



Office for Human Research Protections
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July 12, 2012

William Mellon, Ph.D.
Associate Dean for Research
University of Wisconsin-Madison
327 Bascom Hall, 500 Lincoln Drive
Madison, WI 53706

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) - 5399

Dear Dr. Mellon:

Thank you for your June 8, 2012 response to our May 8, 2012 questions and concerns letter stemming from the Office for Human Research Protections (OHRPs') not-for-cause evaluation of the University of Wisconsin – Madison (UW-Madison) system for protecting human research subjects. Based on the documentation provided, we make the following determinations:

A. Determinations Regarding UW-Madison's System for Protecting Human Subjects

1. We have determined that UW-Madison does not have written Institutional Review Board (IRB) procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any department or agency head, and OHRP of any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB, as required by Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(a) and 46.103(b)(5). To be specific, we have found that UW-Madison written IRB procedures do not cover the reporting of serious or continuing noncompliance with 45 CFR part 46 involving IRB acts or omissions.

UW-Madison Corrective Actions: UW-Madison acknowledged that the UW-Madison Human Research Protection Program (HRPP) policies did not contain language specific to the reporting of noncompliance by UW-Madison IRBs. As a result, UW-Madison revised its Noncompliance Policy and its Reporting Policy to include provisions on how UW-Madison handles noncompliance by UW-Madison IRBs and by the institution. We have determined that the corrective action noted above adequately addresses our determination and is appropriate under the UW-Madison FWA.

2. We have determined that the UW-Madison IRB approved consent form for H-2007-0249 did not include an explanation of whom to contact for answers to pertinent questions about research subjects' rights, as required by HHS regulations at 45 CFR 46.116(a)(7).

UW-Madison Corrective Actions: UW-Madison acknowledged that the IRB approved consent form for this study did not include this informed consent element. Upon discovering this oversight, the research team was notified and asked to revise the consent documents and provide a plan for re-consenting previously enrolled subjects. The revised consent forms and protocol were submitted and approved by the IRB. Moreover, we note this study was approved prior to the implementation of an informed consent checklist, which occurred in 2008. According to UW-Madison, the checklist is completed at initial review to help ensure that all required elements of informed consent and relevant additional elements are included in consent documents. We have determined that the corrective actions noted above adequately address our determination and are appropriate under the UW-Madison FWA.

We acknowledge that the remaining questions and concerns from our May 8, 2012 letter have been adequately addressed.

In summary, we determine that the corrective actions adequately address the determinations noted above. As a result, at this time there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

We appreciate your institution's continued commitment to the protection of human research subjects.

Sincerely,

Lisa A. Rooney, J.D.
Compliance Oversight Coordinator

cc: Ms. Lois Kallunki, Human Research Protection Program Manager, University of Wisconsin-Madison (UWM)
Dr. Yoram Shenker, Chairperson, UWM IRB #1
Dr. Camburn Eric, Chairperson, UWM IRB #2
Dr. Dorothy Farrar-Edwards, Chairperson, UWM IRB #3
Dr. Peter Rahko, Chairperson, UWM IRB #5
Dr. Margaret Hamburg, Commissioner, Food and Drug Administration
Dr. Joanne Less, Food and Drug Administration
Dr. Sherry Mills, OER, National Institutes of Health
Dr. Joe Ellis, OER, National Institutes of Health