats a variety of fruits including bananas and grapes. She drinks citrus or fruit juice everyday. She eats a variety of snacks including potato chips, candy and cookies. The family fries foods in Crisco oil or shortening. She does trim the fat from meat. She sometimes cooks with fatback.

BEHAVIOR AND SYMPTOMS:

Mother has not noted any anorexia, constipation, irritability, behavior changes, sleep changes in her daughter.

SOCIAL HISTORY:

The current family income includes $511 dollars per month from AFDC and $400 dollars per month from food stamps. The current household includes: Barbara Hunter, 38 year old maternal grandmother; Qui-Nette Hall, 31 year old aunt; Sharon Jackson, 17 year old mother; Theodore Cotton, 12 year old uncle; Shayonna, the patient and Keona Featherstone, 1 year old sister. Mother is currently not pregnant. She is not currently employed outside of the home.

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PAST MEDICAL HISTORY:

Mother had good health during pregnancy. The baby was delivered at Johns Hopkins Hospital. She was born via full-term, spontaneous vaginal delivery. She breathed and cried immediately. Birth weight was 8 pounds, 7 1/2 ounces. There were no neonatal problems. Mother and child were discharged home after 48 hours.

DEVELOPMENTAL HISTORY:

Shayonna rolled at 4 months, sat at 5 months, crawled at 7-8 months and walked at 13 months. She currently uses single words and phrases. Shayonna receives her primary medical care from the TAC Clinic. She does not take medication on a regular basis. She has no history of recent exposure to childhood diseases. She has a history of frequent ear infections and had PE tube placement in February, 1994. She has no known drug allergies. Her immunizations are up-to-date.

PHYSICAL EXAMINATION:

Weight - 15.9 kg
Height - 86 cm
Pulse - 106
Blood Pressure - 100/48

General physical examination is noted for obesity, but is otherwise within normal limits. Neurological examination is within normal limits.

LABORATORY DATA:

LAB DATA: Hct - 34; FEP(wb) - 25; FEP(rbc) - 74; PbB - 19, 21 µg/dL whole blood. These laboratory results were shared with mother.

SOCIAL WORK:

During today's clinic appointment, Linda Creighton of Social Work met with Shayonna and her mother who identified housing as a concern. Ms. Jackson was given lead-free housing referral letters to the following agencies: City Homes, Regional Management, Denmore Gardens Apartments and St. Ambrose Housing and Center. Ms. Jackson appears to be an invested mother who is concerned about the well-being of her children. She was given positive reinforcement for her efforts with her children and for obtaining her G.E.D.

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IMPRESSION:

1. Plumbism, CDC Class III; lower end.
2. Obesity.
3. History of ear infections, status post PE tube placement.

DISPOSITION:

1. Cleaning, dietary, and behavior recommendations were reviewed with mother who appears to have a good understanding of these issues. She was given multiple handouts on lead poisoning prevention.
2. As stated above, during today's clinic appointment, mother met with our social worker, Linda Creighton.
3. Follow-up in the KKI Lead Clinic on Wednesday, December 7, 1994 at 1:00 p.m.

Cecilia T. Davoli, M.D.
Developmental Pediatrics

cc: Dr. Chisolm
PMP - TAC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al.	*	
Plaintiffs	*	
v.	*	**Case No. 1:07-CV-01120**
KENNEDY KRIEGER INSTITUTE, INC., et al.	*	
Defendants	*	

* *

EXHIBITS TO PLAINTIFFS' MEMORANDUM

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Exhibit 2	Defendants' Notice of Removal, Exhibit D, page 9	3
Exhibit 3	*Grimes, et. al., v. Kennedy Krieger Institute, Inc., et al.*, 366 Md. 29, 50	3
Exhibit 4	November 23, 1992, Technical Plan Prepared by KKI, et al., page 30	5
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Exhibit 6	November 23, 1992, Technical Plan Prepared by KKI, et al., page 15	7
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Exhibit 11	September 20, 1995, Correspondence from Janet Serwint to Jeanne Butta	10
Exhibit 12	Memorandum Ruling of Hon. William N. Nickerson, *Wallace, et al., v. Kennedy Krieger Institute, Inc., et al.*, Civil Case No.: WMN-07-1140 @ 6, (D. MD. August 14, 2007)	11, 25, 29, 34
Exhibit 13	Transcript of May 5, 1997, deposition of Mark Farfel, *Higgins, et al., v. Polakoff, et al.,* Baltimore City Circuit Court Case No. 95066067, page 6 @ line 17-21	11
Exhibit 14	June 21, 1995, Clinical Investigation Consent Form for Keona Featherstone	12
Exhibit 15	February 10, 1993, Correspondence of Thomas R. Hendrix, Chairman-JCCI to J. Julian Chisolm approving Research Proposal Number 92-11-19-01	12
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Exhibit 17	Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Coles, et al., v. Kennedy Krieger Institute, et al.,* Circuit Court for Baltimore City Case No.: 24-C-01-004337, page 49	13, 34
Exhibit 18	Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Id.*, page 38, lines 15-21	13
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Exhibit 31	Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Id.*, pages 44-45	21
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Exhibit 33	Transcript of October 8, 2003, Deposition of Clark H. McNutt, *Id.*, page 37, lines 5-21	22
Exhibit 34	June 12, 1995, loan agreement for 2418 Jefferson Street between the NACI Corporation and the Maryland Department of Housing and Community Development	23
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Exhibit 38 — June 29, 1993, NIEHS Award/Contract for the TLC study to KKI, pages 9-10 30

Exhibit 39 — June 20, 2003, Deposition of Constance J. Cosky, *Coles, et al., v. KKI, Inc., et al.*, 24-C-01-004337, pages 40-41. . . . . 34, 35

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, ET AL.	*	
Plaintiff,	*	
v.	*	
KENNEDY KRIEGER INSTITUTE, INC., et al.,	*	**Case No. 1:07-CV-1120**
Defendants.	*	

* * * * * * * * * * * * *

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO REMAND

Defendants Kennedy Krieger Institute, Inc., Cecilia Davoli, M.D., The Johns Hopkins University, The Institutional Review Board of the Johns Hopkins University School of Medicine Joint Committee on Clinical Investigation, Thomas R. Hendrix, M.D., Lewis C. Becker, M.D., David R. Cornblath, M.D., Paul Lietman, M.D. and Hayden G. Braine, M.D., by their undersigned counsel, respectfully oppose the Plaintiffs' Motion to Remand and for reasons state:

1. The Treatment of Lead-exposed Children ("TLC") Study is an independent study, unconnected with the Repair and Maintenance ("R&M") Study or any prior research involving children previously exposed to lead paint.

2. Unlike the R&M Study, the TLC Study was a clinical study designed to measure the effectiveness of succimer, a blood chelator known to be successful in reducing blood lead levels. Prior to the commencement of the TLC Study both Keona Featherstone and Shayonna Featherstone had significantly elevated blood lead levels.

3. As Project Officer of the TLC Study, Dr. Walter J. Rogan of the National

Institute of Environmental Health Sciences ("NIEHS") directed and controlled the Defendants' involvement in the design, implementation and follow-up of the TLC Study. Through Dr. Rogan, NIEHS maintained detailed, hands-on control over all phases of this government-sponsored and funded study.

4. The Honorable William Nickerson of this Court recently remanded *Dontae Wallace, et al. v. Kennedy Krieger Institute, et al.* to state court. Judge Nickerson's reasons for remanding *Wallace* are not present in this case because the Notice of Removal and supporting affidavits demonstrate that Dr. Rogan exercised direct and detailed control over the TLC Study. Furthermore, the focus of the TLC Study was to measure the effectiveness of succimer on reducing blood lead levels and not lead remediations of study participants' houses. To the extent that Kennedy Krieger cleaned homes where lead was previously present, they did so pursuant to NIEHS's mandate found in the Contract, the Trial Protocol and the Manual of Operations for the TLC Study.

5. Defendants adopt and incorporate by reference the Memorandum of Law attached hereto.

WHEREFORE, for the aforementioned reasons and the arguments articulated more fully in the accompanying Memorandum of Law, Defendants request that this Court exercise original jurisdiction over this case and that the Plaintiffs' Motion to Remand be denied.

Respectfully submitted,

/s/

Barry C. Goldstein
(Federal Bar No. 34796)
John T. Sly
(Federal Bar No. 26608)
Nicole A. McCarus
(Federal Bar No. 27971)
Waranch & Brown, LLC
1301 York Road, Suite 300
Lutherville, Maryland 21093
410-821-3511

Attorneys for Defendants Kennedy Krieger Institute and Cecilia Davoli, M.D.

/s/

Natalie C. Magdeburger
(Bar No. 7722)
Raymond L. Marshall
(Bar No. 25162)
Whiteford Taylor Preston LLP
210 W. Pennsylvania Avenue
Towson, MD 21204
(410) 832-2000

Attorneys for Defendants The Johns Hopkins University, The Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, M.D., Lewis C. Becker, M.D., David R. Cornblath, M.D. Paul Lietman, M.D. and Hayden G. Braine, M.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al. *

Plaintiffs *

v. *

KENNEDY KRIEGER INSTITUTE, INC., et al. *

Defendants *

Case No. WMN 07 CV 1120

****

NOTICE OF REMOVAL

TO: United States District Court for the District of Maryland:

Pursuant to 28 U.S.C. § 1442 (a)(1), Defendants Kennedy Krieger Institute, Inc. ("Kennedy Kreiger"), and Cecilia Davoli, M.D. (collectively referred to as the "Kennedy Krieger Defendants"), hereby remove this action, *Shayonna Featherstone, et al. v. Kennedy Krieger Institute, Inc., et al.*, case number 24-C-07-002027, from the Circuit Court for Baltimore City, Maryland (hereinafter "State Court Action"), to the United States District Court for the District of Maryland (Northern Division), and allege as follows:

1. In 1992, the federal government, through the National Institute of Environmental Health Sciences ("NIEHS")[1], issued a Request for Proposals ("RFP") seeking clinical centers for a study entitled "Toxicity of Lead in Children." The purpose of the study was to determine whether succimer, a drug approved by the United States Food and Drug Administration ("FDA") for use in treating individuals with blood lead levels greater than 45 micrograms per deciliter, could prevent cognitive delay in young children with blood lead levels less than 45 micrograms per deciliter. This action is brought by Shayonna Featherstone, a minor, and Keona Featherstone, a minor, by their mother and next

[1] NIEHS is a subsidiary of the National Institutes of Health ("NIH") itself a branch of the United States Department of Health and Human Services.

friend, Sharon Jackson (collectively "Plaintiffs"), and arises out of Plaintiff Keona Featherstone's participation in this NIEHS sponsored study conducted by Kennedy Krieger and others and is known as the Treatment of Lead-Exposed Children ("TLC") Study. Plaintiffs' Complaint asserts claims of negligence, negligent misrepresentation, civil conspiracy and breach of fiduciary duty against these Defendants and others and seeks damages in the amount of Four Million Dollars ($4,000,000). *See* Plaintiffs' Complaint, a copy of which is attached hereto as Exhibit A.

2. This Court has jurisdiction over this removal action under 28 U.S.C. § 1442(a)(1) because Plaintiffs filed a civil action in a State court against the Kennedy Krieger Defendants, who were acting under the control of an United States agency. Specifically, Plaintiffs' negligence claims directly call into question Kennedy Krieger's compliance with the contract it entered into with the NIEHS as well as Kennedy Krieger's compliance with the detailed and comprehensive framework of federal regulations that govern research on human subjects.

3. 28 U.S.C. § 1442(a)(1) governs removal for conduct performed under color of federal office. The Supreme Court has "held that the right of removal is absolute for conduct performed under color of federal office, and has insisted that the policy favoring removal 'should not be frustrated by a narrow, grudging interpretation of § 1442(a)(1).'" *See Arizona v. Manypenny*, 451 U.S. 232, 242, 101 S.Ct. 1657 (1981).

4. The purpose of the liberal removal policies underlying section 1442(a)(1) is to protect federal officers and their agents when they conduct business in the states. *See Durham v. Lockheed Martin Corp.*, 445 F.3d 1247, 1252-53 (9th Cir. 2006). "If the federal government can't guarantee its agents access to a federal forum if they are sued or prosecuted, it may have difficulty finding anyone willing to act on its behalf." *Id.* at 1253.

JURISDICTIONAL BASIS FOR REMOVAL

5. This Court has jurisdiction under 28 U.S.C. §1442(a)(1) because: (1) Kennedy Krieger and Dr. Davoli are considered "persons" within the meaning of the statute; (2) the Kennedy Krieger Defendants were acting at the direction of an officer of the United States; (3) a causal nexus exists between Plaintiffs' claims and the Kennedy Krieger Defendants actions under color of federal office; and (4) the Kennedy Krieger Defendants can assert a colorable federal defense. *See e.g., Mesa v. California,* 489 U.S. 121, 125-35 (1989); *Pack v. A.C. and S., Inc.*, 838 F.Supp. 1099, 1101 (D.Md. 1993), *reconsideration denied*, 857 F.Supp. 26 (D.Md. 1994) (holding that 28 U.S.C.§ 1442(a)(1) is satisfied when the moving party can demonstrate that (1) it acted under the direction of a federal officer; (2) it raises a federal defense to plaintiff's claims; and (3) demonstrates a causal nexus between plaintiff's claims and acts it performed under color of federal office). Pursuant to U.S.C. § 1442, a defendant acting under the direction of a federal officer of the United States can unilaterally remove a case to federal court. *See Durham v. Lockhead Martin Corp.*, 445 F.3rd at 1253. *See also Plourde v. Ferguson*, 519 F. Supp. 14, 16 (D.Md. 1980) (Single defendant can remove case from state court to federal court regardless of whether other defendants join in removal petition.)

A. Kennedy Krieger is a "person" under 28 U.S.C. § 1442 (a)(1)

6. Kennedy Krieger qualifies as a "person" as required by 28 U.S.C. § 1442 (a)(1). In *Pack*, this Court held that private corporations, like Kennedy Krieger, are "persons" for purposes of the statute. 838 F.Supp. at 1103.

B. The Kennedy Krieger Defendants were acting under the direction of the United States Government.

1. The Kennedy Krieger Defendants were acting under the direction and control of the National Institute of Environmental Health Sciences

7. The extent of control necessary to bring an individual within the person "acting under" clause of § 1442(a) has been broadly construed. *In re Methyl Tertiary Butyl Ether Products Liability*

Litigation, 342 F.Supp.2d 147, 154-155 (S.D.N.Y. 2004). Federal officer removal is appropriate when the removing party is subject to the direct and detailed control of the federal government. *Pack*, 838 F.Supp. at 1103. "Direct control is established by showing strong government intervention and the possibility that a defendant will be sued in state court as a result of the federal control." *Id.* (citing *Fung v. Abex Corp.*, 816 F. Supp. 569, 572 (N.D.Cal. 1992)); *see also McMahon v. Presidential Airways, Inc.*, 410 F.Supp.2d 1189, 1197 (M.D. Fla. 2006) (holding that private air transportation companies that contracted with the United States government were acting under the direction of a federal officer and met the federal officer removal standard, whereby "the government maintained control over the manner in which the contractor performed the contracted work or *monitored* the performance of the work")(citing *Watson v. Philip Morris Cos.*, 420 F.3d 852, 857 (8th Cir. 2005)) (emphasis added).

8. The federal government directed and controlled all of Kennedy Krieger's activity in the design, implementation and follow up of the TLC study. The federal government, through NIEHS, maintained detailed, hands-on control over all phases of this government sponsored and funded study. The following paragraphs provide a summary of the intimate and meticulous control the federal government maintained over the TLC study.

9. The genesis of the TLC study was an RFP issued by NIEHS. That document contains the government's rationale for embarking on this particular study:

> NIEHS has...supported clinical studies leading to the licensure of the drug succimer, an orally administered chelating drug now labeled for use in children with blood lead levels above 45 ug/dl, a level thought to indicate a high risk for symptomatic lead poisoning and above the levels that produce cognitive delay....The Centers for Disease Control and the American Academy of Pediatrics have revised downward the blood lead levels of concern in young children, and children with blood lead levels greater than 10 ug/dl are now thought to have unacceptable exposure to lead. **NIEHS believes that large numbers of children with blood lead levels below 45 ug/dl will be treated with succimer, and that a clinical trial of the use of succimer in the prevention of lead-associated cognitive delay in young children is both necessary and timely.**

NIEHS Request for Proposals, Section C.1 attached hereto as Exhibit B (emphasis added).

10. NIEHS unequivocally articulated in the RFP that control over the timing parameters for each and every aspect of the TLC study would rest with NIEHS. Furthermore, NIEHS directed the criteria for enrolling into this study. Finally, NIEHS mandated the areas of focus in analyzing the study's data:

> The trial **shall** proceed as follows: 9-12 months for planning; about 1 year for patient enrollment and treatment; the remaining 3 years for follow-up....The trial is of oral chelation therapy with the drug succimer in lead exposed children (blood leads of about 20 ug/dl to 45 ug/dl) of about 18 to 36 months of age. The endpoints are the scores on developmental tests; other endpoints of interest include evidence of drug efficiency and compliance, such as urine and blood lead levels; excretion of other ions like iron, zinc, and calcium; and nervous system, renal and hematopoietic function/toxicity.

Id. at C.2 (emphasis added.) Kennedy Krieger drafted its "proposal" within the specific criteria set forth by NIEHS.

11. In response to Kennedy Krieger's "proposal", NIEHS drafted a contract and forwarded it to Kennedy Krieger for signature.[2] No one from Kennedy Krieger participated in the preparation of that Contract. *See* Affidavit of Merrill Brophy attached hereto as Exhibit C, paragraph 3. This government contract served as the basis for the relationship between NIEHS and Kennedy Krieger in conducting the TLC study. *See* Contract attached hereto as Exhibit D.

12. After the signed contract was approved by NIEHS's contracting officer, the NIH Board of Contract Awards was required to review and provide final approval. *See* June 25, 1993 letter from Thomas M. Hardee, NIEHS Contracting Officer, to Karen Sorenson, Contract Administrator for Kennedy Krieger attached hereto as Exhibit E.

[2] This was a multi-center study and, accordingly, NIEHS contracted with three other Clinical Centers to conduct the TLC study in addition to Kennedy Krieger. Those other sites were Cincinnati, Philadelphia and New Jersey.

13. At the inception of the contractual relationship between NIEHS and Kennedy Krieger, the NIEHS Contracting Officer appointed Walter Rogan, M.D. as Project Officer and Beth Ragan as Alternate Project Officer to oversee the TLC study. *See* June 25, 1993 Department of Health and Human Services Memorandum attached hereto as Exhibit F. This memorandum provides a detailed outline of the Project Officer's duties which require, among other things, that the Project Officer:

> Maintain complete surveillance of the technical performance and contact with the contractor in order to give reasonable assurance that all specified contract deliverables are delivered on time and are in accordance with the specifications/requirements of the contract terms.

