



FOR US POSTAL SERVICE DELIVERY:

Office for Human Research Protections
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National Institutes of Health (MSC 7507)
Rockville, Maryland 20892-7507

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March 26, 2001

Stephen J. Ryan, Jr., M.D.
Senior Vice President for Medical Care
Health Research Association and
University of Southern California Health Sciences
Doheny Eye Institute
1450 San Pablo Street, #5900
Los Angeles, CA 90033

Ms. Lisa Pratt
Chief Executive Officer
Health Research Association
1640 Marengo Street, 7th Floor
Los Angeles, CA 90033

**RE: Human Research Subject Protections Under Multiple Project Assurance
(MPA) M-1372**

Dear Dr. Ryan and Ms. Pratt:

The Office for Human Research Protections (OHRP) has reviewed the February 21, 2001 letter from Dr. Darcy Spicer and Dr. Robert Larsen responding to the allegations presented in OHRP's January 18, 2001 letter. The complainant in this matter had alleged that he was involved in research at your institutions without his informed consent.

OHRP acknowledges your report that there is no evidence that the complainant in this matter was a research subject at any time at your institution.

As a result, 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.

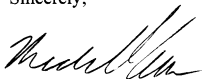
University of Southern California Health Sciences - Stephen J. Ryan, Jr., M.D.

Ms. Lisa Pratt - Health Research Association

March 26, 2001

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,

A handwritten signature in black ink, appearing to read "Michael A. Carome". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael A. Carome, M.D.

Director, Division of Compliance Oversight

cc: Dr. Darcy V. Spicer, Chair, Health Sciences Campus IRB, USC School of Medicine
Dr. Robert A. Larsen, Vice Chair, Health Sciences Campus IRB, USC School of Medicine
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Jeffrey Cohen, OHRP
Mr. George Gasparis, OHRP
Dr. Kamal Mittal, OHRP