DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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January 29, 2003

Robert O. Webster, Ph.D.
Associate Provost for Research Administration
Saint Louis University Health Sciences Center
3556 Caroline Street
Room 301
Saint Louis, MO 63104

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1119

Research Projects Involving Neuroimaging in Epilepsy

Dear Dr. Webster:

The Office for Human Research Protections (OHRP) has reviewed Saint Louis University's (SLU) letter dated August 30, 2002 that was submitted in response to OHRP's July 29, 2002 letter. OHRP has determined that the corrective actions summarized below appropriately address the following finding by OHRP:

> Department of Health and Human Services (HHS) regulations at 45 CFR 46.116(d) require that the Institutional Review Board (IRB) find and document four specific criteria when approving waiver or alteration of some or all of the elements of informed consent. Regarding IRB protocols #10520 and 10523, OHRP finds that the SLU IRB failed to document the required findings under this regulation.
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> **Corrective action:** OHRP finds that SLU has developed and implemented satisfactory corrective action plans to ensure that the IRB documents the findings required under HHS regulations at 45 CFR 46. 116(d). Specifically, the SLU IRB will now require that its principal investigators address in writing the specific reasons for requesting a waiver or alteration in the elements of informed consent, that this information be reviewed by the convened IRB, and the protocol-specific findings be documented in the IRB minutes. OHRP finds that these corrective actions satisfactorily address the above finding and are appropriate under SLU's MPA.

In addition, OHRP finds that SLU has adequately addressed the remaining questions and concerns regarding the above-referenced research outlined in OHRP's July 29, 2002 letter.

As a result, there should be no need for further involvement of OHRP in this matter. OHRP appreciates the continued commitment of SLU to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Leslie K. Ball, M.D.
Division of Compliance Oversight

cc: Mr. Jesse A. Goldner, Chair, IRB, SLU
Ms. Jamie Nehrt, Director, IRB, SLU
Commissioner, FDA
Dr. David Lepay, FDA
Mr. Neil Ogden, FDA
Mr. Yung Pak, FDA
Dr. Melody H. Lin, OHRP
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