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

DONTAE RICO WALLACE, et al.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No:
	)	
KENNEDY KRIEGER INSTITUTE, INC., et al.,	)	
	)	
	)	
	)	
Defendants	)	

NOTICE OF REMOVAL

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

Pursuant to 28 U.S.C. section 1442 (a)(1), Defendants Kennedy Krieger Institute, Inc. ("Kennedy Kreiger") and Mark Farfel, Sc.D (collectively referred to as "Kennedy Krieger Defendants"), and pursuant to 28 U.S.C. sections 1441(a) and (b) and 1331, 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, M.D., Lewis C. Becker, M.D., David R. Cornblath, M.D., Paul Lietman, M.D., Hayden G. Braine, M.D., and Peter Lees, Ph.D. (hereinafter collectively referred to as "IRB"), by their undersigned counsel, hereby remove this action, *Dontae Rico Wallace, et al. v. Kennedy Krieger Institute, Inc, et al.*, case number 24-C-07-002026, from the Circuit Court for Baltimore City, Maryland (hereinafter "State Court Action") to the United States District Court for the District of Maryland (Northern Division).

INTRODUCTION

1. In 1990, the federal government, through the Office of Pollution Prevention and Toxics ("OPPT"), an office within the United States Environmental Protection Agency ("EPA"), issued a work assignment directing the design of a lead paint "Abatement, Repair and Maintenance Study in Baltimore" ("R&M" study). The purpose of the R&M study was to evaluate the short and long-term effectiveness of various levels of repair and maintenance in reducing exposure to lead in the home. This action is brought by Dontae Rico Wallace and Searra Wallace, minors, by and through their mother and next friend, Tiffini Howard ("Plaintiffs"), and arises out of Plaintiffs alleged participation in this EPA-sponsored study conducted by the Kennedy Krieger Defendants and approved by the IRB. *See* Ex. A.

2. This Court has removal jurisdiction over this action under 28 U.S.C. section 1442(a)(1) because Plaintiffs filed a civil action in a state court against the Kennedy Krieger Defendants, who were acting under the control of a federal officer of a United States agency. Specifically, Plaintiffs' negligence claims directly call into question Kennedy Krieger's compliance with the contract it entered into with the EPA as well as Kennedy Krieger's compliance with the detailed and comprehensive framework of federal regulations that govern research on human subjects. Kennedy Krieger's and Dr. Farfel's statement of grounds in support of removal under 28 U.S.C. section 1442(a)(1) is stated below in section I of this Notice of Removal. 28 U.S.C. § 1442(a)(1) governs removal for conduct performed under color of federal office. The Supreme Court has "held that the right of removal is absolute for conduct performed

under color of federal office, and has insisted that the policy favoring removal 'should not be frustrated by a narrow, grudging interpretation of § 1442(a)(1). *See Arizona v. Manypenny*, 451 U.S. 232, 242, 101 S.Ct. 1657 (1981). The purpose of the liberal removal policies underlying section 1442(a)(1) is to protect federal officers and their agents when they conduct business in the states. *See Durham v. Lockheed Martin Corp.*, 445 F.3d 1247, 1252-53 (9th Cir. 2006). "If the federal government can't guarantee its agents access to a federal forum if they are sued or prosecuted, it may have difficulty finding anyone willing to act on its behalf." *Id.* at 1253.

3. Federal removal jurisdiction can also be exercised over state law claims "of which the district courts of the United States have original jurisdiction." 28 U.S.C. § 1441(a). This original jurisdiction includes "all civil actions arising under the Constitution, laws, or treaties of the United States." *Id.* §§ 1331, 1441(b). Relying upon federal law, Plaintiffs have instituted claims against the IRB for its approval and oversight of the R&M study.

4. The United States Supreme Court has held for nearly one hundred years that state law claims arising under federal law confer original jurisdiction in federal court (1) when the plaintiff's claim implicates a significant and disputed federal issue, and (2) exercising jurisdiction will not upset the balance between federal and state judicial responsibilities. *See Grable & Sons Metal Prods., Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308, 312-14, 125 S. Ct. 2363, 2366-67 (2005). The IRB Defendants grounds for removal under 28 U.S.C. sections 1441(a) and (b) are stated in section II of this Notice of Removal.

I. JURISDICTIONAL BASIS FOR REMOVAL FOR THE KENNEDY KRIEGER DEFENDANTS.

5. This Court has original jurisdiction under 28 U.S.C. section 1442(a)(1) because: (1) Kennedy Krieger and Dr. Farfel are considered "persons" within the meaning of the statute; (2) the Kennedy Krieger Defendants were acting at the direction of an officer of the United States; (3) a causal nexus exists between Plaintiffs' claims and the Kennedy Krieger Defendants' actions under color of federal office; and (4) the Kennedy Krieger Defendants can assert a colorable federal defense. *See, e.g., Mesa v. California,* 489 U.S. 121, 125-35 (1989); *Pack v. A.C. and S., Inc.*, 838 F. Supp. 1099, 1101 (D. Md. 1993), *reconsideration denied*, 857 F. Supp. 26 (D. Md. 1994) (holding that 28 U.S.C. section 1442(a)(1) is satisfied when the moving party can demonstrate that (1) it acted under the direction of a federal officer; (2) it raises a federal defense to plaintiff's claims; and (3) demonstrates a causal nexus between plaintiff's claims and acts it performed under color of federal office). The EPA's Pre-Intervention Findings clearly summarize the direct involvement and control over the R&M study exhibited by the EPA. "The U.S. Environmental Protection Agency ("EPA") was responsible for managing the Study, for providing technical oversight, guidance and direction, and overseeing the peer review and finalization of the report." *See* Ex. N, entitled "Lead-Based Paint Abatement and Repair and Maintenance Study in Baltimore: Pre-Intervention Findings."

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

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

B. Kennedy Krieger was acting under the direction of the United States Government.

1. The EPA exercised direct control over the R&M study.

7. The extent of control necessary to bring an individual with the "acting under" clause of section 1442(a) has been construed broadly. See Gurda Farms Inc. v. Monroe County Legal Assistance Corp., 358 F.Supp. 841, 844 (S.D.N.Y. 1973) ("even a cursory survey of the application of [section 1442(a)] reveals it has been construed broadly, and its "persons acting under" provision particularly so). The Supreme Court has emphasized that the federal officer removal statute is neither narrow nor limited, and has rejected lower court interpretations that circumscribe its scope. See Willingham v. Morgan, 395 U.S. 402, 407, 89 S. Ct. 1813, 1816 (1969) (the policies underlying section 1442(a) "should not be frustrated by a narrow, grudging interpretation"); see also In re "Agent Orange" Product Liability Litigation v. Dow Chemical Company, et al., 304 F. Supp.2d 442, 447 (E.D.N.Y. 2004) ("Courts interpret the [persons acting under color of federal office or agency] rule broadly to achieve the protective purpose of the statute.").