Id. (*See also*, Paragraph 14, *infra*).

14. The contract contained a detailed description of the estimated cost of the study including specific instructions regarding permissible expenditures such as salary rate limitations, restrictions on travel expenses, patient care costs, patient enrollment incentives, and permissible expenditures for house "clean-up." The Principal Investigator at Kennedy Krieger (and all clinical sites) was required to seek approval from NIEHS in order to allocate funds for *any* purpose that deviated *in any way* from the contract as drafted by NIEHS. *See* Affidavit of Cecilia Davoli, M.D., attached hereto as Exhibit I, paragraph 11; July 1995 letter from Kennedy Krieger to NIEHS regarding approval for funds attached hereto as Exhibit G.

15. The contract governing Kennedy Krieger's conduct in connection with the TLC study adopted *verbatim* the language contained in NIEHS's RFP expressing the rationale for why NIEHS believed this study was necessary. Further, the Statement of Work section of the contract, in describing the specific criteria to be used in protocol development, adopted *verbatim* the study criteria initially set forth by NIEHS in its RFP:

> The trial **shall** proceed as follows: 9-12 months for planning; about 1 year for patient enrollment and treatment; the remaining 3 years for follow-up....The trial is of oral chelation therapy with the drug succimer in lead exposed children (blood leads of about 20

> ug/dl to 45 ug/dl) of about 18 to 36 months of age. The endpoints are the scores on developmental tests; other endpoints of interest include evidence of drug efficiency and compliance, such as urine and blood lead levels; excretion of other ions like iron, zinc, and calcium; and nervous system, renal and hematopoietic function/toxicity.

Exhibit D at p. 10. NIEHS directed the Steering Committee, subject to federal government approval, to further develop the protocol and strategies for the TLC trial. This committee consisted of the NIEHS Project Officer, the Principal Investigators of the Central Lab (in this case the lab at the Centers for Disease Control, also a branch of the United States Department of Health and Human Services), as well as the Principal Investigators of each Clinical Center participating in the study (Kennedy Krieger was one of four Clinical Centers) and the Principal Investigator of the Coordinating Center (Harvard School of Public Health). *Id.* The NIEHS Project Officer and Alternate Project Officer participated in nearly every subcommittee created for the TLC study. *See* Protocol attached hereto as Exhibit H at 40-42. *Id.*

16. The NIEHS Project Officer supervised regular meetings and conference calls with Kennedy Krieger and the other centers regarding study design to ensure that the plans developed consistent with NIEHS objectives. *see* Affidavit of Cecilia Davoli, M.D. attached hereto as Exhibit I at ¶ 4; *see also*, Exhibit C at ¶ 4. Final authority over each and every aspect of this study rested with the NIEHS Project Officer. *Id.* at ¶ 5. *see also* Exhibit D at ¶ 21. Pursuant to the contract, Kennedy Krieger did not have the authority to deviate from the NIEHS approved study protocol. Indeed, NIEHS retained the ability to terminate the contract if Kennedy Krieger deviated from the study protocol. "Failure of the contractor to abide by the approved shared protocol may result in the termination in accordance with the termination clause." *See* Exhibit D at ¶19.

17. Pursuant to federal regulation (*see* ¶¶ 25-29, *infra*), Kennedy Krieger was required to obtain Institutional Review Board ("IRB") approval of the Informed Consent Form to be utilized in enrolling study participants. After the local IRB utilized by Kennedy Krieger approved a form, Kennedy Krieger was required to forward that form to the NIEHS' own IRB for further review. The

NIEHS IRB initially rejected the Kennedy Krieger Consent Form because the reading level required for comprehension of the Consent Form was too high. *See* Exhibit C at ¶ 10 and Exhibit I at ¶ 12. Only after Kennedy Krieger revamped its form, secured local IRB approval again and resubmitted the form to NIEHS was it approved such that the study could proceed. *Id.*

18. NIEHS imposed substantial reporting requirements on the Clinical Centers participating in the study. Kennedy Krieger was required to submit to NIEHS technical reports as well as racial/ethnic enrollment reports. Exhibit D at 15. During the first year of the study, Kennedy Krieger submitted semi-annual reports that described the progress in planning, recruitment, community activity and screening with particular emphasis on the material not covered in the Steering Committee meetings. *Id.* For all subsequent years, Kennedy Krieger submitted quarterly reports outlining the numbers of families contacted and screened, all activities planned and all activities executed during the reporting periods, again with particular emphasis on the materials not covered in the Steering Committee meetings. *Id.* NIEHS also required Kennedy Krieger to submit enrollment reports providing a summary of the planned study population and a summary of the actual number of participants enrolled according to designated racial/ethnic categories. *Id.*

19. NIEHS also maintained oversight of the study's implementation through periodic site visits. *See* Exhibit C at ¶ 6 and Exhibit I at ¶ 7. These visits were conducted to ensure that Kennedy Krieger was complying with the TLC study protocol. *Id.* During these visits, the NIEHS Project Officer reviewed study participant charts[3] to ensure compliance with federal regulations, observed the study facilities, and conducted visits to houses involved in the study. *Id.*

20. This study, as noted above, involved assessment of the drug succimer under certain clinical conditions. Because this drug was not approved by the FDA for use under those conditions, NIEHS submitted an Investigational New Drug ("IND") application to the FDA. *See* Exhibit D at p.13;

[3] The FDA imposes regulations regarding how researchers should document their use of investigational new drugs.

See also, Exhibit C at ¶ 8 and Exhibit I at ¶ 8. Because NIEHS held the IND for the use of Succimer in children with blood lead levels less than 45 micrograms per deciliter, NIEHS's Project Officer was actively engaged in ensuring that the Clinical Centers understood Succimer's biochemical behavior. *Id.*

21. The TLC study was fully funded by NIEHS with support from the Office of Research on Minority Health of the National Institutes of Health ("ORMH, NIH"). *See* Exhibit H at ¶ 2.2.

22. In addition to NIEHS, the United States Centers for Disease Control ("CDC") was actively involved in the TLC study. The CDC laboratory in Atlanta, Georgia, served as the central laboratory and performed blood lead analysis on all study participants. *Id.* at p. 28. Managers of the CDC participated on several TLC study committees. *Id.* at pp. 40-42.

23. The CDC had responsibility for all activities related to drawing study participants' blood. *See* Exhibit C at ¶ 9 and Exhibit I at ¶ 9. Prior to the implementation of the Study, the CDC held a training session for all Clinical Centers to ensure that all centers were drawing blood consistent with CDC protocol. *Id.* In addition to training, the CDC provided the Clinical Centers with the supplies needed to draw study participants' blood as well as the supplies needed to send the blood samples to the CDC lab in Atlanta. *Id.*

24. The intimate control exercised by NIEHS over the TLC study extended through to the study's conclusion. NIEHS prohibited Kennedy Krieger from writing-up and summarizing the results of the study absent NIEHS approval. Exhibit D at pp.11, 13.

2. Kennedy Krieger was acting under the authority of the United States Congress and the Department of Health and Human Services

25. In addition to the federal government's active involvement in the creation, design, and implementation of the TLC study pursuant to its contract with Kennedy Krieger, the actions of Kennedy Krieger were at all times subject to exceedingly complex regulations and guidelines in the conduct of this research study. *See* 42 U.S.C. § 289; 45 CFR § 46.101, et seq. For example, when conducting research on human subjects, the federal government requires an Institutional Review Board ("IRB") to

approve the study. 42 U.S.C. § 289. The IRB is essentially an oversight committee that "shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy." 45 C.F.R. § 46.109(a). Federal regulations further govern, among other things, the membership of the IRB (45 C.F.R. § 46.107); IRB functions and operations (45 C.F.R. § 46.108); the review procedures that the IRB may use in certain types of research (45 C.F.R. § 46.109); additional protections for children involved as subjects in research (45 C.F.R. § 406); and criteria for IRB approved research (45 C.F.R. § 46.111).

26. Exercising removal jurisdiction will also promote uniformity in the application and interpretation of the federal laws at issue. According to a Guidebook published by the DHHS, the regulations cited in Plaintiffs' Complaint and relied upon by the Plaintiffs were promulgated by sixteen federal agencies that conduct, support, or regulate human research. *See* Exhibit J, Department of Health and Human Services Institutional Review Board Guidebook Introduction. The DHHS Guidebook chronicles the detailed and deliberative process the federal government employed in arriving at the regulations at issue here. *Id.*

The Introduction states:

> The DHHS regulations are codified at Title 45 Part 46 of the Code of Federal Regulations. Those "basic" regulations became final on January 16, 1981, and were revised effective March 4, 1983, and June 18, 1991. The June 18, 1991, revision involved the adoption of the Federal Policy for the Protection of Human Subjects. **The Federal Policy (or "Common Rule," as it is sometimes called) was promulgated by the sixteen federal agencies that conduct, support, or otherwise regulate human subjects research**; the FDA also adopted certain of its provisions. **As is implied by its title, the Federal Policy is designed to make uniform the human subjects protection system in all relevant federal agencies and departments.** The Federal Policy is discussed in depth in Chapter 2, Section A(i).

Id. (emphasis added).

27. A substantial federal interest exists in the uniformity of interpretation and application of federal laws governing scientific research involving children.

28. Because the TLC study involved use of an Investigational New Drug Exemption, Kennedy Krieger was also required to comply with extensive FDA regulations controlling the use of IND's.

29. These regulations expressly and in great detail governed Kennedy Krieger's handling of all aspects of the TLC study including enrolling study participants, obtaining informed consent and ensuring study participant safety.

C. A causal nexus exists between Plaintiffs' claims and Kennedy Krieger's actions pursuant to its contract with the National Institute of Environmental Health Sciences

30. The causal nexus prong requires that Plaintiffs' suit arise out of acts by Kennedy Krieger taken pursuant to the direction of a federal officer. *See Pack*, 857 F.Supp. at 28. A direct causal relationship exists between Plaintiffs' claims and Kennedy Krieger's actions under color of federal office. The allegations made against the Kennedy Krieger Defendants in Plaintiffs' Complaint and their relationship to action taken by the Kennedy Krieger Defendants pursuant to formal authority are summarized in the following chart:[4]

Plaintiffs' Allegations	**Conduct of Kennedy Krieger Taken Pursuant to Federal Authority**
"The parents of TLC research subjects, including the Plaintiffs, were not informed by KKI or Davoli that drugs like succimer should not be used as a substitute for the complete abatement of lead hazards to which a child is exposed nor were they informed that succimer should not be used on a child who continues to be exposed to lead hazards." *See* Complaint, Exhibit A at ¶ 8.	The process for enrolling Study participants and the information provided to Study participants was directly controlled by NIEHS in the Contract. *See* Contract, Exhibit D at 11 and the Steering Committee, *Id.* at 10. The Informed Consent provided to Study participants was governed by NIEHS, and through the Contract. *See* Contract, Exhibit D at § H; Exhibit C at ¶ 10; Exhibit I at ¶ 12.

[4] To the extent that this Court finds that Plaintiffs have asserted non-federal claims, it is appropriate for the Court to exercise its supplemental jurisdiction. *Rosmer v. Pfizer Incorporated*, 263 F.3d 110 (4th Cir. 2001); *Shanaghan v. Cahill*, 58 F.3d 106, 109 (4th Cir. 1995); *Parker, PPA v. Della Rocco, Jr.*, 252 F.3d 663, 665 (2nd Cir. 2001) (holding that the exercise of supplemental jurisdiction was appropriate after an agent of the federal government properly removed an action to federal court pursuant to 28 U.S.C. § 1442 (a)(1)).

"Via the Informed Consent Form ("IC") Parents and guardians of the children used in the TLC Study were promised that during the "treatment phase another doctor would know the results of blood-lead tests (in case their [was] a problem" and that the childrens' blood-lead levels would also be reported to the Baltimore City Health Department." *See* Complaint, Exhibit A at ¶ 9.	Measures taken to insure the safety of the Study participants was covered by the protocol created under the direct supervision of the NIEHS Project Officer (*See* Protocol, Exhibit H) and is further governed by Federal Regulation. ***See* ¶¶ *23-25.*** Obtaining of informed consent in the Study was governed by the NIEHS by the Contract and by Federal Regulation. Furthermore, the researcher/subject relationship Kennedy Krieger entered into was based solely on the NIEHS Contract, NIEHS approved trial protocol, and the NIEHS approved Informed Consent form; Exhibit C at ¶ 10, Exhibit I at ¶ 12.
"Via the IC Parents and the guardians of the children used in the TLC Study were promised that KKI and Davoli and/or their agents such as Lady "H" would clean up the lead in the homes of the study subjects." *See* Complaint, Exhibit A, ¶ 12.	Kennedy Krieger monitored and "cleaned" Plaintiffs' residences to the extent that it was required to pursuant to its Contract with NIEHS and the NIEHS approved trial protocol. *See* Contract, Exhibit D at 10, 13; Protocol, Exhibit H at 18-20; Exhibit C at ¶ 10, Exhibit I at ¶ 12.
"Pursuant to 45 C.F.R. § 46.101 (2005) approval and oversight by an Institutional Review Board (IRB) is required whenever research on human beings is conducted, supported, or is subject to federal regulation." Md. Code Health Gen. Art. § 13-201, *et seq.* (2005) requires that all research conducted in Maryland on human subjects to be conducted in compliance with federal regulations, regardless of the source of funding and/or support for the research." *See* Complaint, Exhibit A at ¶ 16.	The measures taken to insure the safety of Study participants was covered by the protocol created under the direct supervision of the NIEHS Project Officer. *See* Protocol, Exhibit H. It is further governed by federal regulation. *See* ¶¶ 23-25, *infra.;* Exhibit C at ¶ 10, Exhibit I at ¶ 12.
"There was no direct benefit to the child research subjects from participating in the TLC Study and the monitoring procedure employed in the TLC Study, including but not limited to "blinding" the results of Plaintiffs' blood-lead tests, was less beneficial to the child research subjects' well-being than the monitoring regime already in place." *See* Complaint, Exhibit A at ¶ 21.	The use of "blinding" blood-lead tests results was approved and required by the NIEHS Protocol. *See* Protocol, Exhibit H at 2.
"The IRB assisted the TLC study investigators in concealing the fact that the child research subjects would be placed in serious risk of permanent harm as a result of participating in the study, and concealing that recognize and approved therapies already existed for children with similar lead levels, to wit, the removal from the leaded environment." *See* Complaint,	Information provided to the TLC participants and their guardians were governed by the trial protocol. *See* Protocol, Exhibit H; Exhibit C at ¶ 10, Exhibit I at ¶ 12.

Exhibit A at ¶ 23.	
"The Defendants knew, or should have known, that the properties identified in paragraphs 4 (a) and 4 (b), contained numerous surfaces covered in lead-based paint. However, KKI, Davoli and/or their agents nonetheless represented to the Plaintiffs' family, the Plaintiffs' treating physician, and to the Baltimore City Health Department, hereinafter BCHD, that the homes were free of lead hazards." *See* Complaint, Exhibit A at ¶ 30.	Provision of information and obtaining of informed consent in the Study, was governed by the NIEHS and. and through the Contract and by Federal Regulation. *See* Exhibit C at ¶ 10, Exhibit I at ¶ 12.
"Prior to the lease of the premises to the property set forth in paragraphs 4 (a) and 4 (b), Baltimore, Maryland, the Defendants herein negligently made, and/or negligently permitted to be made misrepresentations to the Plaintiffs and their families regarding the condition of the premises." *See* Complaint, Exhibit A at ¶ 43.	The process of enrolling Study participants was directly controlled by the NIEHS Contract (*See* Contract, Exhibit D at 11) and by the Steering Committee (*See Id.* at 10). Moreover, the informed consent provided to the study participants was governed by NIEHS in and through the Contract as well as by federal regulation. *See* Contract, Exhibit D at Attachment 8; Exhibit C at ¶ 10 and Exhibit I at ¶ 12.
"The Defendants, KKI, JHU, the IRB and Davoli, by virtue of the IC form, entered into an agreement with the Plaintiffs, that in exchange of the Plaintiffs' participation in the TLC Study, the Defendants herein assumed a duty to: ensure that all children in the TLC Study, including the Plaintiffs, had their homes repaired and/or cleaned to get rid of lead dust and chipped paint, to carefully inspect the properties identified in paragraphs 4(a) and 4(b) to see if they could be repaired and/or cleaned to eliminate lead hazards, if the home did not qualify, the Defendants would assist with relocation to housing that was known to be free from lead-hazards, the Defendants would eliminate any lead hazards in the home, ensure that a doctor would monitor the blood-lead levels of the Plaintiffs and promptly and accurately report those test results to the family of the minor Plaintiffs and to the Baltimore City Health Department, and the Defendants also assumed a duty to provide ongoing medical care of the Plaintiffs' lead paint poisoning and lead toxicity." *See* Complaint, Exhibit A at ¶ 61.	The process for enrolling Study participants was directly controlled by NIEHS and the Contract. *See* Contract, Exhibit D at 11, and by the Steering Committee, *See Id.* at 10. Moreover, the informed consent provided to study participants was governed by NIEHS in and through the Contract as well as by federal regulation. *See* Contract, Exhibit D at Attachment 8; Exhibit C at ¶ 10 and Exhibit I at ¶ 12.
"The Defendants KKI and JHU warranted and agreed to the United States Department of	The TLC Study was conducted pursuant to the Contract with NIEHS (*See* Contract, Exhibit D)

Health and Human Services, hereinafter referred to as DHHS, prior to the constitution of, and during the administration of the TLC Study, that all human research at KKI would be conducted in accordance with the terms of the Belmont Report. *See* Ethical Principles and Guidelines for the Protection of Human Subjects of Research, promulgated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979. The Defendants agreed to abide by the ethical duties and obligations set forth within the Belmont Report in furtherance of the Defendants' KKI and JHU Agreement with DHHS under a Multiple Project Assurance Agreement, hereinunder MPAA. This agreement existed prior to the tortuous acts alleged herein." *See* Complaint, Exhibit A at ¶ 67.	and by the Steering Committee (*See Id.*).
"The minor Plaintiffs allege that the Defendants herein, and each of them, by agreement or understanding agreed to materially breach their duties set forth within the IC to the child research subjects used in the TLC Study, including the minor Plaintiffs. *See* Complaint, Exhibit A at ¶ 78."	KKI's actions and relationship with the study participants was governed by the trial protocol and the Contract with the NIEHS. *See* Contract, Exhibit D; see trial protocol, Exhibit H.

