DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852

Telephone: 301-435-8072
FAX: 301-402-2071
E-mail:kborror@osophs.dhhs.gov

October 1, 2003

William W. Pinsky, M.D.
Executive Vice President for Academic Affairs
and Chief Academic Officer
Ochsner Clinic Foundation
1514 Jefferson Highway
New Orleans, LA 70121

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1046 and Federalwide Assurance FWA-2050

Research Project: Prospective, Randomized, Multi-Center Trial of Pulmonary Artery Catheter (PAC) vs. Central Venous Catheter (CVC) for Management of Acute Lung Injury (ALI) and Acute Respiratory Distress Syndrome (ARDS) and Prospective, Randomized, Multi-Center Trial of 'Fluid Conservative' vs. 'Fluid Liberal' Management of Acute Lung Injury (ALI) and Acute Respiratory Distress Syndrome (ARDS) (FACTT Trial)
Principal Investigator: David E. Taylor, M.D.

Dear Dr. Pinsky:

The Office for Human Research Protections (OHRP) has reviewed Ochsner Clinic Foundation's (OCF) August 25, 2003 report responding to determinations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human subjects involving the above-referenced research.

Based upon its review, OHRP finds that OCF has implemented the required actions stipulated by OHRP's July 25, 2003 letter. In particular, OHRP acknowledges the following:

(1) The OCF does not intend to restart its participation in the FACTT trial. If OCF were to resume participation, your institution would undertake the steps outlined in OHRP's July 25, 2003 letter.

(2) OCF has implemented a variety of procedures to help ensure that the OCF Institutional Review Boards (IRBs) (a) receive sufficient information to make all determinations required under HHS regulations at 45 CFR 46.111; and (b) approve an informed consent process that satisfies all requirements of HHS regulations at 45 CFR 46.116. These procedures include addressing the criteria for IRB approval of research in the IRB Written Procedures; inclusion of information pertinent to HHS regulations at 45 CFR 46.111 and 45 CFR 46.116 in the instructions to investigators in the IRB Written Procedures and in the Clinical Research Handbook; a template informed consent document that solicits all the elements of informed consent under HHS regulations at 45 CFR 46.116; and development of an IRB protocol review standard which addresses all the criteria for IRB review and approval of research under HHS regulations at 45 CFR 46.111.

OHRP finds that the above corrective actions adequately address OHRP's findings and are appropriate under the OCF FWA. As a result, OHRP anticipates no need for further involvement with OCF related to this matter.

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

Sincerely,

Kristina Borror, Ph.D.
Director
Division of Compliance Oversight

Michael A. Carome, M.D.
Associate Director for Regulatory Affairs
Office for Human Research Protections

cc: Dr. Richard Re, Vice President and Director of Research, OCF
Dr. Joseph Breault, Chair, IRB, OCF
Dr. David E. Taylor, M.D., Principal Investigator, FACTT trial, OCF
Dr. Angela Bowen, President, Western Institutional Review Board
Dr. B. Taylor Thompson, ARDS Network Coordinating Center Principal Investigator, Massachusetts General Hospital
Dr. Arthur Wheeler, FACTT Trial Committee Chair, Vanderbilt University
Dr. Gordon R. Bernard, Chairman, ARDS Steering Committee, Vanderbilt University
Dr. Herbert P. Wiedemann, FACTT Trial Committee Chair, Cleveland Clinic Foundation
Dr. James Kiley, Director, Division of Lung Diseases, NHLBI
Dr. Lana Skirboll, Director, Office of Science Policy, NIH
Dr. David Lepay, Director, Good Clinical Practices Program, FDA
Ms. Melinda Hill, OHRP
Ms. Patricia El-Hinnawy, OHRP