8. Federal officer removal is appropriate when the removing party is subject to the direct and detailed control of the federal government. *Pack*, 838 F. Supp. at 1103.

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

9. The federal government, through the EPA, maintained detailed, hands-on control over all phases of this government-sponsored and funded study. The following paragraphs provide a summary of the extensive control the federal government maintained over the R&M study.

10. Because the United States Congress ("Congress") determined that people were being exposed to large numbers of chemical substances, it passed the Toxic Substances Control Act in 1976 ("TSCA"). *See* 15 U.S.C. § 2601(a)(1). Through this Act, Congress stated that:

> The Administrator **shall**, in consultation and cooperation with the Secretary of Health and Human Services and with other heads of appropriate departments and agencies, conduct such research, development, and monitoring as is necessary to carry out the purposes of this chapter. The Administrator may enter into contracts and may make grants for research, development, and monitoring under this subsection.

15 U.S.C.A. § 2609(a)(emphasis added). OPPT, formerly known as the Office of Toxic Substances, was formed in 1977 with the primary responsibility of administering the TSCA. *See* "About OPPT," attached hereto as Ex. B.

11. The decision to design, and ultimately implement, the R&M study was an expression of OPPT's duties pursuant to the TSCA. For example, in the "Statement of Work" section of the EPA's contract authorizing the design of the R&M study, the EPA stated:

> To help implement the Toxic Substances Control Act of 1976 (TSCA) the Environmental Protection Agency's Office of Toxic Substances requires biostatistical analysis, or studies of the effects of suspicious or selected chemicals of interest on human subpopulations at risk. The range of health effects may cover carcinogenisity, teratogenicity, respiratory effects, and neurotoxicity and other endpoints. When adequate hazard and exposure information is discovered and the hazard is judged meaningful, a full scale quantitative assessment of human risk may be conducted.

See Award/Contract between EPA and Battelle Memorial Institute ("Battelle"), attached hereto as Ex. C at p. 49.

12. The design and initial stage of the data collection phase were governed by a prime contract between EPA and Battelle and a corresponding subcontract between Battelle and Kennedy Kreiger. On May 21, 1990, EPA issued a "work assignment" through its prime contract with Battelle. *Id.* On June 1, 1990 Kennedy Krieger entered into a subcontract with Battelle to complete the "work assignment" issued by the EPA to design the "LBP Abatement, Repair and Maintenance Study." *See* Subcontract between Kennedy Krieger and Battelle, attached hereto as Ex. D. In 1993, EPA entered

into a direct contract with Kennedy Krieger to continue implementation of the R&M study. *See* ¶ 22 *infra.*

13. The original work assignment issued by EPA and the subsequent subcontracts prepared pursuant to that work assignment express the EPA's rationale for conducting the R&M study:

> Lead has been identified as a significant cause of neurobehavioral and learning deficits in young children which are long-lasting, if not indeed permanent. The recent report to Congress by the Agency for Toxic Substances and Disease Registry (July, 1988) points out that lead in existing residential paint, household dust and soil now constitute the major source of high lead exposure in U.S. children. This study would provide a means of evaluating new policies and practices in Maryland for abating lead in residential paint and dust.

See Exhibit C, Design of LBP Abatement, Repair and Maintenance Study, Work Assignment; Ex. D, Section 6.

14. EPA's involvement and control was evident throughout the design phase of the study. For example, in the EPA's "work assignment," it described in detail how the R&M study should proceed:

> The overall study design will have four phases. In the **Planning** phase a proposed schedule and financial plan will be developed for the entire project. Other areas that will be addressed include: objectives, hypotheses to be tested, Data Quality Objectives, measurement method, laboratory method, legal considerations in the type of abatements used (conformance to existing regulations), comparability to Eight-City Study, experimental design, sample design, questionnaire design and a feasibility study which consists of seeing if the original occupants are still in the houses that have already been abated. The analysis plan and non-response adjustment will be addressed. In the **pre-field phase**, a Quality Assurance Project Plan will be written, field manuals will be written, forms and questionnaires will be finalized, computer software for the data analysis will be written and tested, chemical analysis methods will be finalized and if necessary, a pilot test of the field procedures, sample collection protocols, and questionnaire will be conducted. In the **field** phase, data will be collected, samples will be chemically analyzed and the forms will be processed.

> Quality assurance of field and chemical analysis activities will be ongoing during this phase. In the **Reporting** phase, data analysis will be completed, an EPA report will be written, and a journal article will be written and submitted.

Ex. C at Design of LBP Abatement, Repair and Maintenance Study, Work Assignment.

15. Kennedy Krieger designed the R&M study with the control and participation of the EPA. Upon entering into the subcontract with Battelle, Kennedy Krieger agreed to provide "**everything necessary** to perform the services defined in the...Statement of Work." *See* June 25, 1990 letter from Battelle to Kennedy Kreiger, attached hereto as Ex. E (emphasis added); *see also* Ex. D at Article I, Performance ("The Subcontractor...shall provide the necessary facilities, personnel, materials, equipment and shall otherwise do all things necessary or incident to the performance of the services as more specifically outlined in the Statement of Work...."). The EPA maintained oversight throughout this phase of the R&M study. *See* Project Organization and Management chart, attached hereto as Ex. F.

16. EPA approved every step of the design process. *See* Ex. Q, Affidavit of Mark Farfel, Sc.D. at ¶ 6. For example, within seven days after EPA issued the work assignment, the contractor was required to submit a work plan to the EPA Project Officer, Elizabeth Margosches. This work plan had to include a "detailed technical and staffing plan and a detailed cost estimate." Ex. C at p.7. Within fifteen days after receipt of the work plan, EPA Contracting Officer, William Newby, provided written approval or disapproval of the plan. *Id.* If Mr. Newby disapproved of the work plan, the contractor was required to stop work until the problem causing the disapproval was

resolved. *Id.* The Contractor was permitted to resume work only after final EPA approval. *Id.*

17. Elizabeth Margosches provided technical direction over performance of the contract. This technical direction included guidance to the Contractor to assist them in accomplishing the Statement of Work as well as comments and approval of reports or other deliverables. *Id.* at 32. EPA maintained the "prerogative to perform quality control inspections on representative samples of work" performed under the contract. *Id.* at 50. Because Kennedy Krieger completed all of the work necessary to accomplish the Statement of Work issued by the government, *see* ¶ 12, the EPA provided technical direction and approval to Kennedy Krieger in performing the contract.

