DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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April 15, 2004

Thomas F. Hanrahan
Chief Executive Officer
Intermountain Health Care
McKay-Dee Hospital Center
3939 Harrison Blvd.
Ogden, UT 84403

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 645

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: Alan H. Morris, M.D.

Dear Mr. Hanrahan:

The Office for Human Research Protections (OHRP) has reviewed Intermountain Health Care/Urban North Region's and McKay-Dee Hospital Center's (MDH) September 2, 2003 and April 13, 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 MDH has implemented the required actions stipulated by OHRP's July 25, 2003 letter. In particular, OHRP acknowledges the following:

(1) The MDH 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) MDH has provided OHRP with a copy of the final version of the IRB-approved informed

consent document.

(3) MDH has implemented a variety of procedures including the development of an application for investigators, and a protocol review standard and risk benefit assessment for IRB members to ensure that the protocol contains sufficient information to make the determinations required under HHS regulations at 45 CFR 46.111. To ensure that the informed consent document satisfies all requirements of HHS regulations at 45 CFR 46.116, MDH has developed an informed consent checklist which IRB members use when reviewing informed consent documents.

OHRP finds that the above corrective actions adequately address OHRP's findings and are appropriate under the MDH FWA. As a result, OHRP anticipates no need for further involvement with MDH 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: Mr. Roy C. Nelson, Chair, IRB, MDH
Ms. Shireen Imani, IRB Coordinator, MDH
Dr. Charles Lawton, Principal Investigator, ARMA trial, MDH
Dr. Michael Young, Principal Investigator, FACTT trial, MDH
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