31. In sum, the rationale for and purpose of the TLC study is contained in the RFP and Contract, both of which were prepared and promulgated by the federal government. This research study was conducted and implemented pursuant to protocol developed and approved by NIEHS, an agency of the federal government. Kennedy Krieger's recruiting and enrollment of study participants was regulated in great detail by not only the contract approved by NIEHS, but also through an elaborate regulatory scheme enacted pursuant to federal law. *See* B.2. *infra*. Further, Kennedy Krieger was prohibited from deviating from the directives of the contract and/or the research protocol or in taking any action whatsoever unless directly approved by NIEHS. *See* Exhibits D at 19, C at paragraph 13, and I at paragraph 12.

32. Because Plaintiffs' allegations of wrongdoing against Kennedy Krieger implicate conduct and action taken pursuant to federal regulation and mandated by its contract with an agency of the federal government, a direct causal nexus exists between Plaintiffs' claims and the actions Kennedy Krieger took under color of federal office.

D. The "colorable federal defense" requirement of 28 U.S.C. § 1442 (a)(1) is met because Kennedy Krieger is entitled to assert the government contractor defense.

33. The final element required for removal under 28 U.S.C. § 1442(a)(1) – that the defendant must assert a colorable federal defense – is satisfied by Kennedy Krieger's entitlement to the government contractor defense.[5]

34. The government contractor defense shields a contractor from liability when acting under the direction and authority of the United States. *Tozer v. LTV Corp.*, 792 F.2d 403, 405 (4th Cir. 1986)(citing *Yearsley v. W.A. Ross Construction Company*, 309 U.S. 18, 20 (1940)). In *Yearsley*, the United States Supreme Court stated that "it is clear that if this authority to carry out the project was validly conferred, that is, if what was done was within the constitutional power of Congress, there is no liability on the part of the contractor for executing its will." 309 U.S. at 20-21, 60 S. Ct. at 414-15.

35. *Boyle v. United Technologies Corp.*, 487 U.S. 500 (1988) sets forth the elements required to satisfy the government contractor defense: (1) the United States approved reasonably precise specifications; (2) the contractor's performance conformed to those specifications; and (3) the contractor warned the United States about the dangers associated with the contract that were known to the contractor but not to the United States. *Id.* at 512, 108 S. Ct. at 2518. It is well established that the defense is viable in the context of non-military performance contracts such as the one Kennedy Krieger entered into with NIEHS. *See Boyle*, 487 U.S. at 506, 108 S. Ct. at 2515 (stating that "[t]he federal

[5] For purposes of satisfying 28 U.S.C. § 1442 (a)(1), Kennedy Krieger need not definitively **prove** the asserted defense. It need only articulate it's "colorable applicability to plaintiff's claims." *Jamison v. Wiley*, 14 F.3d 222, 238 (4th Cir. 1994) (citing *Mesa*, 489 U.S. at 133).

interest justifying this holding surely exists as much in procurement contracts as in performance contracts; we see no basis for distinction."); *Richland-Lexington Airport District v. Atlas Properties, Inc.*, 854 F.Supp. 400, 422 (D.SC. 1994)(in holding that the defense applies to performance contracts, the court stated that "the dispositive issue is not one of performance versus procurement, but whether there is a uniquely federal interest in the subject matter of the contract"); *Yeroshefsky v. Unisys Corp.*, 962 F.Supp. 710, 717 (D.Md. 1997)(holding that the government contractor defense is applicable in the civilian as well as military context).[6]

36. Consistent with the first prong of the *Boyle* test, the United States, through NIEHS, approved precise specifications for developing, implementing, and reporting on the TLC study. *See* ¶¶ 5-23. The RFP, Award/Contract, and supervision and participation in the TLC study clearly demonstrate that NIEHS provided reasonably precise specifications. *Id.*

37. As required by the second prong of the *Boyle* test, Kennedy Krieger fully complied with the federal government's detailed specifications. As required by contract, Kennedy Krieger followed the NIEHS approved study protocol throughout its implementation of the TLC study. *See* Exhibit D at p.19. Kennedy Krieger was obligated to follow, and did comply with, the strict and comprehensive requirements imposed by the federal government when conducting research on human study participants. *Id.* at 26; *See also* Exhibit C at ¶ 13 and Exhibit I at ¶ 13.

38. Finally, the third prong of the *Boyle* test is satisfied. Kennedy Krieger did not withhold from NIEHS any information regarding potential dangers associated with the TLC study. As set forth in

[6] Arguably, *Richland* recognized an additional element to the defense. The *Richland* Court suggested that the party claiming the defense must first demonstrate that the conduct at issue constituted a "discretionary function" of the federal government. 854 F.Supp. at 423. Pursuant to this "discretionary function", Kennedy Krieger will not be liable to Plaintiffs if the challenged government action involved an element of judgment or choice and if the challenged government action is based on considerations of public policy. *Id.* Without question, as described herein, the genesis for this study, as expressly articulated in the RFP, was NIEHS's concern regarding (1) the large numbers of children with blood lead levels below 45 micrograms per deciliter will be treated with Succimer and (2) NIEHS's belief that a clinical trial of the use of Succimer in the prevention of lead-associated cognitive delay in young children was both necessary and timely. Exhibit B. This is precisely the type of conduct contemplated in the *Richland* "discretionary function" analysis.

¶¶ 5-28 *supra*, NIEHS was intimately involved in all aspects of the study and therefore was fully aware of all risks and benefits associated with the TLC study.

39. The foregoing facts and analysis establish, at a minimum, that the Kennedy Krieger Defendants are entitled to assert the government contractor defense in this matter.

PROCEDURAL REQUIREMENTS FOR REMOVAL

40. On April 3, 2007, the Kennedy Krieger Defendants became aware of Plaintiffs' Complaint after Defendant Thomas R. Hendrix was served with a copy of the Complaint. On April 16, 2007, counsel for the Kennedy Krieger Defendants sent a letter to Plaintiffs' counsel agreeing to accept service of the Plaintiffs' Complaint. *See* Exhibit K. Because this Notice of Removal is filed within 30 days of the service of the Complaint, it is timely filed under 28 U.S.C. § 1446(b). Copies of all process and pleadings filed in state court are attached to this Notice of Removal as Exhibit L.

41. Kennedy Krieger files and presents herewith the sum of $350.00 as required by Title 28, U.S.C. § 1446.

42. The United States District Court for the District of Maryland (Northern Division) embraces the City of Baltimore in which the state court action is now pending, and thus, this Court is a proper venue for this action pursuant to 28 U.S.C. § 100(1).

43. There is no consent requirement for removal under 28 U.S.C. § 1442 (a)(1).

44. The Kennedy Krieger Defendants are filing written notice of this removal, in substantially the form attached hereto as Exhibit M with the Clerk of the State Court in which the action is currently pending pursuant to 28 U.S.C. § 1446(d). A copy of the Kennedy Krieger Defendants' Notice to the Circuit Court for Baltimore City of Filing of Notice of Removal to the United States District Court, together with this Notice of Removal, are being served upon Plaintiffs' counsel and all other parties in this action pursuant to 28 U.S.C. § 1446(d).

WHEREFORE, Defendant Kennedy Krieger Institute, Inc. and Cecilia Davoli, M.D., respectfully remove this action from the Circuit Court for Baltimore City, bearing case number 24-C-07-00202, to this Court, pursuant to 28 U.S.C. § 1442 (a)(1).

Respectfully submitted,

Barry C. Goldstein
(Federal Bar No. 24796)
Nicole A. McCarus
(Federal Bar No. 27971)
Waranch & Brown, LLC
1301 York Road, Suite 300
Lutherville, Maryland 21093
(410) 821-3511
ATTORNEYS FOR DEFENDANTS KENNEDY KRIEGER INSTITUTE, INC. and CECILIA DAVOLI, M.D.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 1st day of May, 2007, a copy of the foregoing Notice of Removal was mailed first-class, postage prepaid, to:

Evan K. Thalenberg, Esquire
Evan K. Thalenberg, P.A.
11 E. Chase Street, Suite 7F
Baltimore, Maryland 21202

Attorney for Plaintiffs

Timothy P. Knepp, Esquire
P. O. Box 21221
Baltimore, Maryland 21221

Attorney for Pythagoras Passas and Anne L. Passas

Michael D. Vogelstein, Esquire
201 N. Charles Street
Suite 801
Baltimore, Maryland 21201

Attorney for Marc Medin, Nancy Medin and Shenan Management, Inc., and N.A.C.I. Corporation

Natalie Magdeburger, Esquire
Raymond Marshall, Esquire
Whiteford, Taylor & Preston, L.L.P.
210 W. Pennsylvania Avenue
Towson, MD 21204-4514

Attorneys for The Johns Hopkins University, The Institutional Review Board of The Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman, Hayden G. Braine and Peter Lees.

Barry C. Goldstein

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al. *

Plaintiffs *

v. *

KENNEDY KRIEGER INSTITUTE, INC., et al. *

Defendants *

Case No. WMN 07 CV 1120

****

NOTICE OF REMOVAL

TO: United States District Court for the District of Maryland:

Pursuant to 28 U.S.C. § 1442 (a)(1), Defendants Kennedy Krieger Institute, Inc. ("Kennedy Kreiger"), and Cecilia Davoli, M.D. (collectively referred to as the "Kennedy Krieger Defendants"), hereby remove this action, *Shayonna Featherstone, et al. v. Kennedy Krieger Institute, Inc., et al.*, case number 24-C-07-002027, from the Circuit Court for Baltimore City, Maryland (hereinafter "State Court Action"), to the United States District Court for the District of Maryland (Northern Division), and allege as follows:

1. In 1992, the federal government, through the National Institute of Environmental Health Sciences ("NIEHS")[1], issued a Request for Proposals ("RFP") seeking clinical centers for a study entitled "Toxicity of Lead in Children." The purpose of the study was to determine whether succimer, a drug approved by the United States Food and Drug Administration ("FDA") for use in treating individuals with blood lead levels greater than 45 micrograms per deciliter, could prevent cognitive delay in young children with blood lead levels less than 45 micrograms per deciliter. This action is brought by Shayonna Featherstone, a minor, and Keona Featherstone, a minor, by their mother and next

[1] NIEHS is a subsidiary of the National Institutes of Health ("NIH") itself a branch of the United States Department of Health and Human Services.

friend, Sharon Jackson (collectively "Plaintiffs"), and arises out of Plaintiff Keona Featherstone's participation in this NIEHS sponsored study conducted by Kennedy Krieger and others and is known as the Treatment of Lead-Exposed Children ("TLC") Study. Plaintiffs' Complaint asserts claims of negligence, negligent misrepresentation, civil conspiracy and breach of fiduciary duty against these Defendants and others and seeks damages in the amount of Four Million Dollars ($4,000,000). *See* Plaintiffs' Complaint, a copy of which is attached hereto as Exhibit A.

2. This Court has jurisdiction over this removal action under 28 U.S.C. § 1442(a)(1) because Plaintiffs filed a civil action in a State court against the Kennedy Krieger Defendants, who were acting under the control of an United States agency. Specifically, Plaintiffs' negligence claims directly call into question Kennedy Krieger's compliance with the contract it entered into with the NIEHS as well as Kennedy Krieger's compliance with the detailed and comprehensive framework of federal regulations that govern research on human subjects.

3. 28 U.S.C. § 1442(a)(1) governs removal for conduct performed under color of federal office. The Supreme Court has "held that the right of removal is absolute for conduct performed under color of federal office, and has insisted that the policy favoring removal 'should not be frustrated by a narrow, grudging interpretation of § 1442(a)(1).'" *See Arizona v. Manypenny*, 451 U.S. 232, 242, 101 S.Ct. 1657 (1981).

4. The purpose of the liberal removal policies underlying section 1442(a)(1) is to protect federal officers and their agents when they conduct business in the states. *See Durham v. Lockheed Martin Corp.*, 445 F.3d 1247, 1252-53 (9th Cir. 2006). "If the federal government can't guarantee its agents access to a federal forum if they are sued or prosecuted, it may have difficulty finding anyone willing to act on its behalf." *Id.* at 1253.

JURISDICTIONAL BASIS FOR REMOVAL

5. This Court has jurisdiction under 28 U.S.C. §1442(a)(1) because: (1) Kennedy Krieger and Dr. Davoli are considered "persons" within the meaning of the statute; (2) the Kennedy Krieger Defendants were acting at the direction of an officer of the United States; (3) a causal nexus exists between Plaintiffs' claims and the Kennedy Krieger Defendants actions under color of federal office; and (4) the Kennedy Krieger Defendants can assert a colorable federal defense. *See e.g., Mesa v. California,* 489 U.S. 121, 125-35 (1989); *Pack v. A.C. and S., Inc.*, 838 F.Supp. 1099, 1101 (D.Md. 1993), *reconsideration denied*, 857 F.Supp. 26 (D.Md. 1994) (holding that 28 U.S.C.§ 1442(a)(1) is satisfied when the moving party can demonstrate that (1) it acted under the direction of a federal officer; (2) it raises a federal defense to plaintiff's claims; and (3) demonstrates a causal nexus between plaintiff's claims and acts it performed under color of federal office). Pursuant to U.S.C. § 1442, a defendant acting under the direction of a federal officer of the United States can unilaterally remove a case to federal court. *See Durham v. Lockhead Martin Corp.*, 445 F.3rd at 1253. *See also Plourde v. Ferguson*, 519 F. Supp. 14, 16 (D.Md. 1980) (Single defendant can remove case from state court to federal court regardless of whether other defendants join in removal petition.)

A. Kennedy Krieger is a "person" under 28 U.S.C. § 1442 (a)(1)

6. Kennedy Krieger qualifies as a "person" as required by 28 U.S.C. § 1442 (a)(1). In *Pack*, this Court held that private corporations, like Kennedy Krieger, are "persons" for purposes of the statute. 838 F.Supp. at 1103.

B. The Kennedy Krieger Defendants were acting under the direction of the United States Government.

1. The Kennedy Krieger Defendants were acting under the direction and control of the National Institute of Environmental Health Sciences

7. The extent of control necessary to bring an individual within the person "acting under" clause of § 1442(a) has been broadly construed. *In re Methyl Tertiary Butyl Ether Products Liability*

Litigation, 342 F.Supp.2d 147, 154-155 (S.D.N.Y. 2004). Federal officer removal is appropriate when the removing party is subject to the direct and detailed control of the federal government. *Pack*, 838 F.Supp. at 1103. "Direct control is established by showing strong government intervention and the possibility that a defendant will be sued in state court as a result of the federal control." *Id.* (citing *Fung v. Abex Corp.*, 816 F. Supp. 569, 572 (N.D.Cal. 1992)); *see also McMahon v. Presidential Airways, Inc.*, 410 F.Supp.2d 1189, 1197 (M.D. Fla. 2006) (holding that private air transportation companies that contracted with the United States government were acting under the direction of a federal officer and met the federal officer removal standard, whereby "the government maintained control over the manner in which the contractor performed the contracted work or *monitored* the performance of the work")(citing *Watson v. Philip Morris Cos.*, 420 F.3d 852, 857 (8th Cir. 2005)) (emphasis added).

8. The federal government directed and controlled all of Kennedy Krieger's activity in the design, implementation and follow up of the TLC study. The federal government, through NIEHS, maintained detailed, hands-on control over all phases of this government sponsored and funded study. The following paragraphs provide a summary of the intimate and meticulous control the federal government maintained over the TLC study.

9. The genesis of the TLC study was an RFP issued by NIEHS. That document contains the government's rationale for embarking on this particular study:

> NIEHS has...supported clinical studies leading to the licensure of the drug succimer, an orally administered chelating drug now labeled for use in children with blood lead levels above 45 ug/dl, a level thought to indicate a high risk for symptomatic lead poisoning and above the levels that produce cognitive delay....The Centers for Disease Control and the American Academy of Pediatrics have revised downward the blood lead levels of concern in young children, and children with blood lead levels greater than 10 ug/dl are now thought to have unacceptable exposure to lead. **NIEHS believes that large numbers of children with blood lead levels below 45 ug/dl will be treated with succimer, and that a clinical trial of the use of succimer in the prevention of lead-associated cognitive delay in young children is both necessary and timely.**

NIEHS Request for Proposals, Section C.1 attached hereto as Exhibit B (emphasis added).

10. NIEHS unequivocally articulated in the RFP that control over the timing parameters for each and every aspect of the TLC study would rest with NIEHS. Furthermore, NIEHS directed the criteria for enrolling into this study. Finally, NIEHS mandated the areas of focus in analyzing the study's data:

> The trial **shall** proceed as follows: 9-12 months for planning; about 1 year for patient enrollment and treatment; the remaining 3 years for follow-up....The trial is of oral chelation therapy with the drug succimer in lead exposed children (blood leads of about 20 ug/dl to 45 ug/dl) of about 18 to 36 months of age. The endpoints are the scores on developmental tests; other endpoints of interest include evidence of drug efficiency and compliance, such as urine and blood lead levels; excretion of other ions like iron, zinc, and calcium; and nervous system, renal and hematopoietic function/toxicity.

Id. at C.2 (emphasis added.) Kennedy Krieger drafted its "proposal" within the specific criteria set forth by NIEHS.

11. In response to Kennedy Krieger's "proposal", NIEHS drafted a contract and forwarded it to Kennedy Krieger for signature.[2] No one from Kennedy Krieger participated in the preparation of that Contract. *See* Affidavit of Merrill Brophy attached hereto as Exhibit C, paragraph 3. This government contract served as the basis for the relationship between NIEHS and Kennedy Krieger in conducting the TLC study. *See* Contract attached hereto as Exhibit D.

12. After the signed contract was approved by NIEHS's contracting officer, the NIH Board of Contract Awards was required to review and provide final approval. *See* June 25, 1993 letter from Thomas M. Hardee, NIEHS Contracting Officer, to Karen Sorenson, Contract Administrator for Kennedy Krieger attached hereto as Exhibit E.

[2] This was a multi-center study and, accordingly, NIEHS contracted with three other Clinical Centers to conduct the TLC study in addition to Kennedy Krieger. Those other sites were Cincinnati, Philadelphia and New Jersey.

13. At the inception of the contractual relationship between NIEHS and Kennedy Krieger, the NIEHS Contracting Officer appointed Walter Rogan, M.D. as Project Officer and Beth Ragan as Alternate Project Officer to oversee the TLC study. *See* June 25, 1993 Department of Health and Human Services Memorandum attached hereto as Exhibit F. This memorandum provides a detailed outline of the Project Officer's duties which require, among other things, that the Project Officer:

> Maintain complete surveillance of the technical performance and contact with the contractor in order to give reasonable assurance that all specified contract deliverables are delivered on time and are in accordance with the specifications/requirements of the contract terms.

Id. (*See also*, Paragraph 14, *infra*).