18. The EPA imposed extensive reporting requirements during the design phase of the study. *See* Ex. Q at ¶ 12. For example, the Contractor had to submit monthly technical progress reports that outlined the work that was accomplished during each calendar month. The technical reports had to be "brief, factual and informal" and prepared in accordance with a specific EPA format. Ex. C at 54; *See also* Kennedy Krieger Institute October 28, 1992 Progress Report, attached hereto as Ex. G. EPA also required submission of financial management reports that detailed the projected and actual rates of expenditure under the contract. Ex. C at p. 56. The Contractor was required to prepare a study design report that outlined the "exact study design, data analysis scheme, assumptions, and scientific methodologies." *Id.* at 57. The study design report had to be approved by the EPA Project Officer. *Id.* In addition to these reporting requirements, EPA required the Contractor to submit a Quality

Assurance Plan report. The Quality Assurance Plan report "describes specific procedures and responsibilities needed to accomplish the QA specifications in the work assignment." *Id.* at 58. The Contractor was required to submit a "proposed final report" within thirty days after the study design was completed. The report had to include:

> (2) The proposed report shall document in detail all of the work performed under the contract including data, analysis, and interpretations, as well as recommendations and conclusions based upon results obtained. The report shall include tables, graphs, diagrams, curves, sketches, photographs, and drawings in sufficient detail to comprehensively explain the results achieved under the contract. The report shall be complete in itself and contain no reference, directly or indirectly, to the periodic reports. (3) The content of the proposed report must be of a quality suitable for publication, and it shall be prepared in accordance with...[the] "Handbook for Preparing Office of Toxic Substance reports: Revised." After receipt of the Contractor's proposed final report, the Contracting Officer or the Project Officer may require the Contractor to present, at a site chosen by the requestor, an informal briefing and review of all work performed under the contract. Approval or disapproval...of the final report will be accomplished by the Project Officer within 60 calendar days after receipt. Disapproved reports shall be resubmitted for review following correction of the sited deficiency unless otherwise directed by the Contracting Officer or Project Officer.

Id. at 59.

19. The Final Report – *Quality Assurance Project Plan for the Kennedy-Krieger Institute Lead-Based Paint Abatement and Repair and Maintenance Study ("QAPjP")* – was submitted to the EPA on July 22, 1992. *See* July 22, 1992 QAPjP Final Report, attached hereto as Ex. H. This report included the following: a project description outlining, among other things, the objectives, hypothesis, experimental design, quality control measures, anticipated cost and duration of the project; project organization and management; the experimental design including a detailed description of the field

studies and measurement processes; an outline of the sample collection procedures for blood, settled dust, soil, paint, and drinking water; a description of the equipment they will use to collect the samples; a description of the laboratory analysis and measurements; a detailed explanation of the statistical data processing and analysis procedures; procedures for system, performance, and data audits; and finally recognition that Kennedy Krieger would maintain a master Quality Assurance Project Plan.

20. The QAPjP for the R&M study was approved by the EPA on August 4, 1992. Even so, EPA staff met with Kennedy Krieger twice thereafter to discuss revisions to the study design. Modifications of the QAPjP included:

> Major revisions were made to the experimental design of the study, sample collection of dust samples, and analysis of blood samples. Minor modifications were made to several analytical protocols and field collection forms.

See Amendment to Revision No. 3, Summary of Revisions, attached hereto as Ex. I.

21. In August 1993, the EPA's Contracts Management Division published a notice indicating that it intended to award a direct contract to Kennedy Krieger to conduct the R&M study. *See* Request for Proposal, attached hereto as Ex. J. In this notice, the EPA explained why it was necessary to conduct the R&M study:

> The U.S. Environmental Protection Agency (EPA) is interested in less costly and potentially more cost-effective Repair and Maintenance (R&M) interventions to reduce exposure to lead (Pb) in residential house dust and paint. Given the extent of lead based paint (LBP) in U.S. housing (57 million homes) and the staggering costs associated with abating the potential lead hazards in these housing units, **it is imperative that the Federal Government investigate low-cost and practical R&M approaches, in addition to more comprehensive forms of LBP abatement.** Low-cost R&M approaches may provide a practical means of reducing Pb exposure for future generations of children who will continue to

> occupy older housing which cannot be fully abated or rehabilitated without substantial subsidies....**Award of a sole source contract to KKI [Kennedy Krieger], for the purpose of completing this project which was initiated under other EPA contract instruments employing KKI resources,** ***is the only means by which EPA can meet its Congressionally mandated technical support function to the Department of Housing and Urban Development.***

Id. (emphasis added).

22. Following this notice of intention to award the contract to Kennedy Krieger, the EPA drafted a Solicitation/Offer and Award. *See* Solicitation/Offer and Award, attached hereto as Exhibit K. The EPA issued identical contracts to implement the R&M study on October 18, 1993 and on June 2, 1994. *See* Contract/Awards, attached hereto respectively as Ex. L and Ex. M.

23. The EPA had direct control and participation in the R&M Study. *See* Exs. L, M, and Q, Affidavit of Mark Farfel, Sc.D. at ¶¶ 9,12. Furthermore, final authority over each and every aspect of the Study rested with the EPA. *Id.*

24. By 1993, the EPA's objective for pursuing the R&M study, while bolstered by new information regarding lead issues, remained the same:

> EPA is interested in less costly and potentially more cost-effective Repair and Maintenance (R&M) interventions to reduce exposure to lead (Pb) in residential house dust and paint, which in turn should reduce Pb in children's blood. This work is important because Pb-containing house dust, soil and paint have been identified as major pathways and sources of Pb in children's blood via hand-to-mouth route of ingestion....Given the extent and potential costs of the problem in U.S. housing, both public and private, it is imperative that EPA investigate low-cost and practical R&M approaches to provide fiscal relief to already financially troubled public housing authorities. Low-cost R&M approaches may provide a practical means of reducing Pb exposure for future generations of children who will continue to occupy older housing which cannot be fully abated or rehabilitated without substantial subsidies.

