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 30, 2007

Winfred M. Phillips, D.Sc.
Vice President
University of Florida
223 Grinter Hall
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. Malphurs:

The Office for Human Research Protections (OHRP) has reviewed your institutions' May 16, 2007 correspondence responding to OHRP's May 2, 2007 determination letter regarding the above-referenced research. Based upon its review, OHRP finds that the corrective actions described below adequately address the findings in paragraphs (3) and (4) of OHRP's May 2, 2007 determination letter. As the findings set forth in paragraphs (1) and (2) of OHRP's May 2 letter were adequately addressed in your prior report dated May 5, 2006, there should be no need for further OHRP involvement in this matter. However, you should notify OHRP if you subsequently uncover any additional relevant information.

(1) OHRP found that informed consent documents reviewed and approved by the University of Florida (UF) institutional review board (IRB) between November, 1993

and May, 2000 for the above-referenced protocols inaccurately described the foreseeable risks and discomforts of the research, in contravention of the requirements of 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 found 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.

Corrective Action: OHRP acknowledges the UF's statement that its current informed consent form template includes language informing subjects of the risk that collected information could be revealed inappropriately or accidentally, causing embarrassment or affecting insurability or employability. OHRP notes that the above-referenced research study was closed to enrollment of new subjects in 2001.

(2) 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 found no evidence that the UF IRB's May 2, 2002 suspension of enrollment in the above-referenced research was reported to OHRP. OHRP has no record of receiving a report that on April 5, 2006, the UF IRB suspended all active protocols of the principal investigator, and on April 12, 2006, all of his studies regardless of status.

Corrective Action: UF's current Policy and Procedure Manual for IRB-01 includes a definition of reportable suspensions that includes: "[a]n action taken by the IRB Chair, Vice Chair, convened IRB, or Institutional Official or his representatives to temporarily stop some or all previously approved research activities (recruitment, enrollment, or specific procedures) typically taken "for cause." OHRP notes UF's statement that all suspensions issued by the IRB, the University and/or the North Florida/South Georgia Veterans Health System are promptly reported by the appropriate institutional official. OHRP further notes that UF drafted but never sent a notice to OHRP reporting its suspensions of the principal investigator's active protocols. UF received OHRP's April 3, 2006 inquiry letter concerning the above-referenced research before the suspension notice drafted to OHRP was mailed, and opted to include the suspension information in its response to that letter on May 5, 2006.

OHRP appreciates your continued commitment to the protection of human research subjects. Feel free 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
Dr. Ana M. Alvarez, IRB Chair, University of Florida IRB #3
Dr. Charles S. Wingo, Associate Chief of Staff/Research, Malcom Randall VA Medical Center (VAMC)
Dr. J.Chris Sackellares, Principal investigator for relevant research
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Tom Puglisi, ORO, Department of Veterans Affairs
Dr. David J. Miller, Southern Regional Office, VAMC Atlanta
Dr. Sam Shekar, Office of Extramural Research, NIH
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Ms. Shirley Hicks, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms. Pat El-Hinnawy, OHRP
Ms. Carla Brown, OHRP