



Office for Human Research Protections  
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July 31, 2009

Don M. Colemand, Ph.D.  
Interim 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. Colemand:

Thank you for your May 21, 2009 report submitted in response to our April 13, 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

Based on our review of your response, we make the following determinations:

- (1) HHS regulations at 45 CFR 46.116 state that no investigator may involve a human being as a subject in research covered by the regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative, or the institutional review board (IRB) has appropriately waived the requirements to obtain informed consent. We determine that the investigator initiated human subject research without obtaining legally effective informed consent of subjects and without the IRB appropriately waiving these requirements. In specific, we note that the protocol envisions that identifiable private information about the subjects may be obtained from family members for research purposes prior to obtaining informed consent, but we can find no evidence that the HU IRB waived informed consent for these subjects to the obtaining of this information.

- (2) HHS regulations at 45 CFR 46.116(a) require that when seeking informed consent specific information shall be provided to each subject unless the IRB approves a consent procedure which does not include, or which alters, some or all of the required basic elements of informed consent provided in accordance with 45 CFR 46.116 (c) or (d). We determine that the informed consent documents reviewed and approved by the IRB for this study failed to include a description of any reasonably foreseeable risks and discomforts as required by HHS regulations at 45 CFR 46.116(a)(2). We note that the protocol states that there is a theoretical risk that subjects may be identified on the basis of DNA information and that the informed consent document “notifies subjects of this theoretical risk as suggested by NIMH.” In addition, the protocol indicates that one of the risks of the research is violation of confidentiality which could be embarrassing to subjects and their relatives or could damage a subject’s reputation. We cannot locate this information in the informed consent document.
- (3) We determine that the institution does not have written IRB procedures that adequately describe the following activities, as required by HHS regulations at 45 CFR 46.103(a) and 46.103(b)(4) and (5): 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 notes that the written procedures do state that such verification will occur, but does not state how projects needing such verification will be identified.

OHRP notes that such a specific procedure should include specific criteria used to make these determinations, such as:

- (a) randomly selected projects;
- (b) complex projects involving unusual levels or types of risk to subjects;
- (c) projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; and
- (d) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

**Required Actions:** By August 31, 2009 please provide OHRP with a corrective action plan to address the above determinations. Please also provide the following with your response:

- (a) a summary of the corrective actions taken by HU to address the concerns raised by the inspection of the HU IRB by the Food and Drug Administration in August 2008; and
- (b) a copy of the minutes of HU IRB meetings since September 2008.

**B. Questions and concerns regarding HU's system for protecting human subjects**

Based on our review of your May 21, 2009 report, we have the following questions and concerns:

(1) [Redacted]

(2) [Redacted]

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[Redacted]

(3) [Redacted]

[Redacted]

(4) [Redacted]

(5) [Redacted]

(6) [Redacted]

[Redacted]

(7) [Redacted]

Please provide us with responses to the above determinations, questions and concerns by August 31, 2009, including a corrective action plan for the determinations of noncompliance. Feel free to contact me if you would like guidance in developing a corrective action plan.

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  
Mr. Joseph Ellis, National Institutes of Health  
Dr. Thomas R. Insel, Director, National Institute of Mental Health