See Ex. L, Attachment A; Exhibit M, Attachment A.

25. Pursuant to the contracts, the EPA Project Officer, Phil Robinson, was authorized to provide technical direction of contract performance including direction to the contractor in accomplishing the Statement of Work as well as comments on an approval of reports or other deliverables. Ex. L at p. 21; Ex. M at p. 39. The EPA Contract Specialists, Sue Miller (1993 contract) and Wendell Carpenter (1994 contract), were responsible for contract administration. *Id.*

26. The direct contracts contained a detailed description of the estimated cost of the study including specific instructions regarding permissible expenditures such as salary rate limitations and a list of equipment Kennedy Krieger was permitted to purchase in order to conduct the study. The contracts also contained a list of three "options" that the government could elect to require Kennedy Krieger to perform. The EPA provided estimated costs and fixed fees for each option. Ex. L at p. 69; Ex. M at p. 31. Furthermore, levels of lead remediation implemented in the study homes was determined by the EPA through the contracts with Kennedy Krieger. *See* Ex. Q at ¶ 10; Ex. L, pp.71-74; Ex. M, pp. 75-78.

27. The contracts contained specific directives regarding how Kennedy Krieger would implement the R&M study:

> The contractor **shall** collect environmental samples (dust, soil and water) before the interventions and 2 to 24 months after the interventions and analyze the samples for Pb content. The contractor **shall** monitor blood samples from children in the homes for Pb levels. The contractor **shall** compare data from the R&M houses to similar data collected from two groups of control houses – (1) previously abated houses utilizing comprehensive abatement methods, and (2) modern urban houses known to be free of lead based paint....The following work **shall** be performed by the contractor to complete the R&M intervention study: (a) The contractor shall implement and complete the R&M study

> according to the specifications in the Repair and Maintenance Quality Assurance Plan (QAPjP) as amended on December 14, 1992....The contractor **shall** collect and chemically analyze environmental and blood samples according to schedules defined in the study plan in the QAPjP....(b) The contractor shall prepare and submit a study plan, including a complete schedule of delivery dates for all deliverables...within thirty (30) days of the effective date of the contract **for EPA review and approval**....(d) The contractor **shall** coordinate with the EPA Office of Prevention, Pesticides and Toxic Substances, Office of Pollution Prevention and Toxics, Chemical Management Division, Technical Program's Branch's (TPB) statistical analysis support contractors on how the environmental field samples and other data are being collected....(f) The contractor **shall immediately** notify the EPA Project Officer of **any circumstances where work cannot be conducted in accordance with the specifications for this study as defined in the QAPjP**. The contractor **shall not deviate from performance in accordance with the QAPjP without approval of the Contracting Officer.**

Ex. L at pp. 68-69; Ex. M at pp. 71-73 (emphasis added).

28. The EPA exhibited control over how the Study was implemented through its contracts with Kennedy Krieger and the QAPjP. *See* Ex. Q at ¶¶ 9, 12. Furthermore, information conveyed to study participants and their families was governed by the contracts between the EPA and Kennedy Krieger and the QAPjP. *Id.* at ¶ 10. In addition, the method and extent to which Kennedy Krieger (1) assessed the presence of lead-based paint hazards; (2) reported findings to the Study participants; and (3) monitored the Study participants blood lead levels were determined by the contracts between the EPA, QAPjP, and Kennedy Krieger. *Id.*

29. Final authority over each and every aspect of this study rested with the EPA. *See* Ex. Q at ¶¶ 9,12. Pursuant to the contracts, Kennedy Krieger did not have the authority to deviate from the EPA approved QAPjP. Indeed, EPA retained the ability to terminate the contracts if Kennedy Krieger deviated from the study protocol. Ex. L at p. 69; Ex. M at p. 73.

30. The EPA imposed substantial reporting requirements on Kennedy Krieger during the course of the R&M study. EPA required Kennedy Krieger to participate in weekly conferences with the EPA Project Officer "to discuss the status of the R&M study and any problems that were encountered during the preceding week." *See* Ex. L at p. 77; Ex. M at p. 81. In addition to the weekly conference calls, Kennedy Krieger was required to submit monthly technical and financial progress reports. Ex. L at pp. 78-79; Ex. M at p. 79. In addition to the monthly progress reports, EPA required Kennedy Krieger to submit eleven technical reports including: (1) a report on enrollment activities; (2) a summary of the statistics of lead levels in dust, soil, drinking water, and blood at the time of enrollment; (3) a report on comparison of side-by-side wipe and vacuum dust samples; (4) a report analyzing lead levels in dust, soil, drinking water and blood taken pre- versus immediately post-R&M Level I-III interventions; (5) a report on enrollment dust lead levels in previously abated dwellings compared to pre-abatement and Maryland State clearance lead levels; (6) a report on enrollment lead levels in modern dwellings compared to enrollment levels in previously abated dwellings; (7) a summary of the statistics of lead levels in R&M homes collected during the 'two month' post-R&M data collection activity; (8) preliminary analysis of the data collected at the 'six month' post intervention data collection activity and a comparison of this data to post-intervention data and 'two month' data on R&M Levels I-III; (9) summary of statistics of lead levels in dust, soil, and drinking water by study group at 'twelve months' after R&M interventions; (10) preliminary analysis of 'eighteen month' data on R&M Levels I-III; and (11) a statistical analysis of the dust, soil, blood-lead, and

drinking water collected twenty four months after the R&M intervention. This analysis and a complete documentation of study protocols constituted the final technical report for the study. Ex. L at pp. 77-78; Ex. M at pp. 81-82.

31. Each technical report listed above required EPA comment and approval before it could be considered "final":

> [F]or each technical report…the contractor shall submit an outline for the report to EPA approval. The contractor shall assume that each report will undergo an internal Technical Programs Branch review, a second level review including other Offices within EPA and other Federal Agencies, and an external technical peer review in accordance with EPA procedures. The contractor shall allow a minimum of 30 days for each review and allow a maximum of 30 days for incorporating comments and producing a revised version of the report. Upon completing the last required review, the contractor shall provide a camera ready copy of the final report and a copy of the final document on floppy disk in Word Perfect 5.1 or later format.

Ex. L at p. 77; Ex. M at p. 81.

