DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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November 3, 2003

Mark R.Tolosky
Chief Executive Officer
Baystate Medical Center
759 Chestnut Street
Springfield, MA 01107

RE: Human Research Subject Protections Under Federalwide Assurance FWA-4355

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 Investigators: Dr. Steingrub and Dr. Tidswell

Dear Mr. Tolosky:

The Office for Human Research Protections (OHRP) has reviewed Baystate Medical Center's (BMC) September 26 and October 24, 2003 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.

OHRP acknowledges the following:

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

(3) BMC has implemented a variety of procedures including an IRB Reviewer Sheet and education of IRB members and investigators to ensure that the BMC IRBs receive sufficient information to make all determinations required under HHS regulations at 45 CFR 46.111. In addition, the Instructions for Informed Consent, the Informed Consent Form Template, and the IRB Reviewer Sheet help ensure that the BMC IRBs approve an informed consent process that satisfies all requirements of HHS regulations at 45 CFR 46.116. OHRP recommends that the criteria for IRB approval under HHS regulations at 45 CFR 46.111 and the requirements for informed consent under HHS regulations at 45 CFR 46.116 be included in the BMC IRB application.

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

OHRP appreciates the commitment of BMC 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: Warren E. Foote, Ph.D., Chair, IRB, BMC
Dr. Steingrub and Dr. Tidswell, Principal Investigators, FACTT trial, BMC
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