DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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July 6, 2004
(Revised August 2, 2004)

Todd G. Guttman, M.D., J.D.
Associate Vice President for Research Compliance
The Ohio State University
208 Bricker Hall
190 North Oval Mall
Columbus, OH 43210-1321

RE: Human Research Subject Protections Under Federalwide Assurance FWA-6378 (formerly Multiple Project Assurance M-1238)

Research Activity: Research Conducted at the Ohio State University Comprehensive Cancer Center

Dear Dr. Guttman:

The Office for Human Research Protections (OHRP) has reviewed The Ohio State University's (OSU) reports dated October 16, 2003; November 21, 2003; January 12, 2004; February 25, 2004; and June 14, 2004, in response to allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects.

Based upon its review of the OSU reports, OHRP makes the following determinations with regard to the above-referenced research:

(1) HHS regulations at 45 CFR 46.103(b) and 46.109(a) require that an institutional review board (IRB) review and approve all nonexempt human subjects research covered by an assurance.

OHRP finds that the collection and analysis of remnant cells taken from a discarded filter used in a bone-marrow transplant, along with associated identifiable patient information, was human subjects research that required prior review and approval by the OSU IRB. OHRP further finds that the OSU IRB did not approve this research, as required by HHS regulations.

(2) HHS regulations at 45 CFR 45.116 state that, except as provided elsewhere in the regulations, 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.

OHRP finds that the collection and analysis of remnant cells taken from a discarded filter with associated identifiable patient information was human subjects research. Thus, the investigator was required to obtain the legally effective informed consent of the subject or the subject's legally authorized representative, unless the IRB found that the criteria for waiver of consent were satisfied.

Corrective Action: OHRP acknowledges the thorough inquiry conducted by OSU and its IRB into the actions taken by its investigator, and the corrective actions already implemented by OSU, as stated in your report dated February 25, 2004.

OHRP notes that OSU has taken the following corrective actions:

(a) Informing the investigator that OSU policies, HHS regulations, and the terms of the OSU FWA require that an IRB review and approve all nonexempt human subjects research.

(b) Informing the investigator that OSU policies, HHS regulations, and the terms of the OSU FWA require that the informed consent of the subject be obtained prior to commencing human subjects research.

(c) Requiring the investigator to forward copies of research specimen control policies and procedures to the IRB for review.

(d) Requiring the investigator and some of his research staff to provide the OSU IRB with documentation that they have completed additional human subjects-related education.

(e) Requiring the investigator to organize and support one or more workshops on the importance of compliance with human subjects protection rules in research specimen procurement.

In addition, OHRP recommends that OSU consider taking steps to ensure that all investigators at OSU are advised of OSU policies, HHS regulations, and the terms of the OSU FWA, including (i) IRB review and approval of all nonexempt human subjects research, and (ii) the obtaining and documentation of informed consent of research subjects prior to commencing human subjects research, unless these requirements have been appropriately waived by the IRB.

OHRP finds that the corrective actions above adequately address OHRP's concerns and findings, and that they are appropriate under the OSU FWA. As a result of these determinations, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified that might alter this determination.

OHRP appreciates OSU's commitment to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Rina Hakimian, J.D., M.P.H.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Judith Neidig, Director, Office of Responsible Research Practices, OSU
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