32. The intimate control exercised by the EPA over the R&M study extended through to the study's conclusion. The EPA prohibited Kennedy Krieger from drafting, summarizing, and publishing the results of the study absent EPA approval. Ex. L at pp. 32, 70; Ex. M at pp. 37, 74. Pre-Intervention, One-Year and Two-Year R&M study reports were published by the EPA as EPA documents are printed and distributed by the federal Government Printing Office. *See* EPA Lead-Based Paint Abatement and Repair and Maintenance Study in Baltimore: Pre-Intervention Findings, attached hereto as Exhibit N; EPA Lead-Based Paint Abatement and Repair and Maintenance Study in Baltimore: Findings Based on the First Year of Follow-up, attached hereto as Ex. O; EPA

Lead-Based Paint Abatement and Repair and Maintenance Study in Baltimore: Findings Based on Two Years of Follow-up, attached hereto as Ex. P.

33. As stated previously, the EPA's Pre-Intervention Findings clearly summarize the direct involvement and control over the R&M study exhibited by the EPA. "The U.S. Environmental Protection Agency ("EPA") was responsible for managing the Study, for providing technical oversight, guidance and direction, and overseeing the peer review and finalization of the report." *See* Ex. N at iii.

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

34. In addition to the federal government's active involvement in the creation, design, and implementation of the R&M study pursuant to its contract with Kennedy Krieger, Kennedy Krieger's actions were at all times subject to exceedingly complex regulations and guidelines authorized by the United States Congress and the DHHS in the conduct of this research study. See 42 U.S.C. § 289; 45 CFR § 46.101, et seq. For example, when conducting research on human subjects, the federal government requires an Institutional Review Board ("IRB") to approve the study. 42 U.S.C. § 289. The IRB is essentially an oversight committee that "shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy." 45 C.F.R. § 46.109(a). Federal regulations further govern, among other things, the membership of the IRB (45 C.F.R. § 46.107); IRB functions and operations (45 C.F.R. § 46.108); the review procedures that the IRB may use in certain types of research

(45 C.F.R. § 46.109); additional protections for children involved as subjects in research (45 C.F.R. § 406); and criteria for IRB approved research (45 C.F.R. § 46.111).

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

C. A causal nexus exists between Plaintiffs' claims and Kennedy Krieger's actions pursuant to its contracts with the United States Environmental Protection Agency.

36. The causal nexus prong requires that Plaintiffs' suit arise out of acts by the Kennedy Krieger Defendants taken pursuant to the direction of a federal officer. *See Pack*, 857 F.Supp. at 28. A direct causal relationship exists between Plaintiffs' claims and Kennedy Krieger Defendants' actions under color of federal office. The allegations made against the Kennedy Krieger Defendants in Plaintiffs' Complaint and their relationship to action taken by the Kennedy Krieger Defendants pursuant to formal authority are summarized in the following chart:[1]

Plaintiffs' Allegations	**Conduct of Kennedy Krieger Taken Pursuant to Federal Authority**
"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." *See* Complaint, Exhibit A at ¶ 41(c).	The EPA, through the Contract and QAPjP directed whether and the extent to which Kennedy Krieger repaired the Study participants' residences. *See* Contract, Exhibit L at pp. 67-75 and Exhibit M at pp. 71-78; QAPjP, Exhibit H at pp. 2-3 and 15-17; Affidavit of Mark Farfel, Sc.D., Exhibit Q.

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

"The Defendants knew or should have known that Levels I, II and III of intervention were less then full lead-abatements and would leave an ongoing lead hazard in the residence to which the child research subjects would be exposed." *See* Complaint, Exhibit A at ¶ 7.	The EPA, through the Contract and QAPjP directed whether and the extent to which Kennedy Krieger repaired the Study participant's residence. *See* Contract, Exhibit L at pp. 67-75 and Exhibit M at pp. 71-78; QAPjP, Exhibit H. The level of lead-abatement was specifically determined by the QAPjP, Exhibit H, pp. 52-59; Affidavit of Mark Farfel, Sc.D, Exhibit Q.
"Defendants herein negligently made, and/or negligently permitted to be made misrepresentations to the Plaintiffs and their families regarding the condition of the premises." *See* Complaint, Exhibit A at ¶ 44.	The provision of information to study participants and their families, obtaining of informed consent, and interventions, if any, to be performed in the Study was governed by the EPA and through the Contract and by federal regulation. *See* QAPjP, Exhibit H; Contract, Exhibit L; Contract, Exhibit M, Affidavit of Mark Farfel, Sc.D, Exhibit Q.
"The Defendants herein negligently made and/or negligently permitted to be made false representations to the Plaintiffs and their families regarding the risk of harm to the Plaintiffs if they were enrolled in the R&M Study." *See* Complaint, Exhibit A at ¶ 48.	The process for enrolling Study participants was directly controlled by the EPA and the Contract. *See* QAPjP, Exhibit H; Contract, Exhibit L at 68-69; Exhibit M at 71-73. The provision of information to study participants and their families, and the obtaining of informed consent was governed by the EPA in and through the Contract. *See* QAPjP, Exhibit H; Contract, Exhibit L; Contract, Exhibit M, Affidavit of Mark Farfel, Sc.D., Exhibit Q.
"The Defendants KKI, JHU, the IRB, Farfel and Lees by virtue of the IC Form, entered into an agreement with the Plaintiffs, that in exchange for the Plaintiffs' participation in the R&M Study, the Defendants herein would assume a duty to assess the presence of any lead-based paint and lead-based paint hazards within 2234 Booth Street, properly and accurately report the existence of said hazards to the Plaintiffs' family, 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, eliminate any lead-hazards at 2234 Booth Street, and that the	The Informed Consent provided to the Study participants was governed by the EPA in and through the QAPjP as well as by federal regulation. *See* QAPjP, Exhibit H. Kennedy Krieger's actions with regard to the Plaintiffs were directly controlled by the EPA Contract. *See* QAPjP, Exhibit H; Contract, Exhibit L; Contract, Exhibit M, Affidavit of Mark Farfel, Sc.D., Exhibit Q.

