DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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November 24, 2008

Linda A. Bell, Ph.D.
Provost
Haverford College
Office of the Provost
370 Lancaster Avenue
Haverford, PA 19041

Re: Human Research Subject Protections Under Federalwide Assurance FWA-916

Dear Dr. Bell:

Thank you for your December 21, 2007 and October 28, 2008 reports in response to our November 16, 2007 requests that Haverford College evaluate indications of possible noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46) and the September 15, 2008 determination letter.

In our September 15, 2008 letter, we made the following determinations, among others:

(1) We determined that the email process outlined in the Haverford College institutional review board (IRB) procedures did not satisfy the provisions of HHS regulations at 45 CFR 46.108(b) that require that except when an expedited review procedure is used, the IRB review research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary interests are in nonscientific areas. We emphasized that proxy votes may not be counted as votes to approve or disapprove research at convened meetings, nor may they be counted for purposes of establishing a quorum.

Corrective Action: Per your December 21, 2007 letter, we acknowledged that on December 17, 2007, Haverford College IRB changed its procedures to eliminate the

option of convening IRB meetings by email, and implemented the requirement that convened meetings be either in-person or by telephone conferences.

(2) We reviewed the Haverford College IRB procedures and determined that those procedures did not include or (in some cases) provide sufficient details for the procedures required by HHS regulations at 45 CFR 46.103(b)(4 and 5); specifically:

- procedures which the IRB will follow for determining which projects require review more often than annually;
- the procedures which the IRB will follow for conducting its continuing review of research;
- the procedures which the IRB will follow for reporting its findings and actions to investigators and the institution;
- procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;
- procedures which the IRB will follow for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject; and
- procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any department or agency head, and the Office for Human Research Protections (OHRP) of: (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval.

Corrective Action: We acknowledge that Haverford College IRB Policies and Procedures have been revised to provide additional information and detail and now satisfies all requirements outlined in HHS regulations at 45 CFR 46.103(b)(4) and (5).

We also note that the additional modifications and clarifications have been made to the Haverford IRB procedures and adequately address the questions, concerns and recommendations outlined in our September 15, 2008 letter.

We determine that these corrective actions adequately address our determinations and are appropriate under the Haverford College FWA. At this time, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

We appreciate your institution's continued commitment to the protection of human research subjects.

Sincerely,

Lisa R. Buchanan, MAOM, CIP
Division of Compliance Oversight

cc: Dr. John M. Mosteller, Human Protections Administrator
Dr. Robert Scarrow, IRB Chairperson
Dr. Joanne Less, Food and Drug Administration
Dr. Sherry Mills, National Institutes of Health
Mr. Joseph Ellis, National Institutes of Health
Dr. Andrew C. von Eschenbach, Commissioner, U.S. Food and Drug Administration (FDA)