



**FOR US POSTAL SERVICE DELIVERY:**

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December 4, 2000

George R. Newkome, Ph.D.  
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. Newkome:

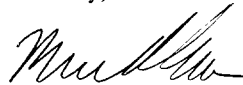
The Office for Human Research Protections (OHRP) has reviewed your November 30, 2000 letter regarding the University of South Florida's (USF's) revised procedures for contacting all surviving subjects (or the parents or legal guardians of children who were subjects) who participated in the above referenced research 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 the Department of Health and Human Services (HHS) regulations at 45 CFR Part 46.

OHRP finds that the proposed procedure for contacting and debriefing the subjects that has been approved by the USF IRB-01 is acceptable. OHRP concurs with implementation of this procedure.

By January 19, 2001, please submit to OHRP a progress report on USF's implementation of this debriefing procedure. Please include with your report a copy of one of the signed and dated final letters for each of the four groups of patients to be debriefed (with redaction of patient names and addresses).

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  
Dr. J. James Rowsey  
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. J. Thomas Puglisi, OHRP  
Dr. Clifford C. Scharke, OHRP  
Dr. Katherine Duncan, OHRP  
Mr. George Gasparis, OHRP  
Dr. Jeffrey M. Cohen, OHRP  
Mr. Barry Bowman, OHRP