DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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October 25, 2006

Ali Cinar, Ph.D.
Vice Provost for Research and
Dean of the Graduate College
Illinois Institute of Technology
3300 South Federal Street
Chicago, IL 60616-3793

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 1463

Research Project:	**A Long-Term Cross-Sectional Study on Gastric Bypass Surgery: Impact of Past Sexual Abuse**
Research Investigators:	**Chow S. Lam and Amy Buser**
Protocol Number:	**2005-125**

Dear Dr. Cinar:

The Office for Human Research Protections (OHRP) has reviewed the Illinois Institute of Technology (IIT) October 10, 2006 response to OHRP's September 6, 2006 letter regarding indications of possible 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 research.

OHRP has determined that the corrective actions summarized below address the issues raised and are adequate and appropriate under the IIT FWA:

> (1) HHS regulations at 45 CFR 46.116(a)(1) require that, unless waived by the institutional review board (IRB), informed consent include an explanation of the purposes of the research. OHRP finds that the informed consent document approved by the IIT IRB failed to include an adequate explanation of the purposes of the above-referenced research (i.e., the effect of past sexual abuse on the outcome of gastric bypass surgery). The HHS regulations at 45 CFR 46.116(d) require that the IRB find and document four specific criteria when approving waiver or alteration of some or all of the

required elements of informed consent. OHRP's review of IIT IRB documents reveal no evidence that the IRB satisfied these requirements.

Corrective Action: When the IIT IRB considers approving potential waivers or alterations of elements of informed consent it will consider and document each of the four specific criteria required by 45 CFR 46.116(d). The IIT IRB written procedures will be revised to reflect this. OHRP recommends that IRB members and staff be provided with training regarding this issue.

(2) OHRP finds that the IIT IRB approved the above referenced research contingent upon substantive modifications or clarifications that are directly relevant to the determinations required by the IRB under HHS regulations at 45 CFR 46.111 without requiring additional review by the convened IRB. OHRP notes that when the convened IRB requests substantive clarifications or modifications regarding the protocol or informed consent documents that are directly relevant to the determinations required by the IRB under HHS regulations at 45 CFR 46.111, IRB approval of the proposed research must be deferred, pending subsequent review by the convened IRB of responsive material. OHRP notes that the July 20, 2004 minutes of the IRB meeting indicate that there was an outstanding request for a copy of a letter from the treating physician to be used in recruiting patients. Further discussion and voting on significant changes to the letter and consent form continued via e-mail outside a convened IRB meeting. The September 20, 2005 IRB minutes reflect that protocol was allowed to proceed despite an outstanding substantive question about who would have access to the patients' medical records.

Corrective Action: Effective immediately the IIT IRB will ensure that substantive clarifications or modifications regarding the protocol or informed consent documents, that are directly relevant to the determinations required by the IRB under HHS regulations at 45 CFR 46.111, be approved at a subsequent review of the responsive material by a convened IRB. Only when the convened IIT IRB stipulates revisions requiring simple concurrence by the investigator will the ITT IRB Chair or his or her designee be authorized to subsequently approve the revised research protocol on behalf of the IRB.

As a result, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

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,

Paul J. Andreason, M.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc:

Mr. Glenn Krell, Director, Office of Research Compliance and Proposal Development, IIT
Dr. Scott Morris, Chair, IIT IRB
Dr. Chow Lam, IIT
Ms. Amy Buser, IIT
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms Shirley Hicks, OHRP
Ms. Patricia El-Hinnawy. OHRP
Ms. Carla Brown, OHRP