DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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August 18, 2005

Richard W. Bianco
Assistant Vice President for Regulatory Affairs
University of Minnesota
420 Delaware Street, SE, MMC820
Minneapolis, MN 55455

RE: Human Research Subject Protections Under Federalwide Assurance FWA-312

Research Project:	**A Randomized Study of the Effect of Sartorius Transposition Following Inguinal-Femoral Lymphadenectomy on Post-Operative Groin Morbidity**
Principal Investigator:	**Linda Carson, M.D.**
Protocol Number:	**9603M10917**

Dear Mr. Bianco:

The Office for Human Research Protections (OHRP) has reviewed the July 14, 2005 report submitted by the University of Minnesota (UM) in response to OHRP's May 31, 2005 letter regarding allegations of noncompliance with Department of Health and Human Services (HHS) regulations at 45 CFR part 46.

After reviewing the UM report and discussing the case at a meeting on July 18, 2005, OHRP makes the following determinations:

(1) OHRP finds that the informed consent document for the above-referenced research failed to include an adequate description of the risks associated with increased surgical time and postoperative complications, as required by HHS regulations at 45 CFR 46.116(a)(2).

Corrective Actions: OHRP notes that UM has made a number of corrective actions as part of its investigation. These corrective actions include: (i) Provision of training to the

investigator's staff on the screening of subjects and documentation of consent; (ii) an assurance that risk information in consent documents will be improved; and (iii) the Department of Gynecologic Oncology's continuing development of requirements for training, audits, and procedures needed to ensure the appropriate conduct of research. OHRP finds that these corrective actions adequately address this determination and are appropriate under the UM FWA.

(2) OHRP notes the following:

(a) It was alleged that the investigators enrolled a subject in the above-referenced research without obtaining the legally effective informed consent of the subject, as required under HHS regulations at 45 CFR 46.116.

(b) It was alleged that the investigators failed to ensure that risks to subjects were minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, as required by HHS regulations at 45 CFR 46.111(a)(1).

(c) It was alleged that the investigators failed to document informed consent by using a written consent form approved by the institutional review board (IRB) and signed by the subject or the subject's legally authorized representative, as required by HHS regulations at 45 CFR 46.117.

(d) The complaint to OHRP indicated that (i) the complainant's medical records included a copy of an informed consent document that indicated she had verbally agreed to the research, along with postsurgical notations appearing to indicate that she was a subject in the research; (ii) the complainant never agreed to enroll in the above-referenced research; (iii) the complainant received a sartorius transposition procedure after lymph node dissection even though she had previously declined to have such procedures; and (iv) the complainant suffered permanent femoral nerve damage as a result of the sartorius transposition after lymph node dissection.

(e) The response to these allegations from UM indicated that (i) the complainant received the lymph node dissection and sartorius transposition procedures as part of clinical care; (ii) the complainant was never enrolled in the above-referenced research; (iii) an audit of the research revealed no data relating to the complainant; and (iv) the presence of an informed consent document and other postsurgical notations in the complainant's medical records were errors by department staff who had assumed the complainant was enrolled in the study.

OHRP is unable to make a determination regarding the allegations noted in items (2)(a), (b), and (c).

(3) OHRP raised an additional concern that the investigators failed to seek consent under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence, as required by HHS regulations at 45 CFR 46.116. OHRP finds that this concern was not substantiated.

As a result of the above determinations, there should be no need for further involvement of OHRP 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,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Moira Keane, Human Protections Administrator, UM
Ms. Bonnie LeRoy, Chair, UM IRB #1
Dr. David Guay, Chair, UM IRB #2
Dr. Michael Miner, Chair, UM IRB #3
Dr. Sarah Jane Schwartzenberg, Chair, UM IRB #4
Dr. David Adson, Chair, UM IRB #5
Dr. Susan Berry, Chair, UM IRB #6
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