DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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May 2, 2007

Winfred M. Phillips, DSc
Vice President
University of Florida
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PO Box 115500
Gainesville, FL 32611-5500

Thomas Sutton
Acting Director
Director's Office (00),
Malcom Randall VA Medical Center
1601 SW Archer Rd
Gainesville, FL 32608-1197

RE: Human Research Subject Protections Under Federalwide Assurances FWA- 5790 & 2606
Research Project: Dynamical Studies in Frontal and Temporal Lobe Epilepsy
Principal Investigator: J.Chris Sackellares, M.D.
Project Numbers: U Florida IRB #447-93; VA IRB #232-95

Dear Dr. Phillips and Mr. Sutton:

The Office for Human Research Protections (OHRP) has reviewed your May 5, 2006 report evaluating allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46) pertaining to the above-referenced research.

OHRP makes the following determinations regarding the above-referenced research:

(1) HHS regulations at 45 CFR 45.116 state that, except as provided elsewhere in the regulations, no investigator may involve a human being as a subject in research covered by the regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. OHRP finds that the principal investigator initiated human subject research without meeting this requirement. The principal investigator stored in his research laboratory at the University of Florida's (UF) McKnight Brain Institute electroencephalogram

(EEG) recordings for at least 174 patients with temporal lobe epilepsy selected by a co-investigator who obtained the EEG recordings during pre-surgical diagnosis at UF's Shands Hospital. The co-investigator subsequently obtained informed consent from 57 of the 174 patients whose EEG signals were recorded. OHRP acknowledges the UF institutional review board's (IRB's) finding that outdated consent documents were erroneously used to obtain consent for some research subjects.

In addition to storing EEG recordings in his laboratory, the principal investigator stored patient lists (dated April 27, 1999; October 1, 1999; and September 18, 2001) which included identifiable private information such as names, birth dates, hospital admission dates, patient identification numbers, and medical record numbers.

(2) HHS regulations at 45 CFR 46.103(b)(4)(iii) require that the IRB review and approve all proposed changes in a research activity, during the period for which IRB approval has already been given, prior to initiation of such changes, except when necessary to eliminate apparent immediate hazards to the subjects. The protocols approved by the UF IRB for the above-referenced research took the following measures to protect the confidentiality of private medical information:

a) During the research, data will be available only to the investigators and will be stored in a locked office.

b) After completion of the research, databases and published reports will not identify patients by name.

OHRP acknowledges that UF's University Privacy Office found that an external hard drive containing identifiable research subject data pertaining to the above-referenced protocols was sent to a private company on March 17, 2006. At that time, the principal investigator was a consultant for, and held stock in, the private company. OHRP further acknowledges that the IRB expressly notified the principal investigator and other members of his research team that the release of any information obtained in the above-referenced research, including EEG data or video recordings, required prior IRB review and approval.

OHRP finds that the transfer of identifiable research data on or around March 17, 2006, constituted a change in research activity without prior IRB approval, as required by 45 CFR 46.103(b)(4)(iii).

Corrective Action: In April 2005, the principal investigator underwent training in human subject protection and the Health Insurance Portability and Accountability Act. In April 2006, UF placed the principal investigator on administrative leave, suspended all of his active research protocols, and informed him not to conduct any

research activities until the suspension was lifted. OHRP finds that these corrective actions adequately address findings (1) and (2) above and are appropriate under the UF FWA.

(3) OHRP finds that informed consent documents reviewed and approved by the IRB between November, 1993 and May, 2000 for the above-referenced protocols inaccurately described the foreseeable risks and discomforts of the research, as required by HHS regulations at 45 CFR 46.116(a)(2). Specifically, the consent form stated that "[p]articipation in this study will not subject you to any risks or discomfort." OHRP finds that the consent form should have included a discussion of the confidentiality risks associated with the transfer and use of private identifiable medical information in the research.

(4) Under HHS regulations at 45 CFR 46.103(a) and 46.103(b)(5), any suspensions or terminations of IRB approval, including suspensions of enrollment in approved research, must be reported to OHRP. OHRP finds no evidence that the UF IRB reported to OHRP that on May 2, 2002, it suspended enrollment in the above research due to concerns about the accuracy of continuing review information filed on April 1, 2002. OHRP has no record that the UF IRB reported to OHRP that on April 5, 2006, the IRB suspended all active protocols of the principal investigator.

Required Action: Please submit to OHRP no later than May 18, 2007, a corrective action plan to address the findings in paragraphs (3) and (4) above, including any noncompliance identified with respect to the reporting of the IRB's April 5, 2006 suspensions.

OHRP appreciates your continued commitment to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Carol J. Weil, J.D.
Compliance Oversight Coordinator
Office for Human Research Protections

cc: Mr. Robert B. Vomacka, Human Protections Administrator, University of Florida
Dr. R. Peter Iafrate, IRB Chair, University of Florida IRB #1
Dr. Ira S. Fischler, IRB Chair, University of Florida IRB #2
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Dr. J.Chris Sackellares, Principal investigator for relevant research
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