EXHIBIT A

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

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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,

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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:

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