DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Public Health and Science

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August 3, 2004

Jordan J. Cohen, M.D.
President
Association of American Medical Colleges
2450 N. Street, NW
Washington, DC 20037

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 1666

Activities Involving the Graduation Questionnaire (GQ)

Dear Dr. Cohen:

The Office for Human Research Protections (OHRP) has reviewed your report of October 24, 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 Association of American Medical Colleges (AAMC).

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 finds that AAMC did not require participating schools to make completion of the GQ a requirement for graduation from medical school.

(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.

OHRP acknowledges AAMC's statement that the GQ was not designed as a research tool, and that any research use of the GQ data could be regarded as exempt from IRB review under HHS regulations at 45 CFR 46.101(b)(2). However, OHRP notes that some

of the survey questions involve student debt, sexual harassment, and concerns about the way in which the school handled complaints about harassment, which OHRP notes could reasonably be damaging to the subjects' financial standing, employability, or reputation. Therefore, if such information were recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, such research would not be exempt. Exemption determinations should be made on a case-by-case basis, and OHRP recommends that such determinations be made by someone other than the investigator. OHRP also notes that the only HHS-supported research that we are aware of that was conducted by AAMC staff using GQ data (Predictive Validity of Specialty Choice Data From AAMC Graduation Questionnaire, Dial, T.H. and Lindley, D.W.; Journal of Medical Education, Vol. 62: 956, December 1987) could arguably be exempt under HHS regulations at 45 CFR 46.101(b)(2).

Corrective Action: OHRP 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's HHS-supported involvement in human subjects research using GQ data was arguably exempt and therefore did not require informed consent under HHS regulations. OHRP also 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 AAMC 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

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