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 20, 2004

Mary Ellen Sheridan, Ph.D.
Associate Vice President for Research
The University of Chicago
University Research Administration
970 East 58th Street
Chicago, Illinois 60637

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1264

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: Gregory Schmidt, M.D.

Dear Dr. Sheridan:

The Office for Human Research Protections (OHRP) has reviewed the University of Chicago's (UC) September 29, 2003 and January 6, 2004 reports 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 the UC has implemented the required actions stipulated by OHRP's July 25, 2003 letter. In particular, OHRP acknowledges the following:

(1) The UC Institutional Review Board (IRB) received the additional supplemental information and the revised model informed consent document for the FACTT trial, and has subsequently re-reviewed and approved the research.

(2) UC has provided OHRP with a copy of the final version of the IRB-approved informed consent document.

(3) UC has implemented a variety of procedures including listing the criteria for IRB approval in the UC Biological Sciences Division/UC Hospitals (BSD/UCH) IRB Member's Handbook, the BSD/UCH investigator Protocol Submission Form, the BSD/UCH IRB Policies and Procedures Manual, the Social and Behavioral Science (SBS) IRB and Investigator Manual, the SBS IRB New Protocol Submission Form, SBS IRB Member Review Guides, the School of Social Service Administration IRB Policies and Procedures, and the BSD/UCH IRB Analysis Sheet to help ensure that the UC IRBs receive sufficient information to make all determinations required under HHS regulations at 45 CFR 46.111. The UC IRBs also list the required elements of informed consent in the BSD/UCH IRB Member's Handbook, in the SBS IRB and Investigator Manual, and in the BSD/UCH IRB Policies and Procedures Manual, utilize Consent Form Checklists and have developed a template informed consent document to help ensure that the UC IRBs approve an informed consent process that satisfies all requirements of HHS regulations at 45 CFR 46.116.

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

OHRP appreciates the commitment of UC to the protection of human subjects. 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. Jonathan Moss, Chair, IRB-01, UC
Dr. Tina Rzepnicki, Chair, IRB-02, UC
Dr. Bennett Bertenthal, Chair, IRB-03, UC
Dr. Gregory Schmidt, Principal Investigator, FACTT Trial, UC
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