



**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: 301-435-8072

FAX: 301-402-2071

E-mail: [borrork@od.nih.gov](mailto:borrork@od.nih.gov)

February 15, 2001

Donald C. Harrison, M.D.  
Senior Vice President and Provost for Health Affairs  
University of Cincinnati  
P.O. Box 670663  
Cincinnati, OH 45267-0663

Elliot G. Cohen  
Senior Executive Officer  
University Hospital, Inc.  
234 Goodman  
Cincinnati, OH 45267

Thomas P. Pishioneri  
Acting Medical Center Director  
Department of Veterans Affairs Medical Center  
3200 Vine Street  
Cincinnati, OH 45220

Glenn D. Warden, M.D.  
Chief of Staff  
Shriners Burns Institute  
3229 Burnet Avenue  
Cincinnati, OH 45229

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA)  
M-1138**

**Research Project: Evaluation of the Hitachi AIRIS II MRI for Image-Guided  
Neurosurgery**

**Principal Investigators: Mary Gaskill-Shiple, M.D. and Ronald Warnick, M.D.**

**UC Study Number: 97-12-16-1**

Dear Dr. Harrison, Mr. Cohen, Mr. Pishioneri and Dr. Warden:

The Office for Human Research Protections (OHRP) has reviewed your report of January 26, 2001, regarding the above referenced research project conducted at the University of Cincinnati (UC).

Based upon its review, OHRP has made the following determinations regarding the above-referenced research:

(1) Department of Health and Human Services (HHS) regulations at 45 CFR 46.404-407 require specific findings on the part of the Institutional Review Board (IRB) for approval of research involving children. OHRP finds that the UC IRB failed to make these required findings when it reviewed and approved this research proposing involvement of children.

**Corrective Action:** OHRP finds that the following corrective actions adequately address this finding: (a) the investigator has been asked to submit an amendment to the protocol; (b) the UC IRB will review the amended study to make the appropriate findings; and (c) the UC IRB procedures have changed to ensure that the findings required under HHS regulations at 45 CFR 46.404-407 are made and documented in the IRB minutes.

(2) HHS regulations at 45 CFR 46.116 prohibit any exculpatory language in informed consent through which the subject is made to waive, or appear to waive, any of the subject's legal rights. OHRP finds that the following language in the IRB-approved informed consent documents is exculpatory: "I will...have no rights to share in any profit...."

**Corrective Action:** OHRP finds that the following corrective actions adequately address this finding: the investigator will be asked to delete the language and submit a revised informed consent document for IRB review, at which time the IRB will determine whether or not subjects should be re-consented.

(3) OHRP finds that your report adequately addresses the additional concerns raised in OHRP's December 11, 2000 letter.

As a result of the above determinations, 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 your institution's continued commitment to the protection of human research subjects. Do not hesitate to contact me if you have any questions regarding this matter.

Sincerely,



Kristina C. Borrer, Ph.D.  
Compliance Oversight Coordinator  
Division of Compliance Oversight

cc: Mr. Michael Walton, Medical Center Director, Chillicothe VAMC  
Dr. Peter Frame, IRB Co-Chair, UC IRB-01/A  
Dr. Frederick J. Samaha, MD, Chair, UC IRB-01/B  
Ms. Carolyn West, UC IRB Administrator  
Dr. Mary Gaskill-Shiple, UC  
Dr. Ronald Warnick, UC  
Dr. John Mather, VA  
Commissioner, FDA  
Dr. David Lepay, FDA  
Dr. James F. McCormack, FDA  
Dr. Greg Koski, OHRP  
Dr. Melody H. Lin, OHRP  
Dr. Michael A. Carome, OHRP  
Ms. Roslyn Edson, OHRP  
Dr. Jeffrey M. Cohen, OHRP  
Mr. George Gasparis, OHRP  
Mr. Barry Bowman, OHRP