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: 301-402-5567
FAX: 301-402-2071
E-mail: mcarome@osophs.dhhs.gov

January 6, 2004

John A. Guest
President and Chief Executive Officer
Harris County Hospital District
2525 Holly Hall
Houston, Texas 77054

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 369

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: Kalpalatha K. Guntupalli, M.D.

Dear Mr. Guest:

The Office for Human Research Protections (OHRP) has reviewed Harris County Hospital District's (HCHD) August 28 and November 17, 2003 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 HCHD has implemented the required actions stipulated by OHRP's July 25, 2003 letter. In particular, OHRP acknowledges the following:

(1) The Baylor College of Medicine (Baylor) 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) HCHD has provided OHRP with a copy of the final version of the IRB-approved informed consent document.

(3) Baylor has implemented a variety of procedures including a standardized checklist for IRB staff members to utilize in pre-review of protocol applications as well as an IRB Board member Checklist to help ensure that the Baylor IRB receives sufficient information to make all determinations required under HHS regulations at 45 CFR 46.111. In addition, the Baylor IRB standardized checklist for pre-review of protocol applications, planned redesign of the sample informed consent document, and implementation of education programs for IRB members and investigators help ensure that the Baylor IRB approves an informed consent process that satisfies all requirements of HHS regulations at 45 CFR 46.116. OHRP recommends that the pre-review and IRB checklists be revised to explicitly include all the required elements of informed consent as outlined in HHS regulations at 45 CFR 46.116.

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

OHRP appreciates the commitment of HCHD 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. Kathleen J. Motil, Chair, IRB, Baylor College of Medicine
Dr. Kalpalatha K. Guntupalli, Principal Investigator, FACTT Trial, HCHD
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