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 30, 2004

Craig J. Hogan, Ph.D.
Vice Provost for Research
Office of Research
Box 351202
University of Washington
G80 Gerberding Hall
Seattle, WA 98195

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1183

Research Project: Prospective, Randomized, Multi-Center Trial of 12 ml/kg vs. 6 ml/kg Tidal Volume Positive Pressure Ventilation for Treatment of Acute Lung Injury and Acute Respiratory Distress Syndrome (ARMA Trial)
Principal Investigator: Kenneth P. Steinberg, M.D.

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: Kenneth P. Steinberg, M.D.

Dear Dr. Hogan:

The Office for Human Research Protections (OHRP) has reviewed the University of Washington's (UW) August 28, 2003 and January 22, 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 (45 CFR Part 46) involving the above-referenced research.

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

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

(3) UW has implemented a variety of procedures including a Human Subjects Review Committee Application to help ensure that the UW IRBs receive sufficient information to make all determinations required under HHS regulations at 45 CFR 46.111. In addition, the UW has developed an informed consent checklist, sample informed consent documents, as well as a chapter on informed consent requirements in the Human Subjects Manual, and has implemented education programs for IRB members and investigators to help ensure that the UW IRBs approve an informed consent process that satisfies all requirements of HHS regulations at 45 CFR 46.116. OHRP recommends that the Human Subjects Review Committee Application include information regarding provision for monitoring the data collected to ensure the safety of subjects and that the Human Subjects Manual explicitly outline the criteria for IRB approval required under HHS regulations at 45 CFR 46.111.

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

OHRP appreciates the commitment of UW 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. Helen McGough, Director, Human Subjects Division, UW
Dr. Zane Brown, Chair, IRB A, UW
Dr. Alan Wilensky, Chair, IRB B, UW
Dr. Patricia Kuszler, Chair, IRB C, UW

Ms. Rebekah Rein, Chair, IRB D, UW
Dr. Nancy Robinson, Chair, IRB G, UW
Dr. Kenneth P. Steinberg, Principal Investigator, FACTT and ARMA trials, UW
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