DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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August 3, 2004

Astra D. Bain-Dowell, MPA
Assistant Vice President for Health Research,
Compliance &Technology Transfer
George Washington University
2300 Eye Street, N.W.
Suite 712
Washington, DC 20037

RE: Human Research Subject Protections Under Federalwide Assurances (FWA) 5945

Activities Involving the Graduation Questionnaire (GQ)

Dear Ms. Bain-Dowell:

The Office for Human Research Protections (OHRP) has reviewed your report of October 31, 2003 regarding 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 activities conducted at the George Washington University (GWU).

OHRP makes the following determinations about the above-referenced activities:

(1) HHS regulations at 45 CFR 46.116 require that procedures for enrolling subjects minimize the possibility of coercion or undue influence. It was alleged that many of the schools that recruit subjects for this research make participation in the research a requirement for graduation from medical school. OHRP acknowledges GWU's statement that GWU does not require completion of the GQ for graduation from medical school, but has implied that it is required.

Corrective Action: OHRP acknowledges that prior to its use in 2004, GWU will notify all medical students that participation in the GQ is totally voluntary and is not a requirement for graduation.

(2) In accordance with HHS regulations at 45 CFR 46.103(b) and 46.109(a), the

institutional review board (IRB) must review and approve all non-exempt human subject research covered by an assurance. It was alleged that human subject research involving the GQ was conducted without IRB review.

Corrective Action: OHRP acknowledges GWU's statement that an article describing research using the GQ data by a GWU faculty member was conducted outside the scope of her institutional responsibilities. OHRP also acknowledges that administrators within the School of Medicine will be notified that all surveys or questionnaires submitted to external organizations must be pre-reviewed by the GWU IRB, and will work with the AAMC to ensure that the GQ receives appropriate IRB consideration prior to its administration to GWU medical students. GWU will also notify the AAMC that responses received to-date from GWU students related to the GQ may only be used for program evaluation purposes and may not be used for research purposes. OHRP also acknowledges that the AAMC intends to seek IRB review of the GQ prior to its next administration.

(3) HHS regulations at 45 CFR 46.116 state that, except as provided elsewhere in the regulations, no investigator may involve a human being as a subject in research covered by the regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. It was alleged that the institutions initiated human subjects research without meeting this requirement.

Corrective Action: OHRP acknowledges that AAMC will provide an opportunity for medical students completing the GQ to provide specific informed consent about whether or not the AAMC may retain their GQ data in a personally identifiable form for research purposes.

(4) HHS regulations at 45 CFR 46.111(a) state that, in order to approve research covered by the regulations, the IRB shall determine that certain requirements are satisfied. It was alleged that this research failed to satisfy the following requirements:

(a) Risks to subjects are minimized.

(b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

(c) Selection of subjects is equitable.

(d) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

OHRP finds that this allegation could not be substantiated.

OHRP finds that the corrective actions above adequately address the concerns raised about the

above-referenced activities and are appropriate under the GWU FWA. As a result of the above determinations, OHRP sees no need for further involvement in this matter.

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,

Kristina C. Borror, Ph.D.
Director
Division of Compliance Oversight

cc: Mr. Leodayann Bojanowski, Director, IRB, George Washington U
Dr. David M. Parenti, Chair, IRB #1, George Washington U
Mr. Robert W. Tuttle, Chair, IRB #2, George Washington U
Dr. Bernard Schwetz, OHRP
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Ms. Shirley Hicks, OHRP
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