DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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February 14, 2008

Daniel E. Ford, MD, MPH
Vice Dean for Clinical Investigation
John Hopkins University School of Medicine
733 N. Broadway
Rm#115
Baltimore, MD 21205

Janet A. DiPietro, Ph.D.
Institutional Official
Johns Hopkins Bloomberg School of Public Health
615 N. Wolfe Street
Suite E1100
Baltimore, MD 21205

Eaton E. Lattman, Ph.D.
Dean for Research
Johns Hopkins University
Office of the Dean
237 Mergenthaler Hall
Baltimore, MD 21218

RE: Human Subject Research Protections Under Federalwide Assurances FWA-5752, FWA-287, and FWA-3834

Research Publication: Peter Pronovost, Dale Needham, Sean Berenholtz, David Sinopoli, Haitao Chu, Sara Cosgrove, Bryan Sexton, et. al. An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU. New England Journal of Medicine 2006; 355: 2725-2732.

Dear Drs. Ford, DiPietro, and Lattman:

Thank you for your December 17, 2007 and January 25, 2008 letters responding to our November 6, 2007, 2007 letter containing determinations of non-compliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46). OHRP greatly appreciates your cooperation in resolving the issues related to this matter.

We acknowledge that in September of 2005 the AHRQ funding for the initial phase of Initiative concluded and no federal funds, directly or indirectly, support JHU's continuing collection of data from the Michigan hospitals.

The corrective actions noted below adequately address the determinations made in our November 6, 2007 letter:

(1) We acknowledge your statement that you understand that any recipient of HHS funds, who will be engaged in human subjects research, including a JHU subcontractor or sub-awardee, must comply with HHS regulations that require a FWA. We appreciate your assurance that this requirement will be met for any future proposed federally funded human subjects research activities.

(2) We note that the Initiative activities have evolved considerably since the inception of the project. In your January 25, 2008 letter, you stated that the interventions that were studied as part of the original project have now been proven to be efficacious in improving care provided in intensive care units. Hospitals in Michigan are not conducting research directed by JHU, and any use of care algorithms or checklists at the hospitals is proceeding for clinical reasons only. Hospitals that have chosen to implement care changes for clinical reasons are collecting data from the intensive care units for internal hospital purposes. We note the interventions are being implemented solely for clinical care purposes and the only data released by hospitals in Michigan to JHU for research purposes are de-identified data that are collected for clinical purposes, and we agree that the project has now evolved to a stage where JHU is no longer engaged in human subjects research related to this project.

(3) We acknowledge your statements that the principal investigator has been asked to submit an application for IRB review to assure that the description of the proposed activity was clear to all involved. IRB approval was granted on 1/4/2008. However, as noted above, the activities no longer involve human subjects research. Therefore, it is not a regulatory requirement for you to obtain IRB review and approval for these activities before continuing with data analysis. We note that you wish to go above and beyond the regulatory requirements in this case.

Because the corrective actions taken adequately address the determinations, we anticipate no further involvement by us regarding this matter.

At this time, we offer the following additional observations:

(4) We note that the human subjects research activities described in the initial grant and IRB applications, as well as similar activities, would likely have been eligible for review by the IRB in an expedited manner.

(5) We note that the human subjects research activities described in the initial grant and IRB applications, as well as similar activities, would likely have been eligible for waiver of informed consent.

We appreciate the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Kristina C. Borror, Ph.D.
Director
Division of Compliance Oversight

cc:

Ms. Barbara L. Starklauf, Assistant Dean for Human Subjects Research Compliance, JHU School of Medicine
Dr. Howard M. Lederman, IRB Chairperson/Professor, Pediatrics & Medicine, John Hopkins Hospital
Dr. Gary Briefel, Chairperson IRB #5/Assoc. Professor, Department of Medicine Nephrology, Johns Hopkins Bayview Medical Center
Dr. David R. Cornblath, IRB Chairperson/Professor, Neurology, Johns Hopkins Hospital
Dr. Richard Moore, Chairperson JHM IRB #3/Professor Department of Medicine, JHU School of Medicine
Ms. Laura E. Rocco, IRB Chairperson/Research Associate, Department of Clinical Pharmacology, The Johns Hopkins Hospital
Ms. Patricia M. German, Director, Research Subjects, Johns Hopkins School of Hygiene and Public Health
Dr. Ronald Gray, IRB Chair, IRB #1, Johns Hopkins Bloomberg School of Public Health
Dr. Jonathan Links, Chair, IRB #2, Johns Hopkins Bloomberg School of Public Health
Dr. Michael E. McCloskey, Professor, JHU
Dr. Peter Pronovost, JHU School of Medicine

Ms. Marlene Hulteen, Michigan Health & Hospital Association
Dr. Francis Chesley, Agency for Healthcare Research and Quality