



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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April 30, 2010

Yonette F. Thomas, Ph.D.
Associate Vice President for Research Compliance
Howard University
2400 Sixth Street, NW
Washington, DC 20059

RE: Human Research Protections Under Federalwide Assurance FWA-891

Research Project: Genetics of Early-Onset Depression

Principal Investigator: William Lawson, MD

HHS Protocol Number: 5R01MH075131

Dear Dr. Thomas:

Thank you for your September 28 and November 23, 2009 reports submitted in response to our July 21, 2009 request that Howard University (HU) respond to questions and concerns regarding allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46).

A. Determinations regarding the above-referenced research made in our January 29, 2010 letter:

In our January 29, 2010 letter, we made the following determinations:

- (1) In order to approve research, the institutional review board (IRB) must determine that the research satisfies the criteria for approval under HHS regulations at 45 CFR 46.111. The minutes of several HU IRB meetings indicate that numerous protocols were approved even though the IRB had substantive questions about how the research was conducted, which information it appears the IRB would have needed in order to make the determinations required under HHS regulations at 45 CFR 46.111. We determined that numerous protocols were approved by the IRB in apparent absence of this information.

Corrective Action: We acknowledge that the HU IRB has instituted an “IRB Determinations and Actions Guide” and “IRB Meeting Minutes Checklist” which has been distributed to members and staff.

- (2) HHS regulations at 45 CFR 46.109(e) require that continuing review of research be conducted by the IRB at intervals appropriate to the degree of risk, but not less than once per year. The regulations make no provision for any grace period extending the conduct of the research beyond the expiration date of IRB approval. We determined that the IRB failed to conduct continuing review of research at least once per year for numerous studies and that research was conducted after expiration of IRB approval.

Corrective Action: We acknowledge your statement that the HU IRB has implemented a new process involving a protocol tracking system and investigators are instructed to submit renewal requests 60, 30, and 15 days prior to the expiration date. A Notice of Study Expiration will be issued immediately upon expiration of IRB approval.

- (3) HHS regulations at 45 CFR 46.115(b) require that IRB records be retained for at least 3 years, and records relating to research which is conducted be retained for at least 3 years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner. We determine that HU failed to retain IRB records and records relating to research for at least 3 years after completion of the research at that study site for protocols IRB-04-MED-16, IRB-06-CAS-03, and nIRB-06-GSAS-01.

Corrective Action: We acknowledge your statement that each protocol is now scanned and saved to an external hard drive. We also acknowledge that HU has established a process for systematically entering approval and expiration dates, submission of final and closeout reports and length of time closed. Reports will be generated, reviewed, and discussed on a monthly basis. We recommend that all records required to be retained under HHS regulations at 45 CFR 46.115(b) be scanned and saved as described above.

- (4) We determined that HU did not have written IRB procedures that adequately describe the following activities, as required by HHS regulations at 45 CFR 46.103 (b)(4): The procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review. OHRP noted that the written procedures did state that such verification will occur, but did not state how projects needing such verification will be identified.

Corrective Action: We acknowledge that HU has drafted a document entitled: “Institutional Review Board: Researcher’s Guide” which describes the factors that will determine which studies require independent verification.

We determine that the corrective actions adequately address our determinations. 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.

B. Recommendations

- (1) Chapter 5.F of the draft “Institutional Review Board: Researcher’s Guide” states that expedited review is allowable for “Initial or continuing review of research falling with specific categories published in the Federal Register.” We recommend that this section be revised to add that the research must also involve no greater than minimal risk to be eligible for expedited review.
- (2) Chapter 5.H of the draft “Institutional Review Board: Researcher’s Guide” states “HU’s employees or agents without the initial and continuing approval of the IRB may conduct at HU or no human subjects research.” We recommend that this sentence be revised to be less awkward.
- (3) Chapter 6.B of the draft “Institutional Review Board: Researcher’s Guide” states “When the research design presents unnecessary or unacceptable risks to subjects without commensurate benefits to the subjects or to others, the research cannot ethically proceed.” We recommend that this section be revised to indicate that a research design that presents unnecessary or unacceptable risks to subjects is never acceptable, even with commensurate benefits to the subjects or to others.
- (4) Chapter 11 of the draft “Institutional Review Board: Researcher’s Guide” describes some of the expedited review categories applicable to social and behavioral research. We recommend that the numbering of the categories be the same as the categories published in the Federal Register ([63 FR 60364-60367, November 9, 1998.](#))

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. Borrer, Ph.D.
Director, Division of Compliance Oversight

cc: Dr. Charles P. Mouton, Professor & Chairman, Dept. of Community & Family
Medicine, HU
Dr. Anthony K. Wutoh, IRB Chair, HU
Dr. William Lawson, HU
Dr. Sherry Mills, National Institutes of Health

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Mr. Joseph Ellis, National Institutes of Health

Dr. Thomas R. Insel, Director, National Institute of Mental Health