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

November 17, 2003

Ariel Gomez, M.D.
Vice President for Research and Graduate Studies
Office of the Vice President
University of Virginia
314 Madison Hall
P.O. Box 400301
Charlottesville, Virginia 22904-4301

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1343

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: Jonathon D. Truwit, M.D.

Dear Dr. Gomez:

The Office for Human Research Protections (OHRP) has reviewed the University of Virginia's (UVA) August 27 and October 30, 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 UVA has implemented the required actions stipulated by OHRP's July 25, 2003 letter. In particular, OHRP acknowledges the following:

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

(3) UVA has implemented a variety of procedures including a research protocol template and a Primary Reviewer's Protocol and Consent Form Review Checklist to help ensure that the UVA IRBs receive sufficient information to make all determinations required under HHS regulations at 45 CFR 46.111. The UVA IRB also has developed a template informed consent document and Consent Form Review Checklists to help ensure that the UVA 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 UVA MPA. As a result, OHRP anticipates no need for further involvement with UVA related to this matter.

OHRP appreciates the commitment of UVA 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. David Hudson, Associate Vice President for Research, UVA
Dr. Karen J. Schwenzer, Chair, IRB-01, UVA
Dr. Jonathon Truwit, Principal Investigator, FACTT Trial, UVA
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