DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852

Telephone: 240-453-8132
FAX: 240-453-6909
E-mail: kristina.borror@hhs.gov

February 14, 2008

Brian Peters
Executive Director
Health Foundation
Michigan Health & Hospital Association
6215 W. St. Joseph Highway
Lansing, MI 48917

RE: Human Subjects Research Protections

Research Project: Keystone: ICU, Accelerating Patient Safety in Michigan
Principal Investigator: Christine A. Goeschel

Dear Mr. Peters:

Thank you for your December 14, 2007 and January 18, 2008 letters responding to our November 6, 2007 letter containing determinations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) involving the above-referenced research. We greatly appreciate 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 the continuation of the Initiative in the Keystone hospitals.

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

(1) We acknowledge your statement that the Michigan Health & Hospital Association (MHA) and the Keystone Hospitals are committed to take all necessary steps to rectify the unintentional error of classifying the initial phase of the Initiative as quality as opposed to human subjects research and will work diligently to ensure such an error does not reoccur.

(2) We note that the Initiative activities have evolved considerably since the inception of the project. In your January 18, 2008 letter, you stated that certain Initiative activities, including the implementation of the evidence-based care bundles for prevention of central line associated blood stream infections and ventilator associated pneumonia and the "Comprehensive Unit-Based Safety Program" have become the standard of practice at the Michigan hospitals. We note the interventions are being implemented solely for clinical care purposes and the only data released to Johns Hopkins University 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 the Michigan hospitals are no longer engaged in human subjects research.

(3) We acknowledge your statements that the Keystone hospitals have been notified that Initiative activities (data collection and the conduct of surveys) are not to be resumed until IRB approval is gained and informed consent is obtained from participants (unless the IRB waives such a requirement). However, as noted above, the activities no longer involve human subjects research. Therefore, it is not a regulatory requirement for the Michigan hospitals to obtain IRB review and approval before continuing with data collection or release of that data to Johns Hopkins University, nor is it necessary for the Michigan hospitals to obtain FWAs, unless they are involved in other HHS-supported human subjects research. If you still wish that IRB review and approval be obtained before continuing these activities, we note your desire 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:

Dr. Daniel E. Ford, MD, John Hopkins University School of Medicine
Dr. Janet A. DiPietro, Johns Hopkins Bloomberg School of Public Health
Dr. Eaton E. Lattman, Ph.D., Johns Hopkins University
Ms. Christine A. Goeschel, Michigan Health & Hospital Association
Dr. Francis Chesley, Agency for Healthcare Research and Quality