UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Baltimore Division)

SHAYONNA FEATHERSTONE, et al.,	*	
Plaintiffs	*	
v.	*	Case No.: 1:07-CV-1120
KENNEDY KRIEGER INSTITUTE, INC., et al.	*	
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.

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.	*	

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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

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.

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.

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.I. 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. Corublath, 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. 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.

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.

- ☐ ½ 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.

FILED SEPARATELY SHEET

Civil Docket No. WMN-07-CV-1120

Criminal Docket No.

FILED SEPARATELY

- ☐ Answer
- ☐ Answer and attachment(s)
- ☐ Attachment(s)
- ☒ Exhibit(s) B 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 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	

(X)	SEC.	DESCRIPTION	PAGE(S)
		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)	

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	9,153
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	$234,804
		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]er 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

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)*

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 OM
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.

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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REV. 6/18/92

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

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)

EXHIBIT E

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 Roger — 6/29/93
Project Officer — Date

Beth Roger — 6-25-93
Alternate Project Officer — Date

Karen R. Cox — 6/29/93
Contractor — Date

cc: Contract File