DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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February 13, 2004

Dr. Francisco G. Cigarroa
President
University of Texas Health Science Center
at San Antonio
Office of the President - MSC 7834
7703 Floyd Curl Drive
San Antonio, TX 78229-3900

RE: Human Research Subject Protections Under Multiple Project Assurances (MPA) M-1403 and Federalwide Assurance FWA-5928

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: Dr. Antonio Anzueto

Dear Dr. Cigarroa:

The Office for Human Research Protections (OHRP) has reviewed University of Texas Health Science Center at San Antonio's (UTHSC) September 3, 2003 and January 29, 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 UTHSC has implemented the required actions stipulated by OHRP's July 25, 2003 letter. In particular, OHRP acknowledges the following:

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

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

(3) UTHSC has implemented a variety of procedures including describing the criteria for IRB approval, and the IRB approval procedures, and adding a form and instructions on Preparing an Application for IRB Review, in the UTHSC Investigator's Handbook to help ensure that the UTHSC IRB receives sufficient information to make all determinations required under HHS regulations at 45 CFR 46.111. In addition, the UTHSC Investigator's Handbook outlines the required elements of informed consent, includes a sample informed consent document and a checklist for informed consent which help to ensure that the UTHSC IRB approves 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 UTHSC MPA. As a result, OHRP anticipates no need for further involvement with UTHSC 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. Wayne Pierson, Director, IRB, UTHSC
Dr. Deborah, Conway, Chair, IRB, UTHSC
Dr. Antonio Anzueto, Principal Investigator, FACTT trial, UTHSC
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