14. The contract contained a detailed description of the estimated cost of the study including specific instructions regarding permissible expenditures such as salary rate limitations, restrictions on travel expenses, patient care costs, patient enrollment incentives, and permissible expenditures for house "clean-up." The Principal Investigator at Kennedy Krieger (and all clinical sites) was required to seek approval from NIEHS in order to allocate funds for *any* purpose that deviated *in any way* from the contract as drafted by NIEHS. *See* Affidavit of Cecilia Davoli, M.D., attached hereto as Exhibit I, paragraph 11; July 1995 letter from Kennedy Krieger to NIEHS regarding approval for funds attached hereto as Exhibit G.

15. The contract governing Kennedy Krieger's conduct in connection with the TLC study adopted *verbatim* the language contained in NIEHS's RFP expressing the rationale for why NIEHS believed this study was necessary. Further, the Statement of Work section of the contract, in describing the specific criteria to be used in protocol development, adopted *verbatim* the study criteria initially set forth by NIEHS in its RFP:

> The trial **shall** proceed as follows: 9-12 months for planning; about 1 year for patient enrollment and treatment; the remaining 3 years for follow-up....The trial is of oral chelation therapy with the drug succimer in lead exposed children (blood leads of about 20

> ug/dl to 45 ug/dl) of about 18 to 36 months of age. The endpoints are the scores on developmental tests; other endpoints of interest include evidence of drug efficiency and compliance, such as urine and blood lead levels; excretion of other ions like iron, zinc, and calcium; and nervous system, renal and hematopoietic function/toxicity.

Exhibit D at p. 10. NIEHS directed the Steering Committee, subject to federal government approval, to further develop the protocol and strategies for the TLC trial. This committee consisted of the NIEHS Project Officer, the Principal Investigators of the Central Lab (in this case the lab at the Centers for Disease Control, also a branch of the United States Department of Health and Human Services), as well as the Principal Investigators of each Clinical Center participating in the study (Kennedy Krieger was one of four Clinical Centers) and the Principal Investigator of the Coordinating Center (Harvard School of Public Health). *Id.* The NIEHS Project Officer and Alternate Project Officer participated in nearly every subcommittee created for the TLC study. *See* Protocol attached hereto as Exhibit H at 40-42. *Id.*

16. The NIEHS Project Officer supervised regular meetings and conference calls with Kennedy Krieger and the other centers regarding study design to ensure that the plans developed consistent with NIEHS objectives. *see* Affidavit of Cecilia Davoli, M.D. attached hereto as Exhibit I at ¶ 4; *see also*, Exhibit C at ¶ 4. Final authority over each and every aspect of this study rested with the NIEHS Project Officer. *Id.* at ¶ 5. *see also* Exhibit D at ¶ 21. Pursuant to the contract, Kennedy Krieger did not have the authority to deviate from the NIEHS approved study protocol. Indeed, NIEHS retained the ability to terminate the contract if Kennedy Krieger deviated from the study protocol. "Failure of the contractor to abide by the approved shared protocol may result in the termination in accordance with the termination clause." *See* Exhibit D at ¶19.

17. Pursuant to federal regulation (*see* ¶¶ 25-29, *infra*), Kennedy Krieger was required to obtain Institutional Review Board ("IRB") approval of the Informed Consent Form to be utilized in enrolling study participants. After the local IRB utilized by Kennedy Krieger approved a form, Kennedy Krieger was required to forward that form to the NIEHS' own IRB for further review. The

NIEHS IRB initially rejected the Kennedy Krieger Consent Form because the reading level required for comprehension of the Consent Form was too high. *See* Exhibit C at ¶ 10 and Exhibit I at ¶ 12. Only after Kennedy Krieger revamped its form, secured local IRB approval again and resubmitted the form to NIEHS was it approved such that the study could proceed. *Id.*

18. NIEHS imposed substantial reporting requirements on the Clinical Centers participating in the study. Kennedy Krieger was required to submit to NIEHS technical reports as well as racial/ethnic enrollment reports. Exhibit D at 15. During the first year of the study, Kennedy Krieger submitted semi-annual reports that described the progress in planning, recruitment, community activity and screening with particular emphasis on the material not covered in the Steering Committee meetings. *Id.* For all subsequent years, Kennedy Krieger submitted quarterly reports outlining the numbers of families contacted and screened, all activities planned and all activities executed during the reporting periods, again with particular emphasis on the materials not covered in the Steering Committee meetings. *Id.* NIEHS also required Kennedy Krieger to submit enrollment reports providing a summary of the planned study population and a summary of the actual number of participants enrolled according to designated racial/ethnic categories. *Id.*

19. NIEHS also maintained oversight of the study's implementation through periodic site visits. *See* Exhibit C at ¶ 6 and Exhibit I at ¶ 7. These visits were conducted to ensure that Kennedy Krieger was complying with the TLC study protocol. *Id.* During these visits, the NIEHS Project Officer reviewed study participant charts[3] to ensure compliance with federal regulations, observed the study facilities, and conducted visits to houses involved in the study. *Id.*

20. This study, as noted above, involved assessment of the drug succimer under certain clinical conditions. Because this drug was not approved by the FDA for use under those conditions, NIEHS submitted an Investigational New Drug ("IND") application to the FDA. *See* Exhibit D at p.13;

[3] The FDA imposes regulations regarding how researchers should document their use of investigational new drugs.

See also, Exhibit C at ¶ 8 and Exhibit I at ¶ 8. Because NIEHS held the IND for the use of Succimer in children with blood lead levels less than 45 micrograms per deciliter, NIEHS's Project Officer was actively engaged in ensuring that the Clinical Centers understood Succimer's biochemical behavior. *Id.*

21. The TLC study was fully funded by NIEHS with support from the Office of Research on Minority Health of the National Institutes of Health ("ORMH, NIH"). *See* Exhibit H at ¶ 2.2.

22. In addition to NIEHS, the United States Centers for Disease Control ("CDC") was actively involved in the TLC study. The CDC laboratory in Atlanta, Georgia, served as the central laboratory and performed blood lead analysis on all study participants. *Id.* at p. 28. Managers of the CDC participated on several TLC study committees. *Id.* at pp. 40-42.

23. The CDC had responsibility for all activities related to drawing study participants' blood. *See* Exhibit C at ¶ 9 and Exhibit I at ¶ 9. Prior to the implementation of the Study, the CDC held a training session for all Clinical Centers to ensure that all centers were drawing blood consistent with CDC protocol. *Id.* In addition to training, the CDC provided the Clinical Centers with the supplies needed to draw study participants' blood as well as the supplies needed to send the blood samples to the CDC lab in Atlanta. *Id.*

24. The intimate control exercised by NIEHS over the TLC study extended through to the study's conclusion. NIEHS prohibited Kennedy Krieger from writing-up and summarizing the results of the study absent NIEHS approval. Exhibit D at pp.11, 13.

2. Kennedy Krieger was acting under the authority of the United States Congress and the Department of Health and Human Services

25. In addition to the federal government's active involvement in the creation, design, and implementation of the TLC study pursuant to its contract with Kennedy Krieger, the actions of Kennedy Krieger were at all times subject to exceedingly complex regulations and guidelines in the conduct of this research study. *See* 42 U.S.C. § 289; 45 CFR § 46.101, et seq. For example, when conducting research on human subjects, the federal government requires an Institutional Review Board ("IRB") to

approve the study. 42 U.S.C. § 289. The IRB is essentially an oversight committee that "shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy." 45 C.F.R. § 46.109(a). Federal regulations further govern, among other things, the membership of the IRB (45 C.F.R. § 46.107); IRB functions and operations (45 C.F.R. § 46.108); the review procedures that the IRB may use in certain types of research (45 C.F.R. § 46.109); additional protections for children involved as subjects in research (45 C.F.R. § 406); and criteria for IRB approved research (45 C.F.R. § 46.111).

26. Exercising removal jurisdiction will also promote uniformity in the application and interpretation of the federal laws at issue. According to a Guidebook published by the DHHS, the regulations cited in Plaintiffs' Complaint and relied upon by the Plaintiffs were promulgated by sixteen federal agencies that conduct, support, or regulate human research. *See* Exhibit J, Department of Health and Human Services Institutional Review Board Guidebook Introduction. The DHHS Guidebook chronicles the detailed and deliberative process the federal government employed in arriving at the regulations at issue here. *Id.*

The Introduction states:

> The DHHS regulations are codified at Title 45 Part 46 of the Code of Federal Regulations. Those "basic" regulations became final on January 16, 1981, and were revised effective March 4, 1983, and June 18, 1991. The June 18, 1991, revision involved the adoption of the Federal Policy for the Protection of Human Subjects. **The Federal Policy (or "Common Rule," as it is sometimes called) was promulgated by the sixteen federal agencies that conduct, support, or otherwise regulate human subjects research**; the FDA also adopted certain of its provisions. **As is implied by its title, the Federal Policy is designed to make uniform the human subjects protection system in all relevant federal agencies and departments.** The Federal Policy is discussed in depth in Chapter 2, Section A(i).

Id. (emphasis added).

27. A substantial federal interest exists in the uniformity of interpretation and application of federal laws governing scientific research involving children.

28. Because the TLC study involved use of an Investigational New Drug Exemption, Kennedy Krieger was also required to comply with extensive FDA regulations controlling the use of IND's.

29. These regulations expressly and in great detail governed Kennedy Krieger's handling of all aspects of the TLC study including enrolling study participants, obtaining informed consent and ensuring study participant safety.

C. A causal nexus exists between Plaintiffs' claims and Kennedy Krieger's actions pursuant to its contract with the National Institute of Environmental Health Sciences

30. The causal nexus prong requires that Plaintiffs' suit arise out of acts by Kennedy Krieger taken pursuant to the direction of a federal officer. *See Pack*, 857 F.Supp. at 28. A direct causal relationship exists between Plaintiffs' claims and Kennedy Krieger's actions under color of federal office. The allegations made against the Kennedy Krieger Defendants in Plaintiffs' Complaint and their relationship to action taken by the Kennedy Krieger Defendants pursuant to formal authority are summarized in the following chart:[4]

Plaintiffs' Allegations	**Conduct of Kennedy Krieger Taken Pursuant to Federal Authority**
"The parents of TLC research subjects, including the Plaintiffs, were not informed by KKI or Davoli that drugs like succimer should not be used as a substitute for the complete abatement of lead hazards to which a child is exposed nor were they informed that succimer should not be used on a child who continues to be exposed to lead hazards." *See* Complaint, Exhibit A at ¶ 8.	The process for enrolling Study participants and the information provided to Study participants was directly controlled by NIEHS in the Contract. *See* Contract, Exhibit D at 11 and the Steering Committee, *Id.* at 10. The Informed Consent provided to Study participants was governed by NIEHS, and through the Contract. *See* Contract, Exhibit D at § H; Exhibit C at ¶ 10; Exhibit I at ¶ 12.

[4] To the extent that this Court finds that Plaintiffs have asserted non-federal claims, it is appropriate for the Court to exercise its supplemental jurisdiction. *Rosmer v. Pfizer Incorporated*, 263 F.3d 110 (4th Cir. 2001); *Shanaghan v. Cahill*, 58 F.3d 106, 109 (4th Cir. 1995); *Parker, PPA v. Della Rocco, Jr.*, 252 F.3d 663, 665 (2nd Cir. 2001) (holding that the exercise of supplemental jurisdiction was appropriate after an agent of the federal government properly removed an action to federal court pursuant to 28 U.S.C. § 1442 (a)(1)).

"Via the Informed Consent Form ("IC") Parents and guardians of the children used in the TLC Study were promised that during the "treatment phase another doctor would know the results of blood-lead tests (in case their [was] a problem" and that the childrens' blood-lead levels would also be reported to the Baltimore City Health Department." *See* Complaint, Exhibit A at ¶ 9.	Measures taken to insure the safety of the Study participants was covered by the protocol created under the direct supervision of the NIEHS Project Officer (*See* Protocol, Exhibit H) and is further governed by Federal Regulation. ***See* ¶¶ *23-25.*** Obtaining of informed consent in the Study was governed by the NIEHS by the Contract and by Federal Regulation. Furthermore, the researcher/subject relationship Kennedy Krieger entered into was based solely on the NIEHS Contract, NIEHS approved trial protocol, and the NIEHS approved Informed Consent form; Exhibit C at ¶ 10, Exhibit I at ¶ 12.
"Via the IC Parents and the guardians of the children used in the TLC Study were promised that KKI and Davoli and/or their agents such as Lady "H" would clean up the lead in the homes of the study subjects." *See* Complaint, Exhibit A, ¶ 12.	Kennedy Krieger monitored and "cleaned" Plaintiffs' residences to the extent that it was required to pursuant to its Contract with NIEHS and the NIEHS approved trial protocol. *See* Contract, Exhibit D at 10, 13; Protocol, Exhibit H at 18-20; Exhibit C at ¶ 10, Exhibit I at ¶ 12.
"Pursuant to 45 C.F.R. § 46.101 (2005) approval and oversight by an Institutional Review Board (IRB) is required whenever research on human beings is conducted, supported, or is subject to federal regulation." Md. Code Health Gen. Art. § 13-201, *et seq.* (2005) requires that all research conducted in Maryland on human subjects to be conducted in compliance with federal regulations, regardless of the source of funding and/or support for the research." *See* Complaint, Exhibit A at ¶ 16.	The measures taken to insure the safety of Study participants was covered by the protocol created under the direct supervision of the NIEHS Project Officer. *See* Protocol, Exhibit H. It is further governed by federal regulation. *See* ¶¶ 23-25, *infra.;* Exhibit C at ¶ 10, Exhibit I at ¶ 12.
"There was no direct benefit to the child research subjects from participating in the TLC Study and the monitoring procedure employed in the TLC Study, including but not limited to "blinding" the results of Plaintiffs' blood-lead tests, was less beneficial to the child research subjects' well-being than the monitoring regime already in place." *See* Complaint, Exhibit A at ¶ 21.	The use of "blinding" blood-lead tests results was approved and required by the NIEHS Protocol. *See* Protocol, Exhibit H at 2.
"The IRB assisted the TLC study investigators in concealing the fact that the child research subjects would be placed in serious risk of permanent harm as a result of participating in the study, and concealing that recognize and approved therapies already existed for children with similar lead levels, to wit, the removal from the leaded environment." *See* Complaint,	Information provided to the TLC participants and their guardians were governed by the trial protocol. *See* Protocol, Exhibit H; Exhibit C at ¶ 10, Exhibit I at ¶ 12.

Exhibit A at ¶ 23.	
"The Defendants knew, or should have known, that the properties identified in paragraphs 4 (a) and 4 (b), contained numerous surfaces covered in lead-based paint. However, KKI, Davoli and/or their agents nonetheless represented to the Plaintiffs' family, the Plaintiffs' treating physician, and to the Baltimore City Health Department, hereinafter BCHD, that the homes were free of lead hazards." *See* Complaint, Exhibit A at ¶ 30.	Provision of information and obtaining of informed consent in the Study, was governed by the NIEHS and. and through the Contract and by Federal Regulation. *See* Exhibit C at ¶ 10, Exhibit I at ¶ 12.
"Prior to the lease of the premises to the property set forth in paragraphs 4 (a) and 4 (b), Baltimore, Maryland, the Defendants herein negligently made, and/or negligently permitted to be made misrepresentations to the Plaintiffs and their families regarding the condition of the premises." *See* Complaint, Exhibit A at ¶ 43.	The process of enrolling Study participants was directly controlled by the NIEHS Contract (*See* Contract, Exhibit D at 11) and by the Steering Committee (*See Id.* at 10). Moreover, the informed consent provided to the study participants was governed by NIEHS in and through the Contract as well as by federal regulation. *See* Contract, Exhibit D at Attachment 8; Exhibit C at ¶ 10 and Exhibit I at ¶ 12.
"The Defendants, KKI, JHU, the IRB and Davoli, by virtue of the IC form, entered into an agreement with the Plaintiffs, that in exchange of the Plaintiffs' participation in the TLC Study, the Defendants herein assumed a duty to: ensure that all children in the TLC Study, including the Plaintiffs, had their homes repaired and/or cleaned to get rid of lead dust and chipped paint, to carefully inspect the properties identified in paragraphs 4(a) and 4(b) to see if they could be repaired and/or cleaned to eliminate lead hazards, if the home did not qualify, the Defendants would assist with relocation to housing that was known to be free from lead-hazards, the Defendants would eliminate any lead hazards in the home, ensure that a doctor would monitor the blood-lead levels of the Plaintiffs and promptly and accurately report those test results to the family of the minor Plaintiffs and to the Baltimore City Health Department, and the Defendants also assumed a duty to provide ongoing medical care of the Plaintiffs' lead paint poisoning and lead toxicity." *See* Complaint, Exhibit A at ¶ 61.	The process for enrolling Study participants was directly controlled by NIEHS and the Contract. *See* Contract, Exhibit D at 11, and by the Steering Committee, *See Id.* at 10. Moreover, the informed consent provided to study participants was governed by NIEHS in and through the Contract as well as by federal regulation. *See* Contract, Exhibit D at Attachment 8; Exhibit C at ¶ 10 and Exhibit I at ¶ 12.
"The Defendants KKI and JHU warranted and agreed to the United States Department of	The TLC Study was conducted pursuant to the Contract with NIEHS (*See* Contract, Exhibit D)

Health and Human Services, hereinafter referred to as DHHS, prior to the constitution of, and during the administration of the TLC Study, that all human research at KKI would be conducted in accordance with the terms of the Belmont Report. *See* Ethical Principles and Guidelines for the Protection of Human Subjects of Research, promulgated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979. The Defendants agreed to abide by the ethical duties and obligations set forth within the Belmont Report in furtherance of the Defendants' KKI and JHU Agreement with DHHS under a Multiple Project Assurance Agreement, hereinunder MPAA. This agreement existed prior to the tortuous acts alleged herein." *See* Complaint, Exhibit A at ¶ 67.	and by the Steering Committee (*See Id.*).
"The minor Plaintiffs allege that the Defendants herein, and each of them, by agreement or understanding agreed to materially breach their duties set forth within the IC to the child research subjects used in the TLC Study, including the minor Plaintiffs. *See* Complaint, Exhibit A at ¶ 78."	KKI's actions and relationship with the study participants was governed by the trial protocol and the Contract with the NIEHS. *See* Contract, Exhibit D; see trial protocol, Exhibit H.

