DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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April 15, 2004

Carol Z. Garrison, Ph.D.
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Eli L. Capilouto, M.D.
Acting Provost
University of Alabama, Birmingham
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RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 5960

Dear Drs. Garrison and Capilouto:

The Office for Human Research Protections (OHRP) has reviewed your April 7, 2004 report that was submitted in response to OHRP's March 10, 2004 letter to the University of Alabama, Birmingham (UAB) regarding the determinations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human subjects (45 CFR Part 46) that were based upon OHRP's February 3-5, 2004 on-site evaluation of human subject protection procedures at UAB. OHRP has determined that the corrective actions summarized below adequately address the findings presented in OHRP's letter of March 10, 2004 and are appropriate under the UAB's FWA.

(1) UAB has submitted an updated FWA to reflect that UAB's Deputy Provost for Human Subjects Research will be its designated Signatory Official and is authorized to act on behalf of UAB under UAB's FWA. OHRP acknowledges that UAB's Deputy Provost for Human Subjects Research reports directly to UAB's Acting Provost and occupies an administrative level higher than the UAB's Acting Vice President for Research.

(2) UAB has revised its policies and procedures to expedite the identification, investigation, and prompt reporting to the institutional review board (IRB), appropriate institutional officials, the department or agency head, and OHRP of (i) any unanticipated problems involving risks to subjects or others; (ii) any serious or continuing noncompliance with HHS regulations or the requirements or determinations of the IRB; and (iii) any suspension or termination of IRB approval, as required by HHS regulations at 45 CFR 46.103(a) and 46.103(b)(5).

(3) UAB has completed its preparation of written minutes of UAB IRB meetings for 2003. OHRP acknowledges UAB's plans to revise its policies and procedures to reflect an updated time frame for the preparation, review, and approval of written minutes of UAB IRB meetings.

(4) OHRP acknowledges UAB's plans to ensure that the four specific criteria for altering or waiving the requirements to obtain informed consent under HHS regulations at 45 CFR 46.116(d) are fully considered and documented by the IRB.

(5) OHRP finds that UAB has adequately addressed additional concerns raised by OHRP in its letter of March 10, 2004.

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

OHRP appreciates the commitment of UAB 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. Samuel J. Tilden, Deputy Provost for Human Subjects Research, UAB
Dr. Ferdinand Urthaler, IRB Chair, UAB
Dr. Albert Oberman, IRB Vice Chair, UAB
Ms. Sheila Moore, IRB Human Protections Administrator and Director, UAB
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Bernard Schwetz, OHRP
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Ms. Melinda Hill, OHRP