DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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August 23, 2002

Michael Klag, M.D.
Vice Dean for Clinical Investigation
The Johns Hopkins University
School of Medicine
School of Medicine Administration Building, Room 124
720 Rutland Avenue
Baltimore, MD 21205-2196

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

Dear Dr. Klag:

As you know, the Office for Human Research Protections (OHRP) conducted a follow-up on-site evaluation of human subject protection procedures at the Johns Hopkins University School of Medicine, (JHUSOM) on June 6, 2002. The evaluation, conducted by three OHRP staff, included meetings with you and the senior leadership of the JHUSOM, the Chairs of the JHUSOM Institutional Review Boards (IRBs), more than 25 IRB members, and the IRB Administrator and her staff.

OHRP Findings

Based upon observations made during its site visit, as well as its review of all documents provided with your previous progress reports, including your report dated July 10, 2002, OHRP finds that the JHUSOM has developed and implemented a markedly enhanced system for protection of human subjects and has adequately completed all required actions stipulated in OHRP's letter of July 19, 2001. Among the many enhancements noted by OHRP are the following:

(1) JHUSOM has implemented a multifaceted education program to ensure that all IRB members, all IRB staff, and all research investigators are educated on an ongoing basis about the ethical principles and regulatory requirements for the protection of human subjects.

(2) Since July 2001, JHUSOM has expanded the number of IRBs from two to four and maintains an additional IRB at the Johns Hopkins Bayview Medical Center, resulting in a significant reduction in the volume of research protocols reviewed and overseen by each IRB. The IRB Chairs and members are highly committed to the protection of human subjects and demonstrated an enhanced knowledge of the ethical issues and regulations related to the protection of human subjects.

(3) JHUSOM has expanded the resources of its IRB offices. OHRP notes that additional staff have been hired to assist the IRBs and the overall administration of the system for the protection of human subjects. These additional staff include a new Vice Dean for Clinical Investigation, as well as a new regulatory affairs group and an IRB systems support group.

(4) JHUSOM has developed and implemented new procedures for the operations of its IRBs, including procedures for (i) format of IRB meetings; (ii) conduct of IRB review of protocols; and (iii) documentation of IRB activities.

OHRP Action

As a result of the above determinations, effective immediately, OHRP has removed the restriction on the JHUSOM Multiple Project Assurance (MPA M-1011), and the JHUSOM no longer needs to submit quarterly progress reports to OHRP. Furthermore, 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, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Edward Miller, Dean and CEO, Johns Hopkins Medicine
Dr. Chi V. Dang, Vice Dean for Research, JHUSOM
Mr. Gregory F. Schaffer, President, The Johns Hopkins Bayview Medical Center
Mr. Ronald R. Peterson, President, The Johns Hopkins Hospital
Dr. Martha Hill, Dean, School of Nursing, JHU

Dr. Jacquelyn Campbell, School of Nursing, JHU
Dr. Gary Goldstein, President, Kennedy Krieger Institute
Ms. Karen Cox, Research Administrator, Kennedy Krieger Institute
Dr. Darrell R. Abernethy, Clinical Director, NIA
Mr. David Grant, Applied Physics Laboratory
Ms. Barbara L. Starklauf, Administrator, Human Subjects Committees, JHU SOM
Dr. Lewis Becker, Chairman, JCCI -I, JHUSOM
Dr. David R. Cornblath, Chairman, JCCI-II, JHU SOM
Dr. Paul Lietman, Chairman, JCCI-III, JHU SOM
Dr. Hayden Braine, Chairman, JCCI-IV, JHU SOM
Dr. Gary Briefel, Chairman, JHBMC-1 IRB
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Greg Koski, OHRP
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Dr. Jeffrey Cohen, OHRP
Mr. George Gasparis, OHRP
Dr. Harold Blatt, OHRP
Mr. Barry Bowman, OHRP