31. In sum, the rationale for and purpose of the TLC study is contained in the RFP and Contract, both of which were prepared and promulgated by the federal government. This research study was conducted and implemented pursuant to protocol developed and approved by NIEHS, an agency of the federal government. Kennedy Krieger's recruiting and enrollment of study participants was regulated in great detail by not only the contract approved by NIEHS, but also through an elaborate regulatory scheme enacted pursuant to federal law. *See* B.2. *infra*. Further, Kennedy Krieger was prohibited from deviating from the directives of the contract and/or the research protocol or in taking any action whatsoever unless directly approved by NIEHS. *See* Exhibits D at 19, C at paragraph 13, and I at paragraph 12.

32. Because Plaintiffs' allegations of wrongdoing against Kennedy Krieger implicate conduct and action taken pursuant to federal regulation and mandated by its contract with an agency of the federal government, a direct causal nexus exists between Plaintiffs' claims and the actions Kennedy Krieger took under color of federal office.

D. The "colorable federal defense" requirement of 28 U.S.C. § 1442 (a)(1) is met because Kennedy Krieger is entitled to assert the government contractor defense.

33. The final element required for removal under 28 U.S.C. § 1442(a)(1) – that the defendant must assert a colorable federal defense – is satisfied by Kennedy Krieger's entitlement to the government contractor defense.[5]

34. The government contractor defense shields a contractor from liability when acting under the direction and authority of the United States. *Tozer v. LTV Corp.*, 792 F.2d 403, 405 (4th Cir. 1986)(citing *Yearsley v. W.A. Ross Construction Company*, 309 U.S. 18, 20 (1940)). In *Yearsley*, the United States Supreme Court stated that "it is clear that if this authority to carry out the project was validly conferred, that is, if what was done was within the constitutional power of Congress, there is no liability on the part of the contractor for executing its will." 309 U.S. at 20-21, 60 S. Ct. at 414-15.

35. *Boyle v. United Technologies Corp.*, 487 U.S. 500 (1988) sets forth the elements required to satisfy the government contractor defense: (1) the United States approved reasonably precise specifications; (2) the contractor's performance conformed to those specifications; and (3) the contractor warned the United States about the dangers associated with the contract that were known to the contractor but not to the United States. *Id.* at 512, 108 S. Ct. at 2518. It is well established that the defense is viable in the context of non-military performance contracts such as the one Kennedy Krieger entered into with NIEHS. *See Boyle*, 487 U.S. at 506, 108 S. Ct. at 2515 (stating that "[t]he federal

[5] For purposes of satisfying 28 U.S.C. § 1442 (a)(1), Kennedy Krieger need not definitively **prove** the asserted defense. It need only articulate it's "colorable applicability to plaintiff's claims." *Jamison v. Wiley*, 14 F.3d 222, 238 (4th Cir. 1994) (citing *Mesa*, 489 U.S. at 133).

interest justifying this holding surely exists as much in procurement contracts as in performance contracts; we see no basis for distinction."); *Richland-Lexington Airport District v. Atlas Properties, Inc.*, 854 F.Supp. 400, 422 (D.SC. 1994)(in holding that the defense applies to performance contracts, the court stated that "the dispositive issue is not one of performance versus procurement, but whether there is a uniquely federal interest in the subject matter of the contract"); *Yeroshefsky v. Unisys Corp.*, 962 F.Supp. 710, 717 (D.Md. 1997)(holding that the government contractor defense is applicable in the civilian as well as military context).[6]

36. Consistent with the first prong of the *Boyle* test, the United States, through NIEHS, approved precise specifications for developing, implementing, and reporting on the TLC study. *See* ¶¶ 5-23. The RFP, Award/Contract, and supervision and participation in the TLC study clearly demonstrate that NIEHS provided reasonably precise specifications. *Id.*

37. As required by the second prong of the *Boyle* test, Kennedy Krieger fully complied with the federal government's detailed specifications. As required by contract, Kennedy Krieger followed the NIEHS approved study protocol throughout its implementation of the TLC study. *See* Exhibit D at p.19. Kennedy Krieger was obligated to follow, and did comply with, the strict and comprehensive requirements imposed by the federal government when conducting research on human study participants. *Id.* at 26; *See also* Exhibit C at ¶ 13 and Exhibit I at ¶ 13.

38. Finally, the third prong of the *Boyle* test is satisfied. Kennedy Krieger did not withhold from NIEHS any information regarding potential dangers associated with the TLC study. As set forth in

[6] Arguably, *Richland* recognized an additional element to the defense. The *Richland* Court suggested that the party claiming the defense must first demonstrate that the conduct at issue constituted a "discretionary function" of the federal government. 854 F.Supp. at 423. Pursuant to this "discretionary function", Kennedy Krieger will not be liable to Plaintiffs if the challenged government action involved an element of judgment or choice and if the challenged government action is based on considerations of public policy. *Id.* Without question, as described herein, the genesis for this study, as expressly articulated in the RFP, was NIEHS's concern regarding (1) the large numbers of children with blood lead levels below 45 micrograms per deciliter will be treated with Succimer and (2) NIEHS's belief that a clinical trial of the use of Succimer in the prevention of lead-associated cognitive delay in young children was both necessary and timely. Exhibit B. This is precisely the type of conduct contemplated in the *Richland* "discretionary function" analysis.

¶¶ 5-28 *supra*, NIEHS was intimately involved in all aspects of the study and therefore was fully aware of all risks and benefits associated with the TLC study.

39. The foregoing facts and analysis establish, at a minimum, that the Kennedy Krieger Defendants are entitled to assert the government contractor defense in this matter.

PROCEDURAL REQUIREMENTS FOR REMOVAL

40. On April 3, 2007, the Kennedy Krieger Defendants became aware of Plaintiffs' Complaint after Defendant Thomas R. Hendrix was served with a copy of the Complaint. On April 16, 2007, counsel for the Kennedy Krieger Defendants sent a letter to Plaintiffs' counsel agreeing to accept service of the Plaintiffs' Complaint. *See* Exhibit K. Because this Notice of Removal is filed within 30 days of the service of the Complaint, it is timely filed under 28 U.S.C. § 1446(b). Copies of all process and pleadings filed in state court are attached to this Notice of Removal as Exhibit L.

41. Kennedy Krieger files and presents herewith the sum of $350.00 as required by Title 28, U.S.C. § 1446.

42. The United States District Court for the District of Maryland (Northern Division) embraces the City of Baltimore in which the state court action is now pending, and thus, this Court is a proper venue for this action pursuant to 28 U.S.C. § 100(1).

43. There is no consent requirement for removal under 28 U.S.C. § 1442 (a)(1).

44. The Kennedy Krieger Defendants are filing written notice of this removal, in substantially the form attached hereto as Exhibit M with the Clerk of the State Court in which the action is currently pending pursuant to 28 U.S.C. § 1446(d). A copy of the Kennedy Krieger Defendants' Notice to the Circuit Court for Baltimore City of Filing of Notice of Removal to the United States District Court, together with this Notice of Removal, are being served upon Plaintiffs' counsel and all other parties in this action pursuant to 28 U.S.C. § 1446(d).

WHEREFORE, Defendant Kennedy Krieger Institute, Inc. and Cecilia Davoli, M.D., respectfully remove this action from the Circuit Court for Baltimore City, bearing case number 24-C-07-00202, to this Court, pursuant to 28 U.S.C. § 1442 (a)(1).

Respectfully submitted,

Barry C. Goldstein
(Federal Bar No. 24796)
Nicole A. McCarus
(Federal Bar No. 27971)
Waranch & Brown, LLC
1301 York Road, Suite 300
Lutherville, Maryland 21093
(410) 821-3511
ATTORNEYS FOR DEFENDANTS KENNEDY KRIEGER INSTITUTE, INC. and CECILIA DAVOLI, M.D.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

CONTRACT ID CODE | PAGE OF PAGES 1 | 16

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
01	October 22,, 1992	N/A	

6. ISSUED BY — CODE

National Institute of
Environmental Health Sciences
Contracts & Procurement Management Branch, OM
P.O. Box 12874 (79 T.W. Alexander Dr.)
Research Triangle Park, NC 27709

7. ADMINISTERED BY (If other than Item 6) — CODE

OMB No.: 0990-0115

ATTN: Thomas M. Hardee

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)

TO ALL POTENTIAL OFFERORS
RFP NIH-ES-92-31
"Toxicity of Lead in Children - Clinical Center"

(X) 9A. AMENDMENT OF SOLICITATION NO.: NIH-ES-92-31

X 9B. DATED (SEE ITEM 11): August 27, 1992

10A. MODIFICATION OF CONTRACT/ORDER NO.

10B. DATED (SEE ITEM 13)

CODE | FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

[X] The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers [ ] is extended, [X] is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

N/A

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(X) A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

[ ] B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

[ ] C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

[ ] D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor [ ] is not, [ ] is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

The purpose of this amendment is to amend SECTIONS C, H and L of the RFP and to provide general information resulting from the preproposal conference held October 8, 1992 as indicated in ARTICLE L.1.1. of the RFP.

The due date for proposals is not extended. Proposals are due 4:00 p.m. local time on November 24, 1992.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	Thomas M. Hardde Contracting Officer, CPMB, OM, NIEHS
15B. CONTRACTOR/OFFEROR — 15C. DATE SIGNED	16B. UNITED STATES OF AMERICA — 16C. DATE SIGNED
(Signature of person authorized to sign)	BY Thomas M. Hardee (Signature of Contracting Officer) — 10/22/92

NSN 7540-01-152-8070 — STANDARD FORM 30 (REV. 10-83)

REFERENCE NO.: Request for Proposal (RFP) NIH-ES-92-31

PROJECT: "Toxicity of Lead in Children Trial -- Clinical Center"

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a. The solicitation is hereby amended as set forth below.

(1) SECTION C entitled "DESCRIPTION/SPECIFICATIONS/WORK STATEMENT", ARTICLE C.2. entitled "STATEMENT OF WORK".

At the end of the Statement of Work (page 24) add the following paragraph:

"Subsequent to the treatment year, each of the 345 children will require 4 blood leads and 2 urine leads in the second year post treatment, and 2 blood leads and 2 urine leads in the 3rd year post treatment. Thus, the grand total for budget purposes is 7,130 blood leads per center, 21,390 for the whole study, and 3,450 urine leads per center, 10,350 for the whole study."

(2) SECTION H entitled "SPECIAL CONTRACT REQUIREMENTS", ARTICLE H.6 entitled GOVERNMENT PROPERTY"

Under paragraph b. entitled Government Furnished Property - Schedule II.B., correct the schedule to read as follows:

"1. The drug, succimer, to be administered during trial

2. Placebo to be administered during trial

NOTE TO OFFERORS: Whether nutritional supplements will be provided has not yet been decided.

3. Laboratory determinations of blood lead levels

NOTE TO OFFERORS: If CDC functions as the central laboratory, the Government will provide the blood leads and urine leads designated in the final protocol to be performed by the central laboratory. If CDC does not function as the central laboratory, those determinations will be done by either one of the clinical centers or by a separate central laboratory. In any case, central laboratory costs should not be included in the clinical center proposals unless they are pursuing the option to be the central laboratory. If they do pursue that option, costs for the central laboratory function must be clearly separable in the proposal.

REFERENCE NO.: Request for Proposal (RFP) NIH-ES-92-31

PROJECT: "Toxicity of Lead in Children Trial -- Clinical Center"

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(3) SECTION L entitled "INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS", 1. entitled "GENERAL INFORMATION", paragraph h. entitled "SELECTION OF OFFERORS":

Under subparagraph (10), add the following clarification:

"For the purposes of this solicitation, an offeror is considered to be a separate physical and/or organizational entity which is not influenced by or involved with another entity within the same general institution in such a manner that a potential conflict of interest, either real or apparent, may arise. For example, different departments, schools, etc. within the same institutions of higher learning, hospitals, etc. could be considered as separate offerors, and may receive separate awards. In such cases where different entities within the same institution choose to submit proposals under NIH-ES-92-31 and NIH-ES-92-32, the proposal(s) shall include organization charts and an explanation of how the entities will act completely autonomously of each other."

b. The following information is provided for general information and clarification purposes only. It is not intended to constitute a change to the RFP unless so stated above. The comments were derived from consideration to questions which have been posed, either prior to, during, or resulting from the pre-proposal conference conducted October 8, 1992 at NIEHS as indicated in Article L.1.1. of the RFP.

General comments:

This will be an interactive project with a shared protocol. Each offeror is encouraged to propose what they believe to be the best approach to this work, since a statement of simple willingness on the part of the offeror does not allow the technical review panel sufficient insight into the qualifications of the offerors.

However, the final protocol will be the result of the deliberations of the steering committee, which will be composed *inter alia* of the PIs of the three clinical centers. It is thus unlikely that the study as performed will be exactly as any one of the offerors proposes. The basic concept, including the ethics, for the study, which was reviewed and approved at NIEHS, is (among other things) a randomized, blind or double blind, placebo controlled trial of succimer at lead levels below 45 µg/dl; open designs or studies of other drugs are not what was approved. Plausible designs include fully blinded ones, such that neither the examining physician, the parents, nor the psychological testers are aware of whether the child was given active drug or not, and a fixed drug regimen (A responsible clinician monitors lab values in such a design). If an offeror believes that children in these ranges must receive drug under circumstances likely to arise in the trial, or that there are plausible final designs for the trial that they could not ethically participate in, then they should state so clearly. If all designs other than the one that they propose in detail are ethically unacceptable, then they should reconsider whether participation in an interactive study is appropriate for them. Offerors must not

propose studies that they would be ethically unwilling to do; offerors must be willing to participate in an interactive research protocol, and must be willing to participate in plausible designs that are arrived at by responsible investigators and cleared by the appropriate committees.

Questions:

Ethics, placebos, etc.

Is a placebo arm ethical?

Although this issue has come up several times, it has not been seen as a major problem by any of the groups or individuals with whom we have discussed the concept of the trial. There is wide variability in the use of chelating agents in the US. This, however, probably represents the facts of practice rather than "standard of care." The current CDC document states:

> Blood lead level 25 to 44μg/dl: For this blood lead range, the effectiveness of chelation therapy in decreasing the adverse effects of lead on children's intelligence has not been shown. Treatment regimens vary from clinic to clinic. Some practitioners treat children with lead levels on this range pharmacologically. (CDC: Preventing Lead Poisoning in Young Children, 1991, p. 61)

The ethics of a placebo arm if the drug were to be effective, or the ethics of a treatment arm if the drug were to be ineffective or toxic or harmful, has come up but was considered to be a question that arises whenever a drug trial is proposed. The ethics of treating children parenterally at these levels provoked greater discussion, and led to the decision not to have an EDTA arm. The issue of liability *per se* has not arisen.

For purposes of the proposal, ethical treatment of children is, of course, paramount, and offerors must only propose regimens that they believe to be ethical. The final protocol will have to be approved by the review boards at each clinical institution, at NIEHS, and possibly, under a recently proposed guideline, a special review board because of the involvement of children. Offerors must propose a regimen that they consider to be best.

Remember, the first sentence of the statement of work says "Independently, and not as an agent of the government". Offerors concerned about legal liability should discuss such matters with appropriate legal staff at their institutions.

Is it legal to treat children with placebo in these ranges?

NIEHS is unaware of any state that requires children to be treated with chelating agents at any level of blood lead. If this trial would be illegal to pursue in its basic form, i.e., a placebo controlled (double) blind experiment, then institutions in such municipalities should consider such constraints before proposing. Some states may require continued monitoring of blood lead and further intervention depending on the persistence of the blood lead above a certain concentration. Again, NIEHS is unaware of any state with regulations detailed at that level, but if state regulations proscribe methods that are plausible for the trial, such as uniform levels of clean-up and efforts at abatement that depend on the initial blood lead, then institutions in those municipalities should give due consideration to the impact of such regulations before offering proposals.

Drug Regimen

The suggestion in the RFP was meant only to indicate that regimens other than the labelled one could be proposed, since the drug was being used for a non-label indication anyway. Offerors are free to propose what they think is the best regimen. The regimen actually used in the trial will be the result of the deliberations of the steering committee and approved by the human subjects committees and the Data and Safety Monitoring Committee.

Monitoring

Are McCarthy and Bayley scales required? What about quality control for the psychometricians?

Yes, for reasons of comparability with the majority of the literature in the area. Offerors are free to propose additional testing and justify it. Testing the testers is a customary part of studies using these instruments; offerors should propose a means of doing so.

Should compliance be monitored?

The RFP said that putting an easily monitored substance, such as riboflavin, in the vitamin supplement could be done. It will be technically more difficult to alter the succimer-placebo. NIEHS believes that compliance is an issue, and a means to monitor it should be proposed.

Can continued monitoring and clean-up of house dust etc be proposed? Can inspection of a new home be proposed?

Yes.

REFERENCE NO.: Request for Proposal (RFP) NIH-ES-92-31

PROJECT: "Toxicity of Lead in Children Trial -- Clinical Center"

How long should the children be monitored?

Children are followed until age 4 to 5; a scheme for monitoring their homes should be proposed.

How frequently should blood lead be monitored?

Offerors are free to propose whatever monitoring scheme they believe to be best. As is true for many aspects of the trial, the approach that the offerors take to the problems posed by this trial will allow the technical review group to evaluate the insight and expertise of the offerors. The actual monitoring scheme will be part of the final protocol, decided upon as noted above. The blood lead and urine lead monitoring scheme in the RFP is designed to allow simple budgeting for those proposing to be the central labs, and should be viewed as a budget device rather than a scientific recommendation.

Clean-up, abatement, etc.

Clean-up short of full abatement is a moving target. Offerors should propose means of clean-up that they believe to be ethical and clinically justified, that can be generalized to most or many of the 3 million children in this lead range, and that do not constitute an emolument of such great value that consent to be in the trial is coerced or appears to be coerced. HUD has recently proposed guidelines for in-place management; CDC offers tactics for temporary management. NIEHS does not discourage abatement, and offerors should expect to pursue their usual avenues of attempting to have housing fully abated; however, the trial is not an abatement trial.

Once a child is eligible for the trial, the aggressiveness with which abatement is pursued should be independent of the blood lead level. Neither CDC nor HUD guidelines state that abatement can be pursued less vigorously if the child's blood lead falls. If drug treatment does alter blood lead levels more than clean-up, and abatement does lower blood lead levels, and abatement is pursued more vigorously in the placebo group, then that will diminish the effect of treatment. Therefor, abatement should be pursued because a child initially had an elevated blood lead and not because the elevated blood lead level persists after initial treatment and clean-up.

Are there cost constraints on clean-up?

