DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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August 3, 2004

Steven G. Ullmann, Ph.D.
Vice Provost for Faculty Affairs,
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University of Miami
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Coral Gables, FL 33124-4628

RE: Human Research Subject Protections Under Federalwide Assurances (FWA) 2247

Activities Involving the Graduation Questionnaire (GQ)

Dear Dr. Ullmann:

The Office for Human Research Protections (OHRP) has reviewed your report of November 6, 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 University of Miami (UM).

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 that UM has not published any research articles using data from the GQ. OHRP recommends that UM not require completion of the GQ for graduation, or that UM require the obtaining of students' informed consent before using their responses for research purposes. 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.

(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 UM's statement that the GQ was not designed as a research tool, but rather as an exempt survey. However, OHRP notes that the exemptions only apply to human subjects research. In addition, 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.

Corrective Action: OHRP acknowledges that the GQ will be submitted to the AAMC IRB for review prior to its next administration. In addition, the UM will mandate that its investigators also submit the GQ to the UM IRB for review to determine its exempt status.

(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 UM FWA. As a result of the above determinations, OHRP sees no need for further involvement in this matter.

OHRP offers the following additional guidance regarding UM's Policies and Procedures for the Protection of Human Subjects in Research:

> (5) Written IRB policies and procedures should provide a step-by-step description with key operational details for each of the procedures required by HHS regulations at 45 CFR 46.103(b)(4) and (5):
>
> > (a) A description of what steps are taken to ensure that investigators do not implement any protocol changes without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects (e.g., this might be addressed through training programs and materials for investigators, specific directives included in approval letters to investigators, and random audits of research records).
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> > (b) A description of which office(s) or institutional official(s) is responsible for promptly reporting to the IRB, appropriate institutional officials, any supporting Agency or Department heads, and OHRP any unanticipated problems involving risks to subjects or others, a description of the required time frame for accomplishing the reporting, and the range of possible actions taken by the IRB in response to reports of unanticipated problems involving risks to subjects or others.

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: Ms. Maria J. Arnold, Director, Human Subjects Research Office, U Miami
Dr. Arturo Brito, Chair, IRB A, U Miami
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Dr. Stephen Sapp, Chair, Social and Behavioral Science IRB, U Miami
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Dr. Bernard Schwetz, OHRP
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