



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

November 17, 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 October 29 and November 16, 2000 letters regarding the University of South Florida's (USF's) proposed 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, in general, the proposed procedure for contacting and debriefing the subjects is acceptable. OHRP is concerned that the text of the proposed letter may be confusing and too complex for many subjects. OHRP strongly recommends that the proposed letter to subjects (11-16-00 draft) be revised as follows:

- (1) Use separate letters for adult subjects and for children subjects in order to avoid using the statement "you, or a child for whom you are the parent or legal guardian" in all letters.
- (2) It is OHRP's understanding that the names of most subjects who underwent the Tampa Trephine penetrating keratoplasty procedure are known. If this is correct, it would be appropriate to simplify the first two paragraphs in a manner similar to the following:

“According to our records, you [your child] underwent a corneal transplant performed by Dr. J. James Rowsey in 199X. This transplant involved using the Tampa Trephine, a cutting tool invented by Dr. Rowsey. The cutting tool was used to remove the cornea from the donor eye. The cutting tool did not touch your eye during the transplant surgery. However, using this tool required changing your cornea transplant surgery from the standard surgery, because donor corneas cut out with the Tampa Trephine had a different shape in comparison to donor corneas cut out using the standard tool.

“It has been determined that (a) this type of surgery with the Tampa Trephine involved research; and (b) you should have been informed that you were a subject in the research and the surgery was experimental. I am writing to you to inform you of these events.”

(3) If there is a group of patients who may have undergone the Tampa Trephine penetrating keratoplasty procedure, but this is not known for sure, it would be appropriate to have a separate letter with the first two paragraphs simplified in a manner similar to the following:

“According to our records, you [your child] underwent a corneal transplant performed by Dr. J. James Rowsey between 1995 and 1998. Many of these transplants involved using the Tampa Trephine, a cutting tool invented by Dr. Rowsey. The cutting tool was used to remove the cornea from the donor eye. The cutting tool did not touch the patient’s eye during the transplant surgery. However, using this tool required changing the cornea transplant surgery from the standard surgery because the donor corneas cut out with the Tampa Trephine had a different shape in comparison to donor corneas cut out using the standard tool.

“It has been determined that (a) this type of surgery with the Tampa Trephine involved research; and (b) if you had surgery with the Tampa Trephine, you should have been informed that you were a subject in the research and the surgery was experimental. I am writing to all patients who may have undergone this experimental surgery to inform them of these events.”

Please note that any revised letters should be reviewed and approved by the appropriate USF IRB. By December 8, 2000, please submit copies of the final drafts of proposed letters to patients who did undergo, or may have undergone, the Tampa Trephine penetrating keratoplasty procedure.

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 Klempner, 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