The paramount considerations are the ethical treatment of children and the generalizability of the trial. NIEHS hopes that the regimen tested will reflect "real world" conditions, which unfortunately do not include immediate full remediation for all children. CDC has proposed guidelines for children with blood

levels of 20-44 μg/dl that include environmental investigations within 10 working days, emergency measures to reduce lead exposures, and some "preventive maintenance" practices until abatement is done. In general, abatement is the responsibility of the landlord, housing agency, or owner. Offerors should propose inspection and clean-up practices that reflect the realities of their catchment districts, such that if the intervention succeeds, it can be expected to succeed in practice, and if not, then due diligence on the part of the pediatric care giver has been exercised. Coordination of the trial with other local agencies is encouraged. While no fixed dollar amount has been devoted specifically to clean up, the question reflects the fact that abatement of all dwellings of children in the trial would be extremely expensive and would likely make the conduct of the trial non-feasible. The final protocol will include an inspection and clean-up protocol; this will result from the deliberations of the steering committee.

- *What if performing clean-ups result in children still needing environmental intervention, and are eligibility levels realistic?*

These topics have been subjects of considerable discussion; there are clearly dilemmas and no easy answers. There is nothing in the RFP that says that children should not have their sources of lead abated, and the trial comparison is unaffected by abatement if treated and placebo children have their sources abated similarly. In general, the design of the trial assumes that abatement efforts would proceed as if the trial were not taking place. Whatever efforts those responsible for treating the child would make in any case should still be made, but if the results of the trial are to be applicable to the real world for the next generation or so until abatement is complete, then including immediate abatement for children in the trial when it is not generally available poses problems in generalizability of results. In addition, an emolument worth in some cases thousands of dollars could prevent true informed consent on the part of the parents.

The question does pose a specific difficulty that does affect trial validity; if the signal for more aggressive efforts at abatement is the child's lead level, and drug affects lead level more than placebo, then the extent to which children with higher levels do in fact receive greater abatement and the extent to which that actually translates into lower levels biases the comparisons between groups. If the offerors believe that this will be a frequent chain of events, then they should discuss means of dealing with it. In general, though, the CDC guidelines do not appear to say that continued efforts at abatement can be relaxed if the child's lead level falls. Once a source is identified, then abatement of that source is pursued, and if immediate abatement is not possible, then whatever temporary measures appear appropriate are taken.

REFERENCE NO.: Request for Proposal (RFP) NIH-ES-92-31

PROJECT: "Toxicity of Lead in Children Trial -- Clinical Center"

Can trial funds be used for legally required abatement?

Trial funds may not be used for legally required abatement. If someone is legally required to abate, then their responsibility to do so is not removed by the child's participation in the trial.

Are limited abatements - i.e., scraping and repainting deteriorated surfaces - permitted as a prerequisite to starting succimer?

The final decision will be based on the final protocol. There may not be as much hazard associated with giving succimer to a child who might have further exposure, but it is clearly not desirable.

What is the goal of the dust clean-up? Please express it in terms of blood lead, and, if possible, in terms of dust lead. If there is no such goal, then why is it being done?

The goal of dust clean-up is to reduce the exposure of the child to lead. Since, at the very least, age and the child's behavior would affect the relationship between dust lead and blood lead, it is impossible to state a goal of blood lead by dust lead. The permissible values for dust lead vary. Maryland's 1988 interim numbers were about 2 mg/m^2 for floor dust and 5 mg/m^2 for window sills. The fact that a blood lead level can not be predicted from a dust lead is not a reason not to prevent exposure by cleaning up dust. Prevention of exposure by some degree of clean-up and abatement (with admittedly weak data on exactly what kind, how much, etc) is an explicit part of public health practice, HUD guidelines, and clinical practice, and proposing chelation therapy without some effort at prevention of further exposure would be very unlikely to be approved by an IRB.

What happens if blood lead of a kid rises to the pre-Rx level? Will additional or more frequent clean-up be allowable? What happens of if there is a pattern of such increases across clinical centers? What happens if the levels still don't go down?

This trial is based on the idea that we do not know whether drug treatment of children at these levels confers a net benefit to the child. Clean-up may or may not be effective, but if done properly should be risk-free. The fact that a child's blood lead does not go down does not mean that we know that the child needs drug; it may mean that the child is spending time someplace other than where we thought, or that clean-up was not performed, etc. Offerors must propose what they think is the best way to handle variations in blood lead; however, they must be willing to accommodate to trial protocol, and a fundamental assumption of the trial is that we do not know whether drug treatment at these levels is net good or bad. Thus, the idea that children will "need" drug because clean-up does not work appears to be an unlikely aspect of the final design.

What is the basis for the premise that most houses will not need major remediation?

Perhaps this could have been better stated by saying that a child might achieve blood lead levels in this range without living in seriously deteriorated housing.

Can one use isotopic analysis for environmental Pb Survey?

One can propose it.

Will variation in efforts at abatement in different states affect trial validity?

Differences in abatement practices that are unrelated to active drug treatment do not affect validity; a series of assumptions are necessary to predict whether there would be an effect on power.

Eligibility

Are the age limits for the children set?

No, but if the age range is younger, say one year, then fewer children will be found in any given population who are eligible for the trial. Offerors should take into account the overall lower blood lead levels of one year olds and be sure that their accrual estimates are reasonable for this age if they propose to begin young. Also, recall that the relationship between blood lead and subsequent development is stronger for blood lead at 2 years than it is for blood lead at 1 year.

When is iron deficiency to be identified and treated?

Children should be known to be iron replete or at least being treated for any iron deficiency by the time they are randomized.

Are there conditions or illnesses that preclude a child's participation in the trial?

Probably yes. Offerors should list any conditions that they believe preclude participation and how they are to be diagnosed or recognized.

Does NIEHS want children enrolled that had never had evidence of iron deficiency?

Offerors should propose what they believe to be reasonable eligibility criteria. It seems likely that, in the children eligible for the trial on the basis of their blood lead, that removing iron deficient kids would make the sample size extremely hard to get and would hamper the generalizability of the trial.

Does NIEHS want children enrolled that had never been chelated?

Offerors should propose what they believe to be reasonable eligibility criteria. Children with a history of chelation should be rare at this age.

Does NIEHS want children enrolled that have no risk factors for developmental delay (i.e., premature, multiple gestation, chronic otitis media)?

Offerors should propose what they believe to be reasonable eligibility criteria. Children so impaired that they are "bottoming" on testing are likely to have no effect from treatment even if it works, and thus such children use up trial slots but gain nothing and contribute nothing. Testable children who were premature, or not singletons, or who have otitis might well benefit from treatment, and they are part of the community to which the trial wishes to generalize.

Blinding

What justifies loss of blinding? What level of blinding is required?

Offerors must propose what they believe to be the best study design. Designs consistent with the basic trial include fully blinded designs with an escape, in which the study physician, the parent and child, and the psychometrician are all blind, to single blind designs, in which treatment assignment is random and the psychometrician is blinded but the child's blood lead is managed openly. In general, the more open the design, the more likely it is that questions of bias will be raised about the results. Proposals that do not offer truly random treatment assignment and blind psychometric assessment are proposing in essence a different study than what was approved at NIEHS. The degree of blinding proposed by the offeror will be considered, among other things, in the evaluation of proposals, but the final decision will be made by the Steering Committee.

Can parents be made blind to treatment, if children given active drug smell like mercaptan?

Possibly not. Offerors could consider proposing to query parents about whether they knew if the child was getting active drug, and see if they get it right. NIEHS knows of no agent that smells like a mercaptan and could serve as a placebo.

Do parents get the blood lead information?

Yes, if they want it.

Who knows lead levels?

Lead levels done prior to randomization are open. Those who must evaluate (McCarthy testers) the children cannot know lead levels after randomization. Ideally, no one knows post treatment lead levels; however, offerors may not find this degree of blinding acceptable. If the proposed treatment regimen requires succimer to be given until the blood lead reaches a certain level, then the person administering the drug must know lead level. Offerors are reminded of a fundamental premise of this trial: We do not know if treating lead levels in this range with a drug confers a net benefit to the child. If the drug regimen is fixed, then no one need know except an a safety monitor.

What happens for repeat treatments if, over course of study, succimer is approved for use in this range? i.e., child placebo treated at age 18 months, has lead level of 39 at age 30 months and now succimer is on label? Do you deny treatment or assume randomization covers confounding between groups?

The fact that a drug is labelled for an indication, in this case the lowering of blood lead, does not mean that it provides a therapeutic benefit other than changing a number. FDA did not require evidence that succimer did anything other than lower blood lead with an acceptable degree of safety and efficacy before labelling it for treating blood leads above 45 µg/dl, and they will likely not require any other kind of data in support of relabelling. An analogy might be drugs used to lower blood pressure or cholesterol; the fact that the drugs changed the numbers did not mean that they were known to prevent stroke or heart attack, or that they did so with an acceptable degree of safety.

There is no evidence that chelation changes blood lead long term, i.e., years. Thus, children in either arm should be equally likely to experience higher blood leads later. There would still be no evidence that treating such elevations with drug conferred a net benefit, but treating such children should not affect the validity of the trial.

Miscellaneous

Are crossover designs allowed?

A cross-over design has not been discussed for this trial. As noted above, a parenteral drug would be problematic; penicillamine, has had no constituency in the various persons and groups with whom the trial has been discussed. If an offeror believes that such an approach is the best, or that it is the only ethical approach, then they are free to propose it. However, if the final protocol is succimer, placebo, and no crossover, and the offeror is unwilling to participate in a study so configured, then they should so state clearly in their proposal.

REFERENCE NO.: Request for Proposal (RFP) NIH-ES-92-31

PROJECT: "Toxicity of Lead in Children Trial -- Clinical Center"

Can children come from different institutions?

Offerors are free to propose any reasonable method for enrolling children. Technically, there must be one responsible investigator.

Is there a formal protocol?

The final protocol will result from the deliberations of the steering committee during the planning phase of the trial.

Budget:

a) *Guidelines*: See pages 91-99, and 104-108 of the RFP.

b) *Is there money committed to this project?* NIEHS anticipates that funds will be available to support this project.

c) *Third party payers*: We are not sure we understood this question, even after the meeting. If, for example, in those cases where a "patient" being treated for a separate disorder would otherwise have certain costs covered under an insurance plan, then those costs would continue to be appropriately covered under the plan. Otherwise, in terms of how NIEHS proposes to pay for the project, the information is not considered relevant to constructing a proposal.

Start date:

This depends on a number of variables influencing the length of negotiations. The anticipated start date should be no later than mid to late June, 1993 for the award of the contracts.

Sample size.

The assumptions for the sample size calculations are that the GCI of the McCarthy is the outcome variable of interest, that we wish to be able to detect a difference of 3 points between the drug and placebo groups with 80% power, that the two groups are statistically independent, and that the standard deviation of the GCI is 15 points. There is no analysis involved; the sample size was calculated with a program called POWER, but any method should give the same results.

REFERENCE NO.: Request for Proposal (RFP) NIH-ES-92-31

PROJECT: "Toxicity of Lead in Children Trial -- Clinical Center"

Format. Page 100 of the RFP provides a format.

Breakdown of hours.

The estimated number of hours per general classification and in total set forth in the RFP are primarily provided to give potential offerors an indication of the general magnitude of the effort contemplated. In developing proposals, as indicated in the instructions for preparation of technical and business proposal, offerors are expected to provide sufficient detail, including breakdown of specific labor categories, job titles, hours, rates, etc. to permit reasonable review. Offerors must propose what they think the work will take to do.

Why doesn't this study coordinate with other programs run by CDC and HUD?

Requiring that this trial be performed at sites already participating in CDC or HUD programs would severely and, in our view, unnecessarily restrict competition. This topic has not arisen in our conversations with CDC, nor in our admittedly restricted conversations with HUD.

Do the clinical centers need to submit a data analysis plan?

No. The coordinating center submits a data analysis plan.

Can a clinical center also be a coordinating center?

Yes, subject to some constraints. (See paragraph a. to amendment)

Can the planning period be decreased in order to increase the enrollment period?

NIEHS believes that at least 9 months will be required to plan this study, get necessary clearances, get an IND, etc.

Will animal studies be supported under this RFP?

No.

Elaborate on the pilot study.

Whether or not a pilot phase is needed will arise in the deliberations of the Steering Committee. It appears likely that some aspects of this trial will not have been tried before anywhere, and many will not have been done at any of the successful institutions. Having one institution try out data entry, or recruitment, or clean-up methods etc., may be wise before committing the whole trial to an untried method. The RFP asks whether a given institution wishes to be considered in that role, perhaps because it may already have in place recruitment, or clean-up. or other practices that could be incorporated into the trial.

Apply for the lab option alone?

Since the conduct of the lab work is uncertain at this point, and since the active clinical centers will have to do some lab work, it appeared unreasonable to solicit independent lab proposals for work that, in fact, may not be done by an independent lab. As outlined in the proposal, we think it more sensible to look for an independent lab only if CDC chooses not to do the lab work and none of the clinical centers have capable labs. Making an isolated award to a lab at this point would require solicitation of lab proposals, which we would rather not do until the other options are not open.

Lease equipment? Yes.

Page 102 under additional personnel: With the short time frame involved, it will be very difficult to identify all new additional personnel for the project, and to have their commitment letters included for the RFP submission. Can you extend the time to before the study section review?

From a technical point of view, adequate judgement of the merit of the proposals requires that the PI be committed and that there is sufficient assurance that personnel necessary to carry out the lab work will be available. The time for proposals will not be extended.

Is urine Pb performed on spot sample?

Yes.

REFERENCE NO.: Request for Proposal (RFP) NIH-ES-92-31

PROJECT: "Toxicity of Lead in Children Trial -- Clinical Center"

Why monitor urinary metals? How should peripheral issues such as XRF, chelation challenge, renal function, and other cations be handled?

These are options. If investigators believe that the issue of cation diuresis with succimer is sufficiently settled that no information with the trial is necessary, then they need propose no monitoring. If they believe that clinically relevant information can be gathered by monitoring of urinary cations, then they should propose to do it. If an offeror believes that any of the options are clinically or scientifically necessary, then they should so state. It is not obvious that chelation challenge is a necessary or desirable part of the trial, but it is a practice at some centers. If offerors believe that the options would contribute data of interest or relevance, but that such data are not crucial, then they are free to propose the use of such options, with the realization that they may or may not be fundable.

c. The following documents which may be of interest to offerors are available through the means indicated below.

(1) Attachments:

TLC Laboratory Analyses

(2) Documents available through the public domain:

(a) Notice entitled "NOFA for Lead-Based Paint (LBP) Risk Assessments", Federal Register, June 29, 1992, Part II. Department of Housing and Urban Development

(b) Article entitled "Determination of Lead in blood Using Electrothermal Atomization Atomic Absorption Spectrometry with a L'vov Platform and Matrix Modifier", Analyst, December 1987, Vol 112

(c) Article entitled "Selected Methods for the Small Clinical Chemistry Laboratory", Selected Methods of Clinical Chemistry", Volume 9, 1982, American Association for Clinical Chemistry

(d) Article entitled "Three City Urban Soil-Lead Demonstration Project, EPA, May 1981, US Environmental Protection Agency, Solid Waste and Emergency Response (OS-240) 21S-2001

(3) Documents available from New York State Department of Health, Wadsworth Center Lead Poisoning Laboratory, Empire State Plaza, Albany, New York 12201-0509:

(a) Article entitled "Blood Lead Determination by Electrothermal Atomization Atomic Absorption spectrometry with Perkin-Elmer 4100ZL AAS", DOH, New York State Department of Health, December 18, 1991

REFERENCE NO.: Request for Proposal (RFP) NIH-ES-92-31

PROJECT: "Toxicity of Lead in Children Trial -- Clinical Center"

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(4) Documents available from Centers for Disease Control (CDC):

(a) Article entitled "Spring 1992 Blood Lead Survey Results", Blood Lead Laboratory Reference System, CDC

(b) Article entitled "Quality Assurance of Chemical Measurements", John Keenan Taylor, Lewis Publishers, Inc., 1987

(c) Documents referenced in (2) and (3) not available otherwise

References identified in (2) may be available from libraries and the original source of publication. Offerors interested in obtaining reprints directly from CDC should contact:

Dayton T. Miller, Ph.D.
Chief, Nutritional Biochemistry Branch
Division of Environmental Health Laboratory Sciences
Center for Environmental Health
Centers for Disease Control
Atlanta, Georgia 30333

\\\ END OF AMENDMENT ///

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, N.C. 27709

June 25, 1993

ATTN: Ms. Karen Sorensen
Contract Administrator
Kennedy Krieger Research Institute
707 North Broadway
Baltimore, Maryland 21205

Reference: Contract No. N01-ES-35362 (RFP NIH-ES-92-31)
"Toxicity of Lead in Children - Clinical Center"

Dear Ms. Sorensen:

Reference is made to pending contract N01-ES-35362 entitled "Toxicity of Lead in Children -- Clinical Center". Enclosed are three copies of the contract award document. Please review the contract and, if acceptable in its present format, retain a copy, sign and return two copies no later than 12:00 p.m. June 30 to the following address:

National Institute of Environmental Health Sciences
ATTN: Thomas M. Hardee, Contract Specialist
Contracts & Procurement Management Branch, OM
79 T.W. Alexander Drive, 4401 Research Commons Building
P.O. Box 12874
Research Triangle Park, NC 27709

Failure to return the signed documents in a timely fashion could result in the forfeiture of FY'93 funding to support this project with no guarantee that other funds will be made available to replace those not obligated prior to June 30, 1993.

If for any reason you take exception to the proposed contract, please identify immediately the exact location of any questionable language, provide your complete rationale and reasoning supporting the exception(s), and make suggestions on any changes you deem appropriate. You are advised that the NIH Board of Contract Awards has not yet completed its review and may recommend changes to the pending contract. In such case, you will be informed immediately of any such changes. If received prior to award, with your acknowledgement, the changes will be inserted into the contract. If received after award, the changes will be introduced by modification.

Also forwarded herewith is a copy of the appointment of Project Officer. Please be advised that within the Government no doctrine of apparent authority exists. The limitations on the respective authorities and when they apply are explicit. Should anyone within or outside the Government other than the appointed individuals (except for NIEHS Contracts office personnel) give directions concerning the contract, or if the appointed

individuals should give directions which you believe may exceed their expressed authority, you are required to notify the Contracting Officer in accordance with FAR 15.243-7, Notification of Changes (APR 1984). Please sign and return with the two copies of the contract.

When the document is accepted by the Government, a fully executed copy will be returned to you for your files.

Should you have any questions, please contact me at telephone number (919) 541-0429 or Don Gula at (919) 541-0423. We look forward to a successful contract effort.

