DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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January 18, 2002

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720 Rutland Avenue
Baltimore, MD 21205-2196

Michael Klag, M.D.
Vice Dean for Clinical Investigation
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720 Rutland Avenue
Baltimore, MD 21205-2196

Gary Goldstein, M.D.
President
Kennedy Krieger Institute
707 North Broadway, 6th Floor
Baltimore, MD 21205

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1011

Research Project: Attention Deficit Hyperactivity Disorder (ADHD) Research
Principal Investigator: Dr. Martha B. Denckla

Dear Dr. Dang, Dr. Klag, and Dr. Goldstein:

The Office for Human Research Protections (OHRP) has reviewed your October 31, 2001 report regarding the allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) involving the above-referenced research.

The allegations involved the following:

> (1) Failure of the investigators to ensure that risks to subjects were minimized as required by HHS regulations at 45 CFR 46.111(a)(1).
>
> (2) Failure of the investigators to promptly report the above unanticipated problems involving risks to subjects or others to the Institutional Review Board (IRB), appropriate institutional officials, the funding Agency, and OHRP in accordance with the requirements of HHS regulations at 45 CFR 46.103(b)(5).

Based upon OHRP's review of your October 31, 2001 report, OHRP finds no evidence to substantiate the above allegations. In specific, OHRP notes the following:

> (1) The Kennedy Krieger Institute (KKI) is not able to identify studies conducted by the investigators that involve the diagnosis of ADHD or which involve referring subjects into treatment or educational programs.
>
> (2) Two protocols conducted by the investigators did involve the employment of undergraduates but neither of these studies (i) involved the diagnosis or treatment of ADHD; or (ii) allowed undergraduates to score diagnostically definitive standard instruments.

As a result of the above determination, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Patrick J. McNeilly

Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Mr. Ronald R. Peterson, President, The Johns Hopkins Hospital
Dr. Martha Hill, Interim Dean, School of Nursing, JHU
Dr. Jacquelyn Campbell, School of Nursing, JHU
Ms. Karen Cox, Research Administrator, Kennedy Krieger Institute
Dr. Darrell R. Abernethy, Clinical Director, NIA
Dr. Vincent L. Pisacane, Director, Institute for Advanced Science and Technology in Medicine, Applied Physics Laboratory
Mr. David Grant, Applied Physics Laboratory
Ms. Barbara L. Starklauf, Administrator, Human Subjects Committees, JHUSOM
Dr. Lewis Becker, Chairman, JCCI -I, JHUSOM
Dr. David R. Cornblath, Chairman, JCCI-II, JHUSOM
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Mr. George Gasparis, OHRP
Dr. Harold Blatt, OHRP
Mr. Barry Bowman, OHRP