Defendants herein would provide ongoing medical care of the Plaintiffs' lead-based poisoning and lead toxicity." *See* Complaint, Exhibit A at ¶ 61.	
"The Defendants KKI and JHU warranted and agreed to the United States Department of Health and Human Services, herein referred to as DHHS, prior to the constitution, and during the administration of the R&M Study, that all human research at KKI would be conducted in accordance with the terms of the Belmont Report." *See* Complaint, Exhibit A at ¶ 67.	This allegation attacks the measures taken to insure the safety of Study participants. This issue was covered by the protocol approved by the EPA pursuant to the Contracts with the EPA. *See* QAPjP, Exhibit H; Contract, Exhibit L; Contract, Exhibit M, Affidavit of Mark Farfel, Sc.D., Exhibit Q.
"The minor Plaintiffs allege that the damage 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 the DHHS, and thus, of the duty owed by the Defendants to the Plaintiffs." *See* Complaint, Exhibit A at ¶ 74.	The actions undertaken by Kennedy Krieger were governed by the EPA through its Contract with Kennedy Krieger. *See* QAPjP, Exhibit H; Contract, Exhibit L; Contract, Exhibit M, Affidavit of Mark Farfel, Sc.D.,Exhibit Q.
"The minor Plaintiffs allege that the Defendants herein, each of them, by agreement for understanding agreed to tortiously mislead and/or negligently misrepresent to the parents and/or guardians of the child research subjects used in the R&M Study, including the minor Plaintiffs, as to the serious task of irreversible harm posed by the R&M Study to otherwise healthy children." *See* Complaint, Exhibit A at ¶ 77.	Providing information, obtaining informed consent, and deciminating information to Study participants and their parents and/or guardians was governed by the EPA in and through the Contract. *See* QAPjP, Exhibit H; Contract, Exhibit L; Contract, Exhibit M, Affidavit of Mark Farfel, Sc.D, Exhibit Q.
"The minor Plaintiffs allege that the Defendants herein, and each of them, by agreement and understanding agreed to materially breach their obligations set forth with the MPAA and the Belmont Report to the child research subjects used in the R&M Study, including the minor Plaintiffs." *See* Complaint, Exhibit A at 79.	Providing information, obtaining informed consent, and deciminating information to Study participants and their parents and/or guardians was governed by the EPA in and through the Contract. *See* QAPjP, Exhibit H; Contract, Exhibit L; Contract, Exhibit M. Kennedy Krieger was pursuing the research interests of the EPA in conducting the R&M Study. *See* Contract, Exhibit C at "work

	assignment"; Contract, Exhibit L at pp. 67-68; Contract, Exhibit M at pp. 70-71; QAPjP, Exhibit H; Affidavit of Mark Farfel, Sc.D., Exhibit Q.

37. In sum, the rationale for and purpose of the R&M study was contained in the R&M Contracts, which were prepared and promulgated by the federal government. This research study was conducted and implemented pursuant to protocol approved by the EPA, an agency of the federal government. Kennedy Krieger's recruiting and enrollment of study participants was regulated in great detail by not only the contracts approved by the EPA, but also through an elaborate regulatory scheme enacted pursuant to federal law. *See* ¶ 34; *see also* Affidavit of Mark Farfel, Sc.D., Exhibit Q. Further, Kennedy Krieger was prohibited from deviating from the directives of the contract and/or the research protocol or in taking any action whatsoever unless directly approved by the EPA. Exhibit L at pp. 68-69; Exhibit M at pp. 71-73.

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

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

39. The final element required for removal under 28 U.S.C. § 1442(a)(1) – that the defendant must assert a colorable federal defense – is satisfied by the Kennedy Krieger Defendants' entitlement to the government contractor defense.[2]

40. The government contractor defense shields a contractor from liability when acting under the direction and authority of the United States. *Tozer v. LTV Corp.*, 792 F.2d 403, 405 (4th Cir. 1986)(citing *Yearsley v. W.A. Ross Construction Company*, 309 U.S. 18, 20, 60 S. Ct. 413, 414 (1940)). In *Yearsley*, the United States Supreme Court stated that "it is clear that if this authority to carry out the project was validly conferred, that is, if what was done was within the constitutional power of Congress, there is no liability on the part of the contractor for executing its will." 309 U.S. at 20-21, 60 S. Ct. at 414-15.

41. *Boyle v. United Technologies Corp.*, 487 U.S. 500, 108 S. Ct. 2510 (1988), sets forth the elements required to satisfy the government contractor defense: (1) the United States approved reasonably precise specifications; (2) the contractor's performance conformed to those specifications; and (3) the contractor warned the United States about the dangers associated with the contract that were known to the contractor but not to the United States. *Id.* at 512, 108 S. Ct. at 2518. It is well established that the defense is viable in the context of non-military performance contracts such as the ones Kennedy

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

Krieger entered into with the EPA. *See Boyle*, 487 U.S. at 506, 108 S. Ct. at 2515 (stating that "[t]he federal interest justifying this holding surely exists as much in procurement contracts as in performance contracts; we see no basis for distinction."); *Richland-Lexington Airport District v. Atlas Properties, Inc.*, 854 F. Supp. 400, 422 (D. SC. 1994) (in holding that the defense applies to performance contracts, the court stated that "the dispositive issue is not one of performance versus procurement, but whether there is a uniquely federal interest in the subject matter of the contract"); *Yeroshefsky v. Unisys Corp.*, 962 F.Supp. 710, 717 (D. Md. 1997)(holding that the government contractor defense is applicable in the civilian as well as military context).[3]

42. Consistent with the first prong of the *Boyle* test, the United States, through the EPA, approved precise specifications for developing, implementing, and reporting on the R&M study. *See* ¶¶ 9-33. The Award/Contract, and supervision and participation in the R&M study clearly demonstrate that the EPA provided reasonably precise specifications. *Id.*

43. As required by the second prong of the *Boyle* test, the Kennedy Krieger Defendants fully complied with the federal government's detailed specifications. As required by the contracts, the Kennedy Krieger Defendants followed the EPA-approved

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[3] Arguably, *Richland* recognized an additional element to the defense. The *Richland* Court suggested that the party claiming the defense must first demonstrate that the conduct at issue constituted a "discretionary function" of the federal government. 854 F.Supp. at 423. Pursuant to this "discretionary function", Kennedy Krieger will not be liable to Plaintiffs if the challenged government action involved an element of judgment or choice and if the challenged government action is based on considerations of public policy. *Id.* Without question, as described herein, the genesis for this study, as expressly articulated in the EPA's contracts and RFP, was the EPA's concern regarding (1) the extent of lead based paint in U.S. housing (2) and the staggering costs associated with abating the potential lead hazards in these housing units. Exhibit J. This is precisely the type of conduct contemplated in the *Richland* "discretionary function" analysis.

study protocol throughout its implementation of the R&M study. The Kennedy Krieger Defendants were obligated to follow, and complied with, the strict and comprehensive requirements imposed by the federal government when conducting research on human subjects. *Id.* at 26; *See also* Exs. C and I.

