



Office for Human Research Protections
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April 28, 2005

Richard B. Johnston, M.D.
Executive Vice President for Academic Affairs
National Jewish Medical and Research Center
1400 Jackson Street
Denver, Colorado 80206

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 778

Research Project: Beryllium Medical Surveillance at a Former Nuclear Weapons Facility During Cleanup Operations
Protocol Number: HS-1745
Principal Investigator: Holly M. Sackett

Dear Dr. Johnston:

The Office for Human Research Protections (OHRP) has reviewed National Jewish Medical and Research Center's (NJMRC) April 1, 2005 report, which was submitted in response to OHRP's February 28, 2005 letter regarding the above-referenced research. OHRP has determined that the corrective actions summarized below adequately address the findings presented in OHRP's letter of February 28, 2005, and are appropriate under the NJMRC FWA.

(1) OHRP acknowledges NJMRC's implementation of the written standard operating procedure entitled "SC 503 - Student Research Projects," which outlines the procedures that students at NJMRC must follow to obtain prospective institutional review board (IRB) approval for graduate work involving (i) research on human subjects, (ii) use of databases containing protected health information, or (iii) a clinical investigation, and possibly resulting in a thesis or dissertation.

(2) OHRP acknowledges NJMRC's development of a new research review program to ensure that research is conducted according to approved protocols and in accordance with federal regulations governing human subjects research. OHRP notes that as part of this program, routine site-monitoring visits are conducted to evaluate subject selection, informed consent process/documentation, study documentation, recordkeeping, and subject safety.

As a result of the above determination, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

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

Sincerely,

Robert J. Meyer
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Lynn M. Taussig, President, NJMRC
Dr. Richard B. Meehan, IRB Chair, NJMRC
Ms. Mary E. Travis, IRB Administrator, NJMRC
Commissioner, FDA
Dr. David A. Lepay, FDA
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Ms. Janet Fant, OHRP