



Office for Human Research Protections
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March 5, 2008

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

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

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

Dear Dr. McLaughlin and Dr. Glickman,

Thank you for your October 18, 2007 report in response to our December 20, 2007 letter regarding determinations 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.

In our December 20, 2007 letter, we made the following determination:

HHS regulations at 45 CFR 46.116(a)(2) require that prospective subjects be given a description of any reasonably foreseeable risks and discomforts. We determined that the institutional review board- (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. We acknowledged the corrective actions taken by New York University and requested a copy of a revised informed consent document for this study that includes the risks of neuropsychological testing.

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We have reviewed the revised informed consent document for this study, and find that the corrective actions taken by your institution adequately address the determination in our December 20, 2007 letter. As a result, we anticipate no further involvement in this matter.

Please note that Dr. Robert M. Glickman is still listed as the signatory official on FWA-4952. Please update the FWA if this is in error.

We appreciate 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. Borrer, 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