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 16, 2004

C. Bradley Moore
Vice President for Research
Northwestern University
Rebecca Crown Center
633 Crown St.
Evanston, Illinois 60208-1108

Re: Human Research Subject Protections Under Federalwide Assurance (FWA) 00001549

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: Jane Dematte D'Amico, M.D.

Dear Mr. Moore:

The Office for Human Research Protections (OHRP) has reviewed Northwestern University's (Northwestern's) September 5, 2003 and March 23, 2004 letters 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 Northwestern has implemented the required actions stipulated by OHRP's July 25, 2003 letter. In particular, OHRP acknowledges the following:

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

informed consent document.

(3) Northwestern has implemented a variety of procedures including development of project submission forms and an IRB Reviewer Analysis Sheet to help ensure that the Northwestern IRBs receive sufficient information to make all determinations required under HHS regulations at 45 CFR 46.111. In addition, the IRB Reviewer Analysis Sheet includes a checklist for informed consent which helps to ensure that the Northwestern IRBs approve an informed consent process that satisfies all requirements of HHS regulations at 45 CFR 46.116. OHRP recommends that (a) the project submission forms include the required elements of informed consent, as well as soliciting information regarding provision for monitoring the data collected to ensure the safety of subjects; and (b) IRB Reviewer Analysis Sheet include information regarding provision for monitoring the data collected to ensure the safety of subjects and information regarding provisions to protect the privacy of subjects and maintain the confidentiality of data.

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

OHRP appreciates the commitment of Northwestern University 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 Johnson, Associate Vice President for Research, Northwestern
Dr. Lewis J. Smith, Exec Dir, OPRS, Northwestern
Dr. Darren Gitelman, Chair, IRB #1, Northwestern
Dr. Dennis West, Chair, IRB #2, Northwestern
Dr. Jonathan Goldman, Chair, IRB #3, Northwestern
Dr. Bruce Sherin, Chair, IRB #4XM, Northwestern
Dr. Frank Palella, Chair, IRB #5, Northwestern
Dr. Jane Dematte D'Amico, Principal Investigator, FACTT trial, Northwestern
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