DEPARTMENT OF HEALTH & HUMAN SERVICES

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July 21, 2000

Mr. Dale Surowitz
Chief Executive Officer
Encino-Tarzana Regional Medical Center
18321 Clark Street
Tarzana, California 91356

RE: Human Research Subject Protections Under the Cooperative Project Assurance (CPA) #T-4657

Dear Mr. Surowitz:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks (OPRR), has reviewed your March 24, 2000 report regarding human research subject protections at your institution.

OHRP has determined that Encino-Tarzana Regional Medical Center (ETRMC) has taken appropriate corrective actions to address the major concerns raised by OHRP in its letters of October 27, 1999 and February 18, 2000.

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.

At this time OHRP would like to provide the following additional guidance regarding ETRMC's written Institutional Review Board (IRB) policies and procedures:

(1) In accordance with HHS regulations at 45 CFR 46.103(b)(4)(ii) and (iii), the IRB policies should be expanded to include a description of the procedures that the IRB will follow (a) for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (b) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(2) In accordance with HHS regulations at 45 CFR 46.103(b)(5), the IRB policies should be expanded to include a description of the procedures that the IRB will follow for ensuring prompt reporting to the IRB, appropriate institutional officials, the Department or Agency head, and OHRP of (a) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (b) any suspension or termination of IRB approval.

OHRP is closing its evaluation of this matter with the understanding that ETRMC will revise its IRB policies and procedures in accordance with the above guidance.

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

cc: Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Dr. J. Thomas Puglisi, OHRP
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