DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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September 6, 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) January 13, 2006 response to OHRP's December 1, 2005 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.

Based upon its review, OHRP makes the following determinations:

(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. In specific, OHRP notes the following from page 4 of the IIT response letter:

> The IRB did not require the procedures to be changed but the researchers were asked to add a description and justification of the deception to the research protocol. The researchers provided the following justification in section E of the IRB research protocol: "Patients are not told the target variable under study-patients with a history of sexual abuse. This information is withheld in order to reduce patient stress when filling out the survey packet...."

Required Action: By October 12, 2006, please provide OHRP with a corrective action plan to address the above finding. In your plan, please describe the manner in which the IIT IRB considers potential waivers or alterations of elements of informed consent.

(2) HHS regulations at 45 CFR 46.111(a)(1) require that in order to approve research covered by 45 CFR part 46 the IRB must determine that, among other things, risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. It was alleged that the IIT IRB approved the above-referenced research without appropriate mechanisms in place to ensure that the subjects had adequate counseling available in case of retraumatization. OHRP was also concerned that some of the questions being asked of the subjects related to possible thoughts of suicide. OHRP asked that IIT describe the provisions in place in the protocol for how the investigator would deal with a subject who identified imminent suicidal thoughts. OHRP acknowledges that the following safeguards were put into place to ensure that subjects had adequate counseling in the event that retraumatization or suicidal ideation occurred:

> (a) The consent form provided contact information identifying where research subjects could obtain counseling if re-traumatized. These contacts included the doctoral student who had internship experience dealing with victims of abuse, the original treating surgeon, and the Washtenaw County Crisis Center.
>
> (b) Item #9 (the suicide related symptom item) of the mood rating scale (Beck Depression Inventory II) was reviewed when received by the investigators. If the score on item #9 was either "2" or "3" the original treating surgeon would contact the subject and provide appropriate referrals.

As a result, OHRP finds that the above allegation can not be substantiated.

(3) HHS regulations at 45 CFR 46.108(b) require that, except when an expedited review procedure is used, the IRB shall review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. OHRP finds that the final discussion and

vote on the continuing review of the above-referenced research by the IIT IRB was inappropriately made after the non-scientist member of the IRB had left the meeting and quorum was lost even though she had participated in prior discussion and her written negative vote was obtained.

Corrective Action: OHRP acknowledges the following statements in IIT January 16, 2006 response:

> The IRB will table ongoing business and adjourn the meeting prior to the community member leaving the meeting. If the protocol is subject to a vote, all members will vote during the meeting. If necessary, additional meetings will be scheduled to complete the IRB business.

OHRP finds that the IRB's corrective action is adequate to address the above finding and appropriate under the IIT assurance.

OHRP has the following additional concerns:

(4) [Redacted]

(5) [Redacted]

(6) [Redacted]

OHRP offers the following guidance:

> OHRP notes that one of the principal investigators for protocol 2005-125 obtained identifiable private information by reviewing patient medical records prior to patients giving informed consent for this research activity. Informed consent for medical record review to recruit potential study subjects should be considered formally by the IRB and may reasonably be waived in accordance with the requirements of HHS regulations at 45 CFR 46.116(d). When approving such a waiver of informed consent, the IRB must make and document in the IRB records the four findings outlined in 45 CFR 46.116(d).

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
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Dr. Bernard Schwetz, OHRP
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