DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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October 24, 2001

Ms. Linda Shyavitz
President and Chief Executive Officer
Sturdy Memorial Hospital
211 Park Street
Attleboro, MA 02703-0963

RE: Human Research Protections under Cooperative Project Assurance (CPA) T-3287
Food and Drug Administration (FDA) Letter of October 22, 1999

Dear Ms. Shyavitz:

The Office for Human Research Protections (OHRP) has reviewed the Sturdy Memorial Hospital (SMH) September 24, 2001 report concerning the above referenced matter.

Based on its review of your report, OHRP has determined that SMH has improved its written Institutional Review Board (IRB) policies and procedures and adequately responded to the questions and concerns raised in OHRP's June 5, 2001 letter.

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 provides the following additional guidance.

(1) OHRP recommends that the SMH IRB Policies and Procedures be revised to provide more operational detail to describe the following activities, in accordance with HHS regulations at 45 CFR 46.103(a) and 46.103(b)(4) and (5):

(a) The procedures for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

(b) The procedures which the IRB will follow for ensuring that proposed changes in an approved research activity, 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.

(c) The procedures for ensuring prompt reporting to OHRP of (i) 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 (ii) any suspension or termination of IRB approval.

(2) OHRP recommends that the SMH IRB Policies and Procedures be revised to make it clear that research that may be reviewed by the IRB through an expedited review procedure includes only research in the specific categories published in the Federal Register at 63 FR 60364-60367.

(3) OHRP recommends that the SMH IRB Policies and Procedures be revised to include citation of HHS regulations at 45 CFR 46, and use the correct citation for HHS regulations at 45 CFR Part 46, Subparts B, C, and D. OHRP notes that although the aforementioned Subparts address some additional protections for vulnerable populations, they are not the only populations of subjects who may be vulnerable. HHS regulations at 45 CFR 46.111(b) require the IRB to ensure that additional safeguards have been included in research to protect the rights and welfare of vulnerable subjects, including mentally disabled persons or economically or educationally disadvantaged persons.

(4) OHRP recommends that the SMH IRB Policies and Procedures be revised to clarify that projects that have been designated "closed: enrollment completed, patients still in follow up" still need to receive continuing review and approval by the IRB until the project is terminated or completed.

OHRP appreciates the commitment of your institution to the protection of human subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Kristina Borror, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc Dr. Daniel DeYoung, Chair, IRB, SMH
Dr. Daniel A. Pietro, SMH
Dr. Greg Koski, OHRP
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Mr. George Gasparis, OHRP
Ms. Yvonne Higgins, OHRP
Mr. Barry Bowman, OHRP

Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA