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December 11, 2000

Joan F. Lorden, Ph.D.
Associate Provost for Research
The University of Alabama at Birmingham
1120 Administration Building
701 South 20th Street
Birmingham, AL 35294-0111

RE: Human Research Subject Protections under the University of Alabama at Birmingham(UAB) Multiple Project Assurance (MPA), M-1149

Dear Dr. Lorden:

The Office for Human Research Protections (OHRP) has reviewed your September 29, 2000 progress report, the revised Institutional Review Board (IRB) Policies and Procedures dated November 29, 2000, and the minutes of recent IRB meetings.

Based on its review, OHRP finds that the UAB has greatly enhanced its system for protection of human subjects. Among the enhancements noted by OHRP are the following:

- (1) The UAB has implemented a multifaceted education program to ensure that all IRB members, all IRB staff, and all research investigators are educated on an ongoing basis about the ethical principles and regulatory requirements for the protection of human subjects.
- (2) The UAB has expanded the number of IRB's from one to two, resulting in a significant reduction in the volume of research protocols reviewed and overseen by each IRB. Furthermore, UAB has restructured the UAB Office of the IRB's and increased its staff at nearly all levels.
- (3) The UAB has revised its written IRB policies and procedures in response to OHRP's prior guidance. In particular, the UAB policy and procedures have been revised to assure that all required documents will be provided to IRB members prior to its meetings so that the determinations required for approval of research under HHS regulations at 45 CFR 46.111 will be made.

Joan F. Lorden, Ph.D.-The University of Alabama at Birmingham
December 11, 2000

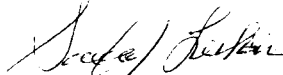
(4) The minutes of recent IRB meetings clearly document substantive and meaningful initial and continuing review of human subject research.

Furthermore, OHRP finds that the UAB has adequately completed all required actions stipulated by OHRP in its January 19, 2000 letter.

As a result of the above findings, effective immediately, OHRP has removed the restriction on the UAB Multiple Project Assurance (MPA M-1149) and is closing its compliance oversight investigation of this matter.

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

Sincerely,



Sanford Leikin, M.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc Dr. Greg Koski, OHRP
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Dr. J. Thomas Puglisi, OHRP
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