44. Finally, the third prong of the *Boyle* test is satisfied. Kennedy Krieger did not withhold from the EPA any information regarding potential dangers associated with the R&M study. As set forth in paragraphs 9-33, the EPA was intimately involved in all aspects of the study and therefore was fully aware of all risks and benefits associated with the R&M study.

II. JURISDICTIONAL BASIS FOR REMOVAL FOR THE IRB DEFENDANTS.

45. Federal removal jurisdiction can be exercised over state law claims "of which the district courts of the United States have original jurisdiction." 28 U.S.C. § 1441(a). This original jurisdiction includes "all civil actions arising under the Constitution, laws, or treaties of the United States." *Id.* §§ 1331, 1441(b).

46. State claims arise under federal law, and therefore confer original federal court jurisdiction, (1) when the Plaintiffs' claim implicates a significant and disputed federal issue, and (2) exercising jurisdiction will not upset the balance between federal and state judicial responsibilities. *Grable*, 545 U.S. at 312-14, 125 S. Ct. at 2366-67.

47. In *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180, 41 S. Ct. 243 (1921), the Court held:

> The general rule is that where it appears from the bill or statement of the plaintiff that the right to relief depends upon the construction or application of the

> Constitution or laws of the United States, and that such federal claim is not merely colorable, and rests upon a reasonable foundation, the District Court has jurisdiction . . . .

Id. at 199, 41 S. Ct. at 244-45. This doctrine "captures the commonsense notion that a federal court ought to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Grable*, 545 U.S. at 312, 125 S. Ct. at 2367 (citation omitted).

48. A defendant need only show that one of the elements of a single claim presents a substantial federal issue in order for this Court to exercise federal removal jurisdiction over the entire case. *See* 28 U.S.C. § 1441(c); *see also Franchise Tax Bd. of Cal. v. Laborers Vacation Trust*, 463 U.S. 1, 13, 103 S. Ct. 2841, 2848 (1983).

49. Throughout their Complaint, the Plaintiffs seek to hold the IRB, which is governed by federal law, liable to the Plaintiffs for the IRB's role in reviewing and approving the R&M study at issue. *See* Ex. A. Although the R&M study has been the subject of prior lawsuits, **this case presents the first time that the IRB has been made a party.**

50. Plaintiffs' claims, as described more fully below, arise under federal law. The IRB's duties, if any, are created by federal law. Moreover, the federal laws relied upon by the Plaintiffs in their Complaint, *see, e.g.*, Ex. A at ¶ 51, are at the core of the dispute between the Plaintiffs and the IRB Defendants.

51. Exercising jurisdiction will not upset the balance of power between federal and state courts. Counsel for the IRB has not located any federal or state reported decision

in which an institutional review board has been sued for negligently approving and supervising a research study. Indeed, a search of all reported federal and state cases nationwide has revealed only two opinions where an institutional review board has been named as a defendant, and on both occasions, the cases were brought against an institutional review board in federal court. *See Mason v. Institutional Review Bd. for Human Research*, 1992 U.S. App. LEXIS 441 (4th Cir. 1992) (unpublished); Halikas *v. University of Minnesota*, 856 F. Supp. 1331 (S.D. Minn. 1994). Exercising removal jurisdiction in this case will not inundate federal courts with state law claims against institutional review boards and will not upset the balance of power between federal and state courts.

52. Exercising jurisdiction will also promote uniformity in the application and interpretation of the federal laws at issue, which is a goal articulated by the Supreme Court in *Grable*. *See Grable*, 545 U.S. at 312, 125 S. Ct. at 2367. According to a Guidebook published by the DHHS, the regulations cited in Plaintiffs' Complaint and relied upon by the Plaintiffs were promulgated by sixteen federal agencies that conduct, support, or regulate human research. *See* Ex. R, Institutional Review Guidebook, www.hhs.gov/ohrp/irb/irb_introduction.htm. The DHHS Guidebook chronicles the detailed and deliberative process the federal government employed in arriving at the regulations at issue here. *Id.* The Introduction states:

> The DHHS regulations are codified at Title 45 Part 46 of the Code of Federal Regulations. Those "basic" regulations became final on January 16, 1981, and were revised effective March 4, 1983, and June 18, 1991. The June 18, 1991, revision involved the adoption of the Federal Policy for the Protection of Human Subjects. **The Federal Policy (or "Common Rule," as it is sometimes called) was promulgated by the sixteen federal agencies that conduct, support, or otherwise regulate human subjects research**; the FDA also adopted certain of its provisions.

> **As is implied by its title, the Federal Policy is designed to make uniform the human subjects protection system in all relevant federal agencies and departments.** The Federal Policy is discussed in depth in Chapter 2, Section A(i).

Id. (emphasis added).

53. A substantial federal interest exists in the uniformity of interpretation and application of federal laws governing scientific research involving children. In fact, there were other similar federal multi-center studies that were ongoing at the same time that the R&M study was being conducted. The Plaintiffs' claims in this case arise under these federal laws. Indeed, the duty elements of their tort claims depend upon them. Because federal laws govern the IRB's conduct, exercising jurisdiction will not upset the balance of power between the federal-state judicial systems. *See Grable*, 545 U.S. at 314,125 S. Ct. at 2367. Rather, exercising removal jurisdiction will promote uniformity in the interpretation and application of the subject regulations.

A. **Federal law governs any duties owed by the IRB to the Plaintiffs.**

54. When a research study involving human subjects is conducted, supported, or regulated by any federal agency, federal law requires that an IRB be created. *See* 42 U.S.C. § 289; 45 C.F.R. § 46.101 *et seq.* Federal law expressly states what the IRB's duties are when it reviews research proposals involving children. *Id.* §§ 46.403, 46.404, 46.405, 46.406, 46.407, 46.408, and 46.409.

55. Federal law establishes the procedures the IRB must follow when reviewing such research. *See, e.g., id.* § 46.103. Federal law also dictates the IRB's membership, as well as its functions and operations. *Id.* §§ 46.107, 46.108. The federal regulations also

govern the IRB's review of research, *id.* § 46.109, including the criteria it must apply for approval of research, i*d.* § 46.111.

