



FOR US POSTAL SERVICE DELIVERY:

Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
National Institutes of Health (MSC 7507)
Rockville, Maryland 20892-7507

FOR HAND DELIVERY OR EXPRESS MAIL:

Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
Rockville, Maryland 20852

Telephone: 301-402-5567
FAX: 301-402-2071
E-mail: mc2a@nih.gov

January 25, 2001

Kenneth G. Preston
Associate Vice President for Research
University of South Florida
4202 East Fowler Avenue, ADM 200
Tampa, Florida 33620-5950

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1284

Research Projects: Studies Involving the Tampa Trephine Penetrating Keratoplasty Procedure for Corneal Transplantation
Principal Investigator: J. James Rowsey, M.D.

Dear Dr. Preston:

The Office for Human Research Protections (OHRP) has reviewed Dr. George Newkome's December 12, 2000 report and Mr. Dennis Freeman's January 18, 2001 report that were submitted in accordance with the required actions stipulated in OHRP's September 28, 2000 letter to the University of South Florida (USF) regarding the above referenced research.

OHRP has determined that USF has implemented all required actions stipulated by OHRP in its September 28, 2000 letter. In specific, OHRP acknowledges that:

- (1) The USF Institutional Review Board (IRB) has developed, and USF has implemented, an appropriate plan for contacting all surviving subjects (or the parents or legal guardians of children who were subjects) who participated in the human subject research involving the Tampa Trephine penetrating keratoplasty procedure and informing them of their previous unwitting participation in the research, the risks associated with the research and the nature of the noncompliance by USF with the requirements of Department of Health and Human Services (HHS) regulations at 45 CFR Part 46.
- (2) USF has conducted a complete audit of all on-going research projects involving human subjects at USF in order to confirm that all nonexempt research had been reviewed and approved by one of USF's IRBs.

As a result of the above determination, OHRP is closing its compliance oversight investigation of this matter, and 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.
Director, Division of Compliance Oversight

cc: Dr. Barry B. Bercu, Chairperson, IRB-01/02, USF
Dr. Martin Klemperer, Chairperson, IRB-03, USF
Dr. William B. Webster, Chairperson, IRB-04, USF
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Robert Fish, FDA
Mr. Timothy J. Couzins, FDA
Dr. John Mather, Office of Research Compliance and Assurance, Department of Veterans Affairs
Dr. Susan Rose, Department of Energy
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Katherine Duncan, OHRP
Mr. George Gasparis, OHRP
Dr. Jeffrey M. Cohen, OHRP
Mr. Barry Bowman, OHRP