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

September 2, 2010

Ellen K. Feder, Ph.D.
Associate Professor and Acting Chair
Department of Philosophy and Religion
American University
4400 Massachusetts Ave., NW
Washington, DC 20018-8056
feeder@american.edu

Alice Dreger, Ph.D.
Professor of Clinical Medical Humanities and Bioethics
Feinberg School of Medicine
Northwestern University
a-dreger@northwestern.edu

Dear Drs. Feder and Dreger:

The Office for Human Research Protections (OHRP) has received your February 3, 2010, and May 17, 2010 letters concerning activities conducted by Dr. Maria New at Weill Cornell Medical College (WCMC) and Mount Sinai School of Medicine (MSSM).

OHRP has responsibility for oversight of compliance with the Health and Human Services (HHS) regulations for the protection of human research subjects (see 45 CFR Part 46 at http://www.dhhs.gov/ohrp/humansubjects/guidance/45cfr46.htm). In carrying out this responsibility, OHRP evaluates, at it's discretion, substantive allegations of noncompliance involving human subject research projects conducted or supported by HHS or that are otherwise subject to the regulations (see OHRP memorandum dated October 14, 2009 at http://www.hhs.gov/ohrp/compliance/ohrpcomp.pdf for an explanation of OHRP's jurisdiction).

In evaluating these allegations, OHRP first received reports from WCMC and MSSM. We then sent them several requests for additional information, which we reviewed thoroughly, including the research protocols and informed consent documents, and publications resulting from the research. We also had numerous discussions with staff at the U.S. Food and Drug Administration (FDA).

Dr. New conducted 3 studies while employed at WCMC involving provision of dexamethasone to pregnant women at risk of carrying a female fetus with CAH. The studies were reviewed and

approved by the WCMC Institutional Review Board (IRB). Written informed consent (which included disclosure of risks) was obtained from subjects for participation in these studies. We find nothing inappropriate in either the IRB approval or conduct of these studies. From the information we reviewed, there appears to be no evidence that Dr. New engaged in clinical use of dexamethasone outside of research while at WCMC.

Since her arrival at MSSM in 2004, Dr. New has conducted one study related to the use of dexamethasone in pregnant women at risk of carrying a female fetus with CAH that enrolled human subjects. This project, which was initially reviewed by a MSSM IRB in 2004, involved cognitive testing and outcomes follow-up on patients who either had or had not been treated with dexamethasone during the prenatal period. According to the protocol, the decision as to whether a pregnant woman was treated or not treated was not part of the study. We find nothing justifying a conclusion that the actions of the clinicians in treating those women should have been considered part of a clinical trial and subjected to IRB review. Dr. New was not the physician at MSSM for any of the cases included in her study. During Dr. New's tenure at MSSM, she prescribed dexamethasone for only one pregnant woman who had already been diagnosed with CAH. In this case, the treatment was not designed to prevent ambiguous genitalia in the fetus, but to continue needed treatment for the CAH-affected mother.

As a result, OHRP determines that your allegations are unproven. We are attaching a memo from the FDA summarizing their evaluation of the matter.

OHRP appreciates your concern about the protection of human research subjects.

Sincerely,

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