



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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Ellen K. Feder, Ph.D.
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4400 Massachusetts Ave., NW
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Anne Tamar-Mattis, J.D.
Executive Director
Advocates for Informed Choice
PO Box 676
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Dear Dr. Feder and Ms. Tamar-Mattis:

The Office for Human Research Protections (OHRP) has received your February 3, 11, and 22, 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 its 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).

OHRP received preliminary reports on this matter from WCMC and MSSM. We are awaiting follow-up reports from the institutions.

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

Sincerely,

Kristina C. Borrer, Ph.D.

Director

Division of Compliance Oversight