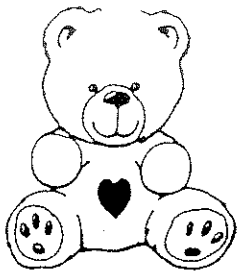
Sincerely yours,

Thomas M. Hardee

Thomas M. Hardee
Contracting Officer
Contracts & Procurement
Management Branch, OM

Enclosures

cc: Contract File



TLC
Treatment of Lead-Exposed Children

June 26, 1995

Tom Hardee
NIEHS
Contracts and Procurement Mgmt Branch
79 T.W. Alexander Drive, Bldg. 4401
Research Commons, PO Box 12874
Research Triangle Park, NC 27709

Dear Tom:

This letter is in reference to the conversation concerning use of transportation funds for either providing taxi transportation or for reimbursement of the family if they provide their own transportation to the clinic. The Baltimore Clinical Site feels that offering the option of the site providing tranportation or reimbursement for transportation will be both cost-effective and will facilitate participation in the trial. Families will have an option of one or the other for each visit to the clinic.

It currently cost us $12.00 to $22.00 every time we send a taxi to pickup a family for clinic. If the family is not ready and another cab, must be sent this is an additional cost. If the family does not come in and does not notify us the day before that they will not be in, the taxi must still be paid. If the family provides their own transportation, the study will not be charged if they are unexpectedly delayed or must reschedule at the last minute.

Although the study will be offering $15.00 for transportation reimbursement, for families that have the option of bringing themselves in this will provide a motivation to them to do so and not miss appointments unnecessarily. Also, instead of staying home when they miss the taxi, they will be more likely to bring themselves into the clinic.

The Kennedy Krieger Institute and Johns Hopkins Pediatric Clinic have received permission from the Hopkins Joint Commission on Clinical Investigation to institute such a plan (attached). They will begin offering the two options immediately. The University of Maryland site is awaiting IRB approval and will institute the plan once that occurs.

2917 East Biddle Street • Baltimore, Maryland 21213
Phone (410) 550-8363 • FAX (410) 550-8365

If you have any further questions concerning this matter, feel free to call me at (410) 550-8293.

Sincerely,

Merrill

Merrill Brophy

Attachments

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

SHAYONNA FEATHERSTONE et al.	:	
	:	
v.	:	Civil No. WMN-07-1120
	:	
KENNEDY KRIEGER INSTITUTE INC. et al.	:	

MEMORANDUM

Before the Court is Plaintiffs' motion to remand this action to the Circuit Court for Baltimore City, Maryland, Paper No. 33, and Defendants' Motion to Dismiss for Failure to Join a Rule 19 Party, or In The Alternative, Motion to Join the NIEHS.[1] Paper No. 22. The motions have been fully briefed and are now ripe for

[1]Defendants' motion to dismiss or to require joinder of the NIEHS, which raises essentially identical arguments as were raised in opposition to the motion to remand, will be denied because Defendants fail to demonstrate that NIEHS is an "indispensable" party to this action. See Fed. R. Civ. P. 19(b) (stating that, if joinder is not feasible, the Court "shall determine whether in equity and good conscience the action should proceed among the parties before it, or should be dismissed, the absent person being thus regarded as indispensable"); See also 7 Charles A. Wright, Arthur R. Miller & Mary K. Kane, Federal Practice and Procedure § 1617 (3d ed. 2001) (noting that "when relief can be granted to a party without affecting the United States, the government usually will not be held to be indispensable to the action"). Joinder is not feasible where sovereign immunity would bar suit and, in the instant case, pursuant to the Federal Tort Claims Act (FTCA), Plaintiffs would be barred by sovereign immunity from bringing suit against NIEHS as they did not exhaust administrative remedies, assuming the facts could even support a claim against NIEHS. See Def.'s Reply at 9 (arguing that the FTCA provides the means by which NIEHS could be sued and acknowledging the existence of "pre-requisites to filing suit" under the FTCA with which Plaintiffs have not complied); See also, e.g., Gould v. United States Dep't of Health and Human Servs., 905 F.2d 738, 741 (4th Cir. 1990) (government's waiver of sovereign immunity under the FTCA is limited and requires "presentation of a claim to the appropriate federal agency" prior to bringing suit).

review. Upon review of the pleadings and the applicable case law, the Court determines that no hearing is necessary and that the Plaintiffs' motion to remand will be granted and Defendants' motion to dismiss will be denied.[2]

I. FACTUAL AND PROCEDURAL BACKGROUND

This action arises out of Plaintiffs' participation in a non-therapeutic[3] research program known as the "Treatment of Lead-Exposed Children" (TLC), which was designed to "assess the effects of lead chelation with succimer[4] in children[.]" Treatment of Lead-Exposed Children Trial Protocol (Protocol) at §

[2]Also pending before this Court is Defendants' Motion for Leave to Respond to Plaintiffs' Request for Costs and Attorneys' Fees. Paper No. 42. Defendants assert that Plaintiffs raised this request for the first time in their Reply brief. Plaintiffs, in their opposition to the motion, withdrew any purportedly new request for attorney's fees, but maintained that they requested "costs" pursuant to 28 U.S.C. § 1447(c) in their Motion to Remand. Paper No. 43, ¶¶ 2, 4. To the extent Plaintiffs still seek costs, the Court denies their request and Defendants' motion is denied as moot.

[3]A therapeutic research study is one designed to "directly help or aid a patient who is suffering from a health condition[.]" Grimes v. Kennedy Krieger Inst., 782 A.2d 807, 812 n.2 (Md. 2001). Non-therapeutic research, by contrast, "is not designed to directly benefit the subjects utilized in the research, but rather, is designed to achieve beneficial results for the public at large[.]" Id. Because succimer, the drug tested in the TLC Study, conferred no known, long-term benefit to children with blood lead levels in the range of the subjects, the study was classified as non-therapeutic.

[4]Succimer is a heavy metal chelating (binding) agent approved by the FDA for treatment of children with blood lead levels in excess of 45 micrograms per deciliter.

1.1.[5] The study was funded by the National Institute of Environmental Health Sciences (NIEHS)[6] in cooperation with the Office of Research on Minority Health (ORMH) at the National Institutes of Health (NIH) and the Center for Disease Control and Prevention (CDC). TLC was carried out at four Clinical Centers (CC) throughout the United States located in Baltimore, Philadelphia, Newark (New Jersey), and Columbus (Ohio). The only CC at issue in the instant case was located in Baltimore and was based at the Kennedy Krieger Institute (KKI), in association with Johns Hopkins University (JHU) and the University of Maryland. Defendants KKI and Cecilia Davoli, an employee of KKI and a co-investigator for TLC, removed this action from the Circuit Court for Baltimore City to this Court pursuant to the federal officer removal statute, 28 U.S.C. § 1442(a)(1), on the assertion that they were acting under the direction of a federal officer in administering the Baltimore portion of the TLC study.

On August 27, 1992, NIEHS began soliciting proposals for what would become TLC. It requested proposals "for the planning, conduct, analysis, and reporting of a randomized, multi-center, placebo controlled trial of succimer in the prevention of lead-

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[5]The study initially was known as the "Toxicity of Lead in Children Trial." See Toxicity of Lead in Children Trial - Clinical Center Contract.

[6]NIEHS is a subsidiary of the NIH. NIH is a branch of the United States Department of Health and Human Services (DHHS).

associated cognitive delay in young children." RFP at C.1. In response to the RFP, on November 24, 1992, KKI submitted a Technical Proposal to NIEHS. On June 29, 1993, NIEHS awarded a contract (the Contract) to KKI to operate one of the four CCs.

Under the Contract, NIEHS would provide funding for 5 years, with a total anticipated cost of $5,765,029.00. Contract at § B.2.a. The five-year period of funding consisted of three phases: 1) 9-12 months for planning; 2) 1 year for enrollment and treatment; and 3) 3 years of follow-up. The precise "protocol and strategies" for the trial were to be developed during the planning phase by a Steering Committee consisting of the Principal Investigator(PI) from each CC, the PI of the Coordinating Center, and the NIEHS Project Officer. Id. at § C.2.

Children generally were referred for participation in TLC by their treating physicians. In order to be eligible to participate in TLC, a child had to reside in a pre-designated area (catchment area) and have a confirmed pre-existing blood lead level in the range of 20-44 micrograms per deciliter. Protocol at § 3. Because succimer was not indicated for children who continued to be exposed to lead, a condition for enrollment in the study was that the child's residence was not "too lead-hazardous to be adequately cleaned." Id. Two home visits were conducted prior to a child being deemed eligible for TLC. Id. at

§§ 3.1-3.2.

Prior to assessing eligibility and again prior to enrollment in TLC, the consent of a parent or legal guardian was required. The Steering Committee drafted and approved the language for two informed consent forms (IC) for the two stages of consent. Each IC stated that "[a]ll children in the TLC study will have their homes cleaned to get rid of lead dust and chipped paint[.]" Id. at App. 2 ("Pre-Enrollment Informed Consent" and "Enrollment Informed Consent" forms).[7]

After enrollment in TLC and prior to randomization, a "TLC cleaning crew" returned to each child's residence to clean it. Id. at § 6.3. The clean-up measures set forth in the Protocol consisted of temporary removal of all furnishings, washing of painted ledges (window sills, etc.) with a detergent solution, vacuuming of most surfaces and rugs with HEPA-equipped vacuums, disposal of deteriorated rugs, and a minimal level of "paint stabilization"[8] as conditions required. Id. The Protocol made

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[7]Both IC forms further stated that the child subjects would benefit from participation in TLC because personnel would "look carefully at [the child's] home for lead dust and chipped paint" and "clean-up the lead dust in [the child's] home." Protocol at App. 2.

[8]"Paint stabilization" as an "interim option" could be utilized where paint deterioration was localized and would consist of the removal of loose paint either with a damp towel or sponge or with a HEPA vacuum, followed by application of contact paper or a fresh coat of paint to the surface. Protocol at § 6.4. If deterioration was "extensive," "proper paint abatement" or relocation of the child was required for the child to be

clear, however, that TLC was not designed to "oversee comprehensive lead paint abatement," id., and the Contract specifically states that the contractor "shall not expend contract funds for lead abatement." Contract at § B.4.g.

Subsequent to clean-up activities and other preliminary testing of the child subjects, the treatment phase of TLC began. In the treatment phase, half of the children received one to three courses[9] of succimer chelation therapy, while the other half received a sugar-pill. Both treatment groups also received identical vitamin and mineral supplements. The children's blood-lead levels and cognitive functioning were then followed and tested to determine the efficacy of the drug for several years after treatment.

Plaintiffs are siblings who participated in the study as minor children. Shayonna Featherstone was born on October 22, 1992, and Keona Featherstone was born on September 11, 1993. From 1994 to 1997, Plaintiffs resided in two homes within the TLC catchment area.[10] Plaintiffs allege that Defendants KKI, JHU, and the Internal Review Board of the Johns Hopkins University

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eligible to participate in TLC. Id.

[9]A course of succimer treatment consisted of 1050 mg/m per day for 7 days (in three doses), followed by 700 mg/m per day for 19 days (in two doses).

[10] It is unclear from the Complaint whether Shayonna and Keona moved midway through the study, whether they resided in separate residences throughout the study, or whether they alternated time at both residences described in the Complaint.

School of Medicine's Joint Committee on Clinical Investigation (IRB),[11] jointly facilitated the administration of the study. Individual Defendant Cecilia Davoli served as a co-investigator in the study. Defendant Helen Heath, individually and trading as "Lady H Enterprises," served as a subcontractor who performed interventions[12] on the study homes. Plaintiffs allege that KKI and Davoli coordinated with Defendants N.A.C.I. Corporation, Shenan Management, Inc., Marc Medin, Nancy Medin, Pythagoras Passas, and Anne Passas, landlords of lead-containing homes, to secure homes for the study which would be rented to tenants with minor children.[13] In exchange, KKI and Davoli assisted the landlords in applying for grants or forgivable loans to perform interventions.

On March 22, 2007, Plaintiffs brought the instant action in

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[11] Individual Defendants Thomas R. Hendrix, Lewis C. Becker, David R. Cornblath, Paul Lietman, and Hayden G. Braine are each named as members of the IRB during the relevant period, along with Defendant John/Jane Doe, representing any unknown members of the IRB.

[12] Plaintiffs use the term "intervention" to refer to activities designed to removed lead dust and lead hazards from the homes. Defendants use the terms "clean" or "clean up."

[13] Plaintiffs allege that, "in order to facilitate recruitment," Defendants offered the parents of the participants, "cash, gift certificates, and other financial rewards for allowing their children to remain in the study." Compl. ¶ 14. Defendants also allegedly promised that they would "look carefully at the children['s] homes to identify lead hazards," that "if their house did not 'qualify'" for the study, the child would be relocated to lead-safe housing, and that they would "clean up the lead" in the homes of children enrolled in the study. Id. ¶¶ 10-12.

the Circuit Court for Baltimore City, Maryland. In their Complaint, Plaintiffs allege eight counts: negligence (Counts I, IV, V and VI), negligent misrepresentation (Counts II, III), civil conspiracy (Count VII), and breach of fiduciary duty (Count VIII). Compl. ¶¶ 36-89. Plaintiffs allege, inter alia, that succimer was "not indicated for prophylaxis of lead poisoning in an environment containing lead hazards," that the parents of the children were not informed of this fact, that Defendants knew or should have known that the interventions performed on the study homes were "not sufficient to remove lead-based paint hazards," and that Plaintiffs received no benefit from participation in TLC, but were in fact harmed by it. Id. at ¶¶ 6-25.

Defendants KKI and Davoli removed this action on the assertion that, as persons acting under an officer of the United States, they are entitled to removal pursuant to 28 U.S.C. § 1442(a)(1).[14] Thereafter, Defendants moved to dismiss the Complaint for failure to join a necessary party or, in the alternative, for joinder of the NIEHS. Plaintiffs opposed the motion, arguing that the NIEHS was neither necessary or indispensable under Rule 19 of the Federal Rules of Civil Procedure in that the challenged aspects of TLC were within the

[14] While JHU and the IRB did not join in KKI and Davoli's Notice of Removal, JHU and the IRB did join in the opposition to Plaintiff's Motion To Remand and raise an independent justification for removal, which will be discussed, infra.

control of the Defendants, not NIEHS. Advancing similar arguments, Plaintiffs moved to remand.

II. STANDARD OF LAW

The federal officer removal statute, 28 U.S.C. § 1442(a)(1), provides that a state court action may be removed by "the United States or any agency thereof or any officer (or any person acting under that officer) of the United States or of any agency thereof, sued in an official or individual capacity for any act under color of such office[.]" The Supreme Court has explained the purpose of Section 1442(a)(1) as follows:

> [T]he Federal Government can only act through its officers and agents, and they must act within the States. If, when thus acting, and within the scope of their authority, those officers can be arrested and brought to trial in a State court, for an alleged offense against the law of the State, yet warranted by the Federal authority they possess, and if the general government is powerless to interfere at once for their protection, - if their protection must be left to the action of the State court, - the operations of the general government may at any time be arrested at the will of one of its members.

Mesa v. California, 489 U.S. 121, 126 (1989) (internal quotations omitted).

Section 1442 creates an exception to the well-pleaded complaint rule "because it operates on the basis of issues generally thought to be defensive in character rather than on the content of the plaintiff's claims." 14C Charles A. Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice and Procedure § 3727 (3d ed. 1998). A defendant seeking removal bears the burden of demonstrating jurisdiction and, generally,

due to federalism concerns, removal statutes are strictly construed and all doubts will be resolved against removal. Md. Stadium Auth. v. Ellerbe Becket Inc., 407 F.3d 255, 260 (4th Cir. 2005). Courts have interpreted the federal officer removal statute broadly when addressing the immunity of individual federal officials, and more narrowly in cases involving government contractors. See Freiberg v. Swinerton & Walberg Prop. Servs., Inc., 245 F. Supp. 2d 1144, 1152 n.6 (D. Colo. 2002). For a government contractor to establish removal jurisdiction under this provision, it must "(1) demonstrate that it acted under the direction of a federal officer, (2) raise a federal defense to plaintiffs' claims and (3) demonstrate a causal nexus between plaintiffs' claims and acts it performed under color of federal office." Pack v. AC & S, Inc., 838 F. Supp. 1099, 1101 (D. Md. 1993) (citing Mesa, 489 U.S. at 124-25, 129-31, 134-35).

III. DISCUSSION

A. The R&M Study

This Court recently granted motions for remand in two actions concerning the "Lead-Paint Abatement Repair and Maintenance Study" (R&M), a study funded by the Environmental Protection Agency (EPA) to assess the effects of different levels of residential lead-paint abatement on the blood-lead levels of children residing in the homes. Wallace v. Kennedy Krieger Institute, Inc. et al., No. 07-1140 (D. Md. Aug. 14, 2007); Covington v. Kennedy Krieger Institute, Inc. et al., No. 07-1761

(D. Md. Oct. 12, 2007). Wallace and Covington involved many of the same Defendants as the instant action, including KKI, JHU, and the IRB.

Plaintiffs argue that the TLC and R&M studies are virtually identical and urge the Court to remand the instant action for the same reasons stated in Wallace.[15] See Mot. at 10-15 (discussing the similarities between TLC and R&M). Defendants respond that TLC and R&M are independent studies, that there are "clear differences between the studies" which warrant a "fresh evaluation of federal jurisdiction," and that "prior rulings by this Court regarding the R&M Study are not relevant to the analysis of the TLC Study and should not be considered." Opp'n at 10.

The Court agrees with Defendants that there are significant differences between TLC and R&M, but disagrees that the R&M study and the prior rulings of this Court are irrelevant to the instant case. The Court will consider the relevant similarities and differences in analyzing the issue of federal jurisdiction over the instant action.

B. Person acting under a federal officer

Defendants KKI and Davoli admittedly are not officers of the United States. Thus, to remove this action under § 1442(a)(1),

[15]As Covington was remanded after briefing in this matter was complete, Plaintiff relies only on the Court's ruling in Wallace. In any event, Covington and Wallace present essentially identical factual scenarios.

they must initially establish that they were "persons[16] acting under the direction of a federal officer." Wright, Miller & Cooper, supra, § 3727. To make this showing, Defendants must demonstrate that they were 1) acting under the direction of a federal officer and 2) that there is a causal nexus between Plaintiffs' claims and those acts performed under color of federal office. As one court has noted, these two elements tend to "converge into a single inquiry: whether the defendants are being sued 'based upon actions taken pursuant to federal direction.'" Ryan v. Dow Chem. Co., 781 F. Supp. 934, 945 (E.D.N.Y. 1992)(quoting Gulati v. Zuckerman, 723 F. Supp. 353, 358 (E.D. Pa. 1989)).

