



FOR US POSTAL SERVICE DELIVERY:

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August 7, 2000

Mr. Steven L. Seiler
Vice President and Chief Executive Officer
Good Samaritan Regional Medical Center
1111 E. McDowell RD.
Phoenix, AZ 85006

RE: Human Subjects Protections Under Cooperative Project Assurance (CPA) # T-3691

Dear Mr. Seiler:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks (OPRR), has reviewed your April 26, 2000 letter concerning Good Samaritan Regional Medical Center's (GSRMC) system for protecting human subjects under CPA T-3691. Based on your report, OHRP makes the following determinations:

1. OHRP finds that GSRMC has developed a satisfactory corrective plan to address all of the findings cited in OHRP's March 27, 2000 letter (copy enclosed), except for finding (6).
2. Regarding finding (6) (written IRB policies and procedures) in OHRP's March 27, 2000 letter, OHRP finds that GSRMC has taken corrective action concerning item (a). However, the Policy and Procedures section provided (Attachment P of GSRMC April 26, 2000 letter) incompletely addresses item (b). GSRMC should expand the description of its procedure for ensuring prompt reporting to appropriate institutional officials, any Department or Agency head, and OHRP, as applicable, of (i) any unanticipated problems involving risks to subjects or others; (ii) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (iii) any suspension or termination of IRB approval.

Mr. Steven L. Seiler-Good Samaritan Regional Medical Center

August 7, 2000

As a result of the above determinations, and assuming that GSRMC will further modify its written IRB policies and procedures as noted above, OHRP anticipates no further involvement in the above matters.

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,



Sanford Leikin, M.D.

Compliance Oversight Coordinator

Division of Human Subject Protections

Enclosure: OPRR's March 27, 2000 letter

cc: Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Dr. J. Thomas Puglisi, OHRP
Dr. Kamal Mittal, OHRP
Ms. Helen Gordon, OHRP
Dr. Richard Mowery, CTEP, NCI
Ms. Joan Mauer, CTEP, NCI
Mr. Gary Smith CTEP, NCI
Dr. Joseph Frank, Good Samaritan Reg Med Ctr.
Ms. Cheryl Thomas, Good Samaritan Reg Med Ctr.
Commissioner, Food and Drug Administration, HF-1
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA