DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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February 5, 2002

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University of Cincinnati
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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: A Dose Response Study of Inhaled Nitric Oxide in the Treatment of Adult Respiratory Distress Syndrome
Principal Investigator: Jay Johannigman, MD
UC Study Number: 94-10-19-2

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

The Office for Human Research Protections (OHRP) has reviewed your report of January 29, 2002 regarding the above-referenced research conducted at the University of Cincinnati (UC).

Based upon its review, OHRP makes the following determination regarding the above-referenced research project:

> Department of Health and Human Services (HHS) regulations at 45 CFR 46.116 stipulate that no investigator may involve a human subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. HHS regulations at 45 CFR 46.102(c) define a legally authorized representative as an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.
>
> OHRP acknowledges the following regarding the above-referenced research:
>
> > (a) 97 subjects enrolled in the study at UC were unable to provide legally effective informed consent, and consent for these subjects instead was obtained and documented from another individual (spouse, parent, adult sibling, adult child).
> >
> > (b) Applicable Ohio law indicates that the following classes of persons are authorized to provide informed consent to termination of life support on behalf of a patient who is not competent to consent:
> >
> > > (i) The appointed guardian of the patient, if any.
> > >
> > > (ii) The patient's spouse.
> > >
> > > (iii) Adult children of the patient.
> > >
> > > (iv) Parents of the patient.
> > >
> > > (v) Adult siblings of the patient.
> > >
> > > (vi) The nearest other related adult.
> >
> > (c) UC interprets applicable Ohio statutes and case law as authorizing spouses and close family members to consent on behalf of a subject to the subject's participation in

medical treatment and in the procedures involved in the research.

As a result of corrective actions already taken by UC in response to OHRP findings (see OHRP's December 20, 2001 letter), OHRP is closing its investigation and anticipates no need for further involvement 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. Borror, 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
Dr. Margaret Miller, Chair, UC IRB-02XM
Ms. Carolyn West, UC IRB Administrator
Dr. Jay Johannigman, UC
Dr. John Mather, VA
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Dr. David Lepay, FDA
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Dr. Michael A. Carome, OHRP
Dr. Jeffrey M. Cohen, OHRP
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