DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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David McLaughlin, Ph.D.
Provost
Office of the Provost
New York University
Bobst, 70 Washington Square South, 1213C
New York, NY 10012

Robert M. Glickman, M.D.
Dean
New York University School of Medicine
550 First Avenue
New York City, NY 10016

RE: Human Research Subject Protections Under Federalwide Assurance (FWA)-4952

Research Project:	**Quantitative MR Imaging and 1H-MRS in Traumatic Brain Injury**
Principal Investigator:	**Robert I. Grossman, M.D.**
Project Number:	**H#: 9875-03A**

Dear Dr. McLaughlin and Dr. Glickman,

The Office for Human Research Protections (OHRP) has reviewed the October 18, 2007 report of the New York University School of Medicine (NYU) in response to OHRP's September 7, 2007 letter 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 research.

After reviewing your report, OHRP makes the following additional determinations:

(1) HHS regulations at 45 CFR 46.116(a)(2) require that prospective subjects be given a description of any reasonably foreseeable risks and discomforts. OHRP finds that the IRB-approved informed consent document does not include any of the risks or

discomforts associated with neuropsychological testing, particularly for subjects with traumatic brain injury.

Corrective Action: OHRP acknowledges that new procedures have been initiated to further ensure that all potential risks and discomforts are properly documented in informed consent documents reviewed by the NYUSOM institutional review boards (IRBs). These include: placing additional representatives on the IRB who have expertise with vulnerable populations; IRB members will receive additional training as part of a newly implemented human research protection program; NYU has incorporated revised protocol reviewer checklists in its review process; training for all staff associated with Dr. Grossman's research team will include implementation of standard operating procedures for obtaining consent, release of study reports, and other areas; Dr. Grossman's staff will also include progress notes for each study visit or phone call and the study coordinator will review each page of the consent document to ensure compliance and completion, and that all appropriate signatures have been documented.

Required Action: By January 25, 2008 please provide OHRP with a revised informed consent document for this study that includes the risks of neuropsychological testing.

(2) It was alleged that MRI and neurocognitive results from the complainant's participation in the above referenced research were not sent to her physicians as stipulated in the informed consent document and further promised in correspondence dated March 4, 2004, in contravention of HHS regulation at 45 CFR 46.103(b)(4)(iii). OHRP acknowledges that copies of all neurocognitive tests along with imaging scans were forwarded to the subject on April 2, 2007 and the same records were hand-delivered to those physicians referenced by the subject in the informed consent document dated May 3, 2003. On October 15, 2007 these records were delivered to the physician the subject referenced in the informed consent document dated December 11, 2003.

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: Mr. Elan Czeisler, Director, Institutional Review Board, NYU
Dr. Thomas J. Blanck, IRB Chair, NYU

Dr. Robert I. Grossman, NYU
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