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 28, 2004

James T. Montgomery
Chief Executive Officer
Tulane University Hospital
1415 Tulane Ave (HC25)
New Orleans, LA 70112

RE: Human Research Subject Protections Under Federalwide Assurance FWA-2056

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: Kevin Kovitz, M.D.

Dear Mr. Montgomery:

The Office for Human Research Protections (OHRP) has reviewed Tulane University's (TU) November 20, 2003 and January 20, 2004 reports that were submitted in response to determinations of noncompliance with the Department of Health and Human Services (HHS) regulations for protection of human subjects involving the above-referenced research.

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

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

(3) TU has implemented a variety of procedures including listing the criteria for IRB approval of research in the TU Protocol Summary form to help ensure that the TU IRB receives sufficient information to make all determinations required under HHS regulations at 45 CFR 46.111. The TU IRB also lists the required elements of informed consent in the TU Consent Form Format Instructions, in the IRB written Policy and includes an informed consent checklist to help ensure that the TU IRB approves an informed consent process that satisfies all requirements of HHS regulations at 45 CFR 46.116. In addition, the TU IRB has conducted investigator training and has initiated audits by the Compliance/Educator staff member.

OHRP recommends that the TU Protocol Summary form include a statement of how the privacy of subjects will be protected, and the confidentiality of data maintained, to help ensure that the TU IRB receives sufficient information to make all determinations required under HHS regulations at 45 CFR 46.111. In addition, HHS regulations at 45 CFR 46.116 require that the informed consent document include a statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. While the TU Consent Form Format Instructions includes the statement "Study subjects may refuse to participate or to withdraw from the study without jeopardizing, in any way, their medical treatment in this institution," OHRP notes that there could be other penalties or losses of benefits other than a subject's medical treatment at TU.

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

OHRP appreciates the commitment of TU 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: Ms. Ina Friedman, Chair, IRB, TU
Ms. Karen Delery, HPA, TU

Dr. Kevin Kovitz, Principal Investigator, FACTT trial, TU
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