DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852
Telephone: 240-453-8298
FAX: 240-453-6909
E-mail: Lisa.Buchanan@HHS.gov

September 15, 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 the December 21, 2007 report, from Robert Scarrow (IRB Chairperson) in response to our November 16, 2007 request that Haverford College investigate possible noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46). We appreciate your investigations in the matters outlined in our request.

A. Determinations regarding institution's system for protecting human subjects:

(1) Since December 2006, Haverford College institutional review board (IRB) reviewed research by email communications amongst IRB members. We have determined that the email process outlined in the 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 emphasize 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: We acknowledge 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 conference calls. Further, the IRB at convened meetings affirmed research proposals that were previously approved during the former email meetings. However, we are concerned that this re-affirmation may not have included reconsideration of the research as it pertains to the criteria for IRB approval of research required in the regulations at 45 CFR 46.111.

Required Action: Please specify the review procedures used by the IRB in the re-affirmation of research previously reviewed by email; specifically the protocol titled, "Effects of Anxiety on Interhemispheric Communitation" which is HHS-supported. Additionally, please provide the procedure the IRB will use to ensure that HHS-supported research is reviewed in compliance with the criteria found at 45 CFR 46.111.

(2) We have reviewed the Haverford College IRB procedures, and determined that those procedures do 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.

Required Action: Please provide a corrective action plan and indicate procedures that the IRB will use to ensure that the written procedures satisfy all requirements outlined in HHS regulations at 45 CFR 46.103(b)(4) and (5). To assist you in developing revised written procedures, please refer to the OHRP Guidance on Written IRB Procedures http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.htm. Also, please provide a copy of the revised written procedure addressing these deficiencies.

B. Questions and Concerns

(1) [Redacted]

(2) [Redacted]

C. Recommendation:

(1) The Haverford College IRB written procedures, under "Membership in the Haverford College IRB," state the following: "a non-scientist member of the faculty – An individual with research and/or medical training (M.D. preferred)." This appears to be an error. We recommend that the definition be revised to clarify that a non-scientist be an individual

with no research and/or medical training.

(2) The Haverford College IRB written procedures, under "Continuing Review and Final Reports" state that "[p]roposals are approved for a period of up to one year from the date of the approval letter." However, we noted that the minutes of the December 17, 2007 meeting, in item 11 state "Clarification that IRB can only approve a proposal for one year from the date of its meeting." We recommend that the written procedures be updated to reflect this clarification--focusing on the date of the convened meeting at which IRB approval occurs and, for expedited review, when final approval occurs.

(3) The Haverford College IRB written procedures state that " 'minimal risk' approved proposals may (at the discretion of the chair person) undergo expedited continuing review." However, expedited review category 9, specifies that "Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified." We recommend that the procedures reflect that only under these specific circumstances may 'minimal risk' approved proposals undergo expedited continuing review.

(4) The procedures state that "[m]ost committee business is handled by email…" We recommend that this statement be deleted or revised to clarify that such business would not include tasks that the regulations require be performed by the convened IRB.

(5) We noted that the procedures requiring the completion of the NIH human subjects training module was discontinued per previous communications with OHRP regarding assurance training. However, these modules have different focuses, so one should not replace the other; rather, one can be in addition to the other. We recommend that both the NIH human subjects training module and OHRP human subject assurance modules continue as part of training for IRB Chairpersons, Human Protections Administrators, Executive Secretaries, etc.

(6) The procedures define research requiring IRB review as research "intended to cover any type of investigation that is meant for print, web-based, or broadcast publication, i.e., whose results will in some form be available to the public, regardless of whether public funding is sought." We recommend using the definitions provided at 45 CFR 46.102, as not all research that would meet the regulatory definition for research is intended for publication, and some activities that are intended for publication do not satisfy the regulatory definition for research.

Please provide us with responses to the above determinations, questions and concerns by October 30, 2008, including a corrective action plan for each of our determinations. Feel free to contact me if you would like guidance in developing a corrective action plan.

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

Sincerely,

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

cc: Dr. John M. Mosteller, HPA
Dr. Robert Scarrow, IRB Chairperson
Dr. Joanne Less, FDA
Dr. Sherry Mills, NIH
Mr. Joseph Ellis, NIH