56. The alleged tort duties owed by the IRB in this case are grounded exclusively in federal law.[4] The federal regulations at issue were promulgated by the sixteen federal agencies that conduct, support, and/or regulate human subject research. The federal government has a strong interest in the uniformity in the application and interpretation of these regulations in order to ensure that scientific research upon children is performed in a consistent manner.

B. Johns Hopkins University's and Kennedy Krieger's alleged breach of The Belmont Report independently -- or in conjunction with the foregoing federal regulations -- raise other significant federal issues warranting the exercise of federal question jurisdiction.

57. Plaintiffs allege that JHU and Kennedy Krieger agreed to be subject to the duties and obligations set forth in The Belmont Report in an agreement with DHHS. *See* Ex. A at ¶ 67. Notably, The Belmont Report is also described by DHHS in its Guidebook. *See* Ex. R. The DHHS Guidebook states that The Belmont Report was prepared by a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Id.* DHHS describes the principles identified in The Belmont Report as "the three quintessential requirements for the ethical conduct of research involving human

[4] Although the Plaintiffs cite to a single section of the Maryland Code, section 13-2002 of the Maryland Annotated Code, Health General actually provides that a person may not conduct research on a human subject unless it is performed in accordance with the "federal regulations on the protection of human subjects." *See* Md. Ann. Code, H.G. § 13-2002. Therefore, Plaintiffs' citation to the Maryland statute emphasizes the federal nature of their claim.

subjects." *Id.* These principles are quote: "(1) "respect for persons," (2) "beneficence," and (3) "justice." *Id.*

58. According to the Guidebook, "respect for persons" includes the requirement of informed consent. *See* Ex. R. Whether the IRB properly approved the method of obtaining informed consent is governed under the federal regulations. *See* 45 CFR §§ 46.111(a)(4), 46.116 - 46.117, and 46.408. "Beneficence" incorporates the risk/benefit analysis for the human subject research under consideration. *See* Ex. R. The federal regulations at issue also govern this concept. *See* 45 CFR §§ 46.110, 46.404 - 407. The Belmont Report's third principle, "justice," states that the subjects of the human research must have been fairly selected. *See* Ex. R. Again, this concept is governed by federal law. *See* 45 C.F.R. § 46.111(a)(3). Therefore, the Plaintiffs' reliance upon The Belmont Report in two counts of their Complaints bolsters the reasons for exercising federal jurisdiction.

C. The federal issues in this case are substantial, disputed and are necessary elements of the Plaintiffs' claims.

59. In Count Four, Plaintiffs allege the IRB had a duty to ensure the safety of the participants, and that the IRB breached that duty, which resulted in negligence. *See* Ex. A. at ¶ 51. In support of that contention, the Plaintiffs expressly rely upon federal law, which governs the IRB for the existence of such a duty.[5] *Id.*

60. In order to establish negligence, the Plaintiffs must prove the essential element of duty. *See Rosenblatt v. Exxon*, 335 Md. 58, 76, 642 A.2d 180, 188 (1994). In this

[5] As noted previously in footnote 1, the Maryland Annotated Code provision cited by Plaintiffs adopts the federal regulations at issue here.

instance, Plaintiffs rely upon federal law in order to establish a duty allegedly owed by the IRB.

61. In Count Four, the Plaintiffs also allege the existence of a special relationship. Ex. A at ¶¶ 55-59. In *Grimes v. Kennedy Krieger Institute, Inc.*, 366 Md. 29, 782 A.2d 807 (2001), the court examined whether a special relationship existed between a researcher institution and the study participants. *Id.* at 88-99, 782 A.2d at 842-50. In deciding that a special relationship could exist under certain circumstances, the court relied upon the subject federal regulations. *Id.* at 98 ("In this case, a special relationship out of which duties might arise might be created by reason of the federally imposed regulations."). Therefore, the duty element alleged in paragraph 55 of the negligence claim in Count Four, if one is owed by the IRB at all, also arises under federal law.

62. Count Five of Plaintiffs' Complaint sounds in negligence and alleges that informed consent was not properly obtained by the IRB Defendants and KKI.[6] Plaintiffs contend that the IRB's duties to the Plaintiffs are set forth in the informed consent agreement. *See* Ex. A at ¶ 62. Whether the IRB properly approved the method in which informed consent was obtained is governed by federal law. *See* 45 CFR §§ 46.111(a)(4), 46.116 - 46.117, 46.403, and 46.408. Therefore, Count Five arises under federal law because the necessary element of duty is again governed by federal law.

63. In Count Three, which alleges a negligent misrepresentation claim sub-titled **Risk of Harm to Plaintiffs**, the Plaintiffs contend that the IRB negligently made or

[6] Plaintiffs also make a number of other references in their Complaint regarding the Defendants' alleged failure to obtain informed consent. *See* Ex. A at ¶¶ 5-7, 21-25, 44, 48, 54, 71-72, 78, and 86.

"Plaintiffs") commenced this action by filing a Complaint in the Circuit Court for Baltimore City, Maryland.

68. Defendant Thomas R. Hendrix, M.D. was served with the Complaint on April 9, 2007. Accordingly, this Notice of Removal is being timely filed within thirty days of service pursuant to 28 U.S.C. section 1446(b).

69. A Notice of Filing of Notice of Removal is being filed on this date with the Clerk of the Circuit Court for Baltimore City, Maryland and is being served on Plaintiffs' counsel as required by 28 U.S.C. section 1446(d). A copy of the Notice of Filing of Notice of Removal filed in the State Court Action is attached. *See* Ex. T.

70. Consent is not required for removals taken pursuant to 28 U.S.C. section 1442 (a)(1). Pursuant to 28 U.S.C. sections 1441(a) and (b) and 1331, undersigned counsel represents that all of the co-defendants in this action that have been served expressly consent to the removal of the State Court Action to this Court. *See* Ex. T.

WHEREFORE, Kennedy Krieger Institute, Inc., Mark Farfel, Sc.D., The Johns Hopkins University, The Institutional Review Board of the Johns Hopkins University School of Medicine's Joint Committee on Clinical Investigation, Thomas R. Hendrix, M.D., Lewis C. Becker, M.D., David R. Cornblath, M.D., Paul Lietman, M.D., Hayden G. Braine, M.D., and Peter Lees, Ph.D. respectfully request that this Court exercise original jurisdiction over this case and that the State Court Action be removed to the United States District Court for the District of Maryland (Northern Division).

Respectfully submitted,

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CERTIFICATE OF SERVICE

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

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