



**FOR US POSTAL SERVICE DELIVERY:**

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August 28, 2000

Joan F. Lorden, Ph.D.  
Associate Provost for Research  
The University of Alabama at Birmingham  
AB 770G  
1530 3<sup>rd</sup> Avenue South  
Birmingham, AL 35294-0107

**RE: Human Research Subject Protections Under  
Multiple Project Assurance (MPA) # M-1149**

Dear Dr. Lorden:

The Office for Human Research Protections (OHRP) has reviewed your report dated July 7, 2000 responding to the allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human subjects (45 CFR Part 46) that were presented in OHRP's May 23, 2000 letter.

OHRP acknowledges the University of Alabama's (UAB's) findings that (a) [REDACTED] was not enrolled in a research project and underwent standard medical care for her detached retina in July 1999; and (b) no research involving a laser eye surgery procedure was conducted on [REDACTED] without [REDACTED] legally effective informed consent.

As a result, 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 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,

Michael A. Carome, M.D.  
Chief, Compliance Oversight Branch  
Division of Human Subject Protections

cc: Ms. Sheila Moore, Director, IRB, UAB  
Dr. Ferdinand Urthaler, Chair, IRB, UAB  
Dr. Robert Morris, UAB  
Dr. C. Douglas Witherspoon, UAB  
Commissioner, FDA  
Dr. David Lepay, FDA  
Dr. James F. McCormack, FDA  
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