Plaintiffs' Complaint alleges injury resulting from KKI and Davoli's negligent management of the "partial lead-abatement interventions" and their alleged misrepresentations and omissions with respect to lead levels in the Plaintiffs' dwellings and the potential harm resulting from exposure to that lead. See, e.g., Compl. ¶¶ 36-41 (alleging that the interventions performed on Plaintiffs' homes violated the Baltimore City Housing Code). Plaintiffs' further allege that, by virtue of the IC forms, KKI and Davoli assumed certain duties towards the Plaintiffs which they subsequently breached. See id. ¶¶ 60-65 (alleging, inter alia, duties to ensure that a doctor monitored Plaintiffs' blood-

[16]It is clear that private corporations may be characterized as "persons" under Section 1442(a)(1). See Pack, 838 F. Supp. at 1103.

lead levels and "promptly and accurately report those test results" to Plaintiffs' family and to provide "ongoing medical care of the Plaintiffs' lead-paint poisoning and lead toxicity").

Plaintiffs contend that KKI and Davoli have failed to demonstrate that they were acting under the direct and detailed control of a federal officer with regard to the alleged acts. As this Court explained in Wallace:

> To demonstrate action under the direction of a federal officer for the purposes of § 1442(a)(1), a defendant must show that "the acts forming the basis of the state suit were performed pursuant to an officer's 'direct orders or comprehensive and detailed regulations.'" Freiberg, 245 F. Supp. 2d at 1149-50 (quoting Ryan[, 781 F. Supp. at 947]). Courts have held that this showing requires a defendant to demonstrate action under the direct control of an officer of the federal government, as opposed to the general control of an governmental agency. See, e.g., Good v. Armstrong World Indus., Inc., 914 F. Supp 1125, 1129 (E.D. Pa. 1996) (holding that "[a]cting under the direction of the Navy . . . is not the same as acting under the direct and detailed control of a federal officer"); see also Ryan, 781 F. Supp. at 947 (noting that proof that "relevant acts occurred under the general auspices of a federal office or officer" or that "a corporation participates in a regulated industry" is insufficient).

Slip. op. at 7-8.

KKI and Davoli contend that the Notice of Removal expressly alleges action under the direction of a federal officer, to wit, Dr. Walter J. Rogan, the NIEHS Project Officer (PO) for the TLC Study. Opp'n, ¶ 3. While the Notice of Removal filed by KKI and Davoli contains numerous allegations of general control exercised

by the NIEHS, the CDC[17], the Food and Drug Administration (FDA)[18], the DHHS, and the United States Congress, see, e.g., Notice of Removal ¶¶ 8-12, 25-29 (stating that "the federal government directed and controlled" KKI's actions and that "NIEHS maintained detailed, hands-on control over all phases" of the study), it also alleges direct control by Dr. Rogan. Specifically, KKI and Davoli assert that Dr. Rogan was appointed PO after the Contract was awarded to KKI; that, as PO, he was responsible for maintaining "complete surveillance of the technical performance" of the contract to ensure that contractors complied with the "specifications/requirements of the contract terms"; that Dr. Rogan was a member of the Steering Committee that developed the TLC Protocol; that "[f]inal authority over each and every aspect of this study rested with the NIEHS Project Officer"; and that Dr. Rogan performed site visits at KKI and visited residences involved in the study. Id. at ¶¶ 13, 15-16, 19-20.

In Wallace, this Court found the Notice of Removal deficient on its face because the defendants made "general reference to multiple agency employees" and alleged generally that the federal government controlled and directed the R&M study. See Wallace, slip op. at 8. In the instant case, KKI and Davoli, while making certain allegations of general control, clearly single out Dr. Rogan as the key federal officer responsible for administering

[17]The CDC performed the laboratory analysis of blood lead samples for study participants.

[18]The FDA approved NIEHS's "Investigational New Drug" application for use of succimer in the study.

TLC.[19]

The Court's inquiry does not end there, however, because under Section 1442(a)(1), Defendants cannot merely allege control on the face of the Notice of Removal, but must make a showing of actual control. See Good, 914 F. Supp. at 1129 (noting that a defendant has the burden to "set forth evidence showing that it did, in fact, act under a federal officer"). The Court begins with the affidavits signed by Davoli and Merrill Brophy, KKI's Project Manager for TLC. The affidavits detail the role of the Steering Committee, Dr. Rogan, NIEHS, the CDC, and the FDA in controlling aspects of the study. With regard to Dr. Rogan, both Davoli and Brophy aver that the Steering Committee "was charged with responsibility for virtually all aspects of the study," that "each and every decision of the Steering Committee was reviewed by Dr. Rogan prior to or during the process of its implementation," and that "[n]o decision was final without review by Dr. Rogan and the NIEHS." Aff. of Merrill Brophy ¶¶ 4-5; Aff. of Cecilia Davoli ¶¶ 4-5. With regard to the IC forms, Davoli avers that "the NIEHS directly controlled and approved the information provided to the Study participants and their families

[19]Defendants also suggest that NIEHS's contracting officer, Thomas Hardee, exercised direct and detailed control over TLC as the "sole agent of NIEHS" for purposes of the study and the only person who could approve funding changes. Opp'n at 5. The Notice of Removal, however, makes only one reference to "NIEHS's contracting officer" with respect to Mr. Hardee's role in approving the Contract after it was signed. Notice of Removal at ¶ 12. The affidavits attached to the Notice of Removal make no mention of Mr. Hardee, either by name or by title. The Court concludes that the Notice of Removal fails to allege any direct and detailed control by Mr. Hardee.

as well as the information contained in the Informed Consent forms" and that the IC form was approved by both the local IRB and the NIEHS IRB before it was used in TLC. Aff. of Cecilia Davoli ¶¶ 6, 12. Thus, Defendants argue that Dr. Rogan's position on the Steering Committee was such that he "specifically directed each and every facet of the TLC study[.]" Opp'n at 11.

The Court's review of the Contract and the Protocol, however, reveals that Dr. Rogan's role on the Steering Committee was more circumscribed. The "Administration" section of the Protocol states that "[c]entral policy for the Trial will be set by a Steering Committee[.]" Protocol at § 2.2; See also Contract at § C.2 ("The protocol and strategies for the trial will result from the deliberations of the Steering Committee during the planning phase."). The Steering Committee was composed of seven members: one representative from each of the four CCs, a representative from the Harvard School of Public Health (serving as the Data Coordinating Center), a representative of the CDC, and the NIEHS PO (Dr. Rogan). Protocol at § 2.2. Dr. Rogan served ex officio and only voted to "resolve ties." Id. Thus, to the extent that the six "regular"[20] members agreed, Dr. Rogan did not have a vote on the Steering Committee.

The Court notes that, even to the extent that Dr. Rogan actively guided the decision making process through the Steering Committee as Brophy and Davoli aver, participation in a collaborative process with a federal officer is not the same as

[20]This is the term used in the Protocol.

acting "pursuant to an officer's 'direct orders or comprehensive and detailed regulations" as is required under Section 1442(a)(1). See Pack, 838 F. Supp. at 1103 (finding direct and detailed control where the government "specif[ied] and approve[d] the type of asbestos cloth to be used" by defendant in building turbine generators); McMahon v. Presidential Airways, Inc., 410 F. Supp. 2d 1189, 1197 (M.D. Fla. 2006)(finding direct and detailed control over a company contracting with the Department of Defense to provide air transportation and operational support services in Afghanistan where the government controlled crew qualifications and equipment and determined flight routes); See also Ryan, 781 F. Supp. at 947-49 (collecting cases). Thus, to the extent that Defendants rely on Dr. Rogan's role on the Steering Committee in support of federal jurisdiction, the Court concludes it has not met its burden of showing "direct and detailed control."

Even were this Court to have found that Dr. Rogan's role on the Steering Committee amounted to direct and detailed control, the lack of a causal nexus between that control and the acts alleged by Plaintiffs also would support remand. The Court initially notes, as KKI and Davoli concede, that a local entity, the Maryland Department of Housing and Community Development (DHCD), not the federal government, funded the "interventions" performed on study homes. See Opp'n at 24 (acknowledging that the "lead dust clean-up" efforts were to be performed "[p]ursuant to an unfunded mandate" in the Contract). Defendants contend,

however, that the funding source is irrelevant given that the study homes were "cleaned . . . in accordance with the strict requirements set forth in the Contract with NIEHS and the Trial Protocol approved by Dr. Rogan." Id. at 23-24.

The "Statement of Work" in the Contract specifically directed that KKI was to "evaluate children's homes" and "provide clean-up according to trial protocol." Contract at § C.2. The Protocol provides precise specifications as to how TLC personnel were to perform the environmental "clean-up" required by the Contract. See, e.g., Protocol at § 6.3 (stating that, "[i]f there is no carpeting on the floor, the floor will be vacuumed at the rate of one minute per square yard" and that floors will be washed using a "two bucket system"). In this respect, the instant case differs from the R&M study addressed by the Court in Wallace and Covington. See Wallace, slip op. at 10-11 (noting that the R&M Contract explicitly excluded the residential lead paint abatement from its scope).

Both the Contract and the Protocol provide a caveat, however, to any centralized policy with regard to clean-up efforts. The "Statement of Work" states that, while central policy for the "clean-up activities" will be developed by a subcommittee of the Steering Committee, "the ultimate decision about clean-up methods at each site rests with the PI of the site and the PO." Contract at § C.2. Further, the Contract states that, "[i]f clean-up efforts involve other institutions, such as health departments, then the Clinical Center shall coordinate

plans for working with them. Each Clinical Center shall be responsible for preparing its own clean-up efforts, in consultation with the Clean-up Subcommittee." Id.

Similarly, while the Protocol "establishes standards of environmental assessment and intervention" for the Clinical Centers, it represents a floor, not a ceiling, with regard to abatement efforts:

> Each Center will meet or exceed applicable local, state, and federal guidelines for the management of children with lead toxicity. See Appendix 3 for copies of the relevant laws, regulations, and guidelines. As resources permit, individual Centers may elect to provide environmental management beyond the common core. TLC efforts are not meant to substitute for lead paint abatement that would be required or encouraged by local health departments. See Appendix 4 for supplemental environmental protocols from the TLC Clinical Centers.

Protocol at § 6.1. In Appendix 4 of the Protocol, entitled "Supplemental Environmental Protocols," each Clinical Center set forth additional measures to be undertaken in its catchment area. The Baltimore protocol is revealing:

> [KKI] is negotiating with the State of Maryland Department of Housing and Community Development (DHCD) for funds to perform supplemental environmental interventions in the houses of children enrolled in the TLC trial. Those funds would enable enrollment of children living in a wider spectrum of housing conditions and would likely increase the effectiveness of the environmental protocols . . . . The primary supplemental protocol described below is referred to as the Repair and Maintenance (R&M) Level II protocol. Also described below is the R&M Level I protocol for houses requiring less intensive R&M work. [KKI] has experience with both R&M protocols as part of ongoing studies of interventions to reduce exposure to lead in residential paint and dust.

Id. at App. 4 (emphasis added); See also Pl's Reply, Ex. 6

(Letter from Mark Farfel at KKI to the Secretary of the DHCD stating that "NIEHS will not provide funds for lead remediation . . . beyond a professional cleanup" and that KKI "anticipate[s] that many children otherwise eligible [for TLC] will be disqualified because their houses will require repair and maintenance in addition to cleanup in order to be made lead-safe") (emphasis added). Thus, contrary to Defendants' contentions, the houses were not cleaned according to the central Protocol, but rather, KKI implemented supplemental measures consistent with its efforts in the R&M study which were funded by the DHCD and which exceeded the steps called for in the Contract and Protocol.

Moreover, as discussed, supra, the Protocol was not the product of detailed federal direction and control because it was developed by the Steering Committee, not by Dr. Rogan and was the product of collaboration with representatives from KKI and the other CCs. Thus, even to the extent that houses were cleaned in compliance with the central Protocol, for the same reasons that the Court found a lack of "direct and detailed control," there is an insufficient causal nexus between the acts complained of and acts performed under "color of federal office."

Similarly, with respect to the negligent misrepresentations[21] and failure to obtain truly informed consent

[21]Some of the negligent misrepresentations alleged by Plaintiffs concern representations made "prior to the lease" of the properties to the Plaintiffs. See Compl. ¶¶ 42-45 (Count II). While it is not entirely clear from the Complaint, it appears that Plaintiffs allege that KKI, Davoli, JHU, and the IRB

alleged by Plaintiffs in their Complaint, the Court concludes that, for the same reason that performance of the interventions was not causally connected to acts performed under color of federal office, representations made to Plaintiffs regarding the condition of their homes and the repairs/clean-up to be performed necessarily lack a causal connection. This is so because it is apparent that Defendants utilized discretion in determining the level of intervention to perform in a given residence and whether to exceed the scope of the work under the Contract/Protocol as discussed above. As such, the representations made necessarily relied on anticipated acts that would be taken outside of any control by Dr. Rogan. For example, the Enrollment IC Form approved by the Steering Committee states: "All children in the TLC study will have their homes cleaned to get rid of lead dust and chipped paint . . . ." Protocol at App. 2 (emphasis added). In contrast, the IC form signed by Plaintiff Keona Featherstone's mother stated: "All children in the TLC study will have their homes repaired and/or cleaned to get rid of lead dust and chipped paint . . . ." Mot., Ex. 14 (emphasis added).[22] Thus, the KKI

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permitted the misrepresentations to be made by the landlords. Although Defendants contend that recruitment and enrollment was governed by the Contract and the Protocol, see Notice of Removal at 13, the Court's review of these documents finds no reference to any measures to encourage subjects to lease properties in order to find participants for TLC. See Contract at § C.2 (discussing recruitment).

[22]The IC Form attached to Plaintiffs' Motion to Remand is 6 pages long and is signed by Keona's mother and KKI personnel. The fifth page of the consent form, however, has a header indicating that it is from the "pre-enrollment" consent form, while the remainder of the pages are from the "enrollment"

IC form represented that homes could receive a greater level of abatement than that provided for in the Contract and Protocol. Accordingly, the Court concludes that Defendants have failed to satisfy their burden under Section 1442(a)(1) and that remand is appropriate.[23]

The Court notes that consideration of the purposes of Section 1442(a)(1) supports this result. As the Freiberg Court opined, "[b]ecause [Section 1442(a)(1)] is premised on the protection of federal activity and an anachronistic mistrust of state courts' ability to protect and enforce federal interests and immunities from suit, private actors seeking to benefit from its provisions bear a special burden of establishing the official nature of their activities." 245 F. Supp. 2d at 1150 (emphasis in original). The instant case involves a research trial of a lead chelating agent. The Plaintiffs' allegations primarily concern the abatement of lead in the homes of the children in the study and representations made to the Plaintiffs' concerning the condition and safety of their homes. The only federal interest asserted by Defendants in its Notice of Removal is the interest in "uniformity of interpretation and application of federal laws

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consent form. The two forms are largely the same as approved by the Steering Committee, but there are some differences. It is unclear whether this page was accidently included at the time that the form was signed or whether this page was mistakenly included in the attachment by Plaintiffs.

[23]Given that Defendants failed to make the requisite showing under the first and third prongs of the Section 1442(a)(1) test, the Court need not address the second prong, whether Defendants raise a colorable claim to a federal defense.

governing scientific research involving children." See Notice of Removal ¶ 27.

In the Court's view, NIEHS's exercise of control over aspects of the study was designed in large part to ensure the relative uniformity of procedures in a multi-center research trial in order to promote the validity of the results of the study, not to further any federal policy. To this end, NIEHS required a central Protocol, but excepted certain aspects of the study from that Protocol if variations would not impact the validity of the results. See, e.g., Amendment to the RFP, p. 7 (noting that "[t]here is nothing in the RFP that says that children should not have their sources of lead abated, and the trial comparison is unaffected by abatement if treatment and placebo children have their sources abated similarly."). In many ways, the interests at stake were uniquely local - finding solutions to the dangerous conditions of the low-income housing stock in Baltimore and the treatment of children in Baltimore who had been exposed to lead paint. This is not a case where federal policy is thwarted by allowing adjudication in a state forum.

Finally, without deciding whether, under the second prong of the federal officer removal test, Defendants have in fact raised a colorable federal defense, several courts have questioned whether the defense asserted by the Defendants - the government contractor defense[24] - is of the type that should support removal

[24]The government contractor defense is based in federal common law and requires a showing that: "(1) the United States approved reasonably precise specifications; (2) the equipment

under Section 1442(a)(1). See Freiberg, 245 F. Supp. 2d at 1151 n.5 (noting that it is questionable whether the government contractor defense "is the type of federal interest or immunity for which § 1442(a)(1) was intended to provide an exclusively federal forum"); Good, 914 F. Supp. at 1131 (stating that the government contractor defense is "not subject to [state court] manipulation" in the way that a federal officer's defense of official immunity might); Ryan, 781 F. Supp. at 951 (opining that the government contractor defense "raises straightforward common law tort issues that the state courts are as adept at handling as the federal judiciary").

C. Removal Under Section 1441

Lastly, Defendants IRB and JHU raise for the first time in Defendants' opposition to the Motion to Remand the argument that this Court has original jurisdiction over this action because certain of Plaintiffs' claims arise under federal law. See Opp'n at 29-32. This identical argument was raised in Wallace based on the same federal regulations cited by Plaintiffs in their

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conformed to those specifications; and (3) the supplier warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States." Boyle v. United Techs. Corp., 487 U.S. 500, 512 (1988). Originally thought to be applicable only to military procurement contracts, several courts have since applied the defense to civilian contracts and to service contracts entered into by the government. See, e.g., Bowers v. J&M Discount Towing, LLC, 472 F. Supp. 2d. 1248 (D.N.M. 2006) (IRS contract with an auto towing company for the towing of vehicles to auction sites for satisfaction of tax liens).

Complaint.[25] Without deciding whether this argument may be raised for the first time at this stage in the removal proceedings,[26] the Court concludes, for the same reasons stated in Wallace, that because "the essential elements of Plaintiffs' state law claims may exist independent of the regulatory duties and because a violation of those duties do[es] not give rise to a private federal cause of action, removal based upon federal question jurisdiction [is] not appropriate. Wallace, slip op. at 11-14.

IV. CONCLUSION

For the above stated reasons, Plaintiffs' Motion to Remand will be granted. A separate order consistent with this memorandum will follow.

/s/
William M. Nickerson
Senior United States District Judge

Dated: November 6, 2007

[25]The regulations at issue can be found at 45 C.F.R. § 46.101 et seq. and 45 C.F.R. § 46.401, et seq. and are discussed in Wallace.

[26]As noted earlier, Defendants IRB and JHU did not join in Defendants KKI and Davoli's Notice of Removal. KKI and Davoli asserted federal jurisdiction only on the basis of Section 1442(a)(1) in the Notice of Removal. While KKI and Davoli did assert that the exercise of removal jurisdiction would "promote uniformity in the application and interpretation" of the federal regulations cited by Plaintiffs, they did not argue this as an independent basis for removal for federal question jurisdiction. See Notice of Removal ¶¶ 25-29.