DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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Vice President for Research
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3333 Green Bay Road
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RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 5002

Activities Involving the Graduation Questionnaire (GQ)

Dear Dr. Sarras:

The Office for Human Research Protections (OHRP) has reviewed your report of October 28, 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 Finch University Health Sciences/Chicago Medical School (CMS).

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 CMS's statement that CMS does not require completion of the GQ for graduation from medical school. However, OHRP notes that in correspondence to medical students about the GQ, CMS uses phrases such as "CMS requires this survey be completed no later than..."and "Please take the time to finish this requirement...."

(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 CMS'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 acknowledges that CMS has not published any research articles using data from the GQ.

Corrective Action: OHRP acknowledges that the CMS intends to seek IRB review of the GQ prior to its next administration. 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 CMS's statement that CMS use of the GQ data was not research under HHS regulations. CMS will provide an opportunity for medical students completing the GQ to provide specific informed consent about whether or not the CMS may retain their GQ data in a personally identifiable form for research purposes. 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 CMS 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:

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