DEPARTMENT OF HEALTH & HUMAN SERVICES

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June 5, 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), formerly the Office for Protection from Research Risks (OPRR), has reviewed the Sturdy Memorial Hospital (SMH) January 26, 2000 report concerning the above referenced matter. OHRP apologizes for the delay in responding to your report.

OHRP acknowledges that SMH has developed written Institutional Review Board (IRB) Policies and Procedures. Based on its review, OHRP makes the following determinations regarding the Policies and Procedures:

(1) Department of Health and Human Services (HHS) regulations at 45 CFR 46.108(b) requires that IRBs review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas.

OHRP finds that the SMH IRB Policies and Procedures state that a quorum for a convened meeting of the IRB consists of "50% of the committee members plus one(1)." The Policies and Procedures fail to state that the quorum must include at least one member whose primary concerns are in nonscientific areas in accordance with 45 CFR 46.108(b).

(2) OHRP finds that the SMH IRB Policies and Procedures do not adequately describe the following activities, as required by HHS regulations at 45 CFR 46.103(a) and 46.103(b)(4) and (5):

(a) The procedures which the IRB will follow for conducting its initial review of research.

(b) The procedures for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

(c) The procedures which the IRB will follow 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.

(d) The procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and 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.

Required Action: By July 31, 2001 SMH must submit to OHRP revised IRB Policies and Procedures that adequately address findings (1) and (2) above. (see enclosed Guidance for Formulating Written IRB policies and Procedures (1/01)).

OHRP has the following additional concerns and guidance:

(3) OHRP is concerned that the minutes of IRB meetings fail to document separate deliberations, actions, and votes for each protocol undergoing continuing review by the convened IRB.

For example, OHRP notes that the minutes of the October 25, 1999 SMH IRB meeting stated that a "motion was made seconded and voted affirmative to renew the IRB approval of the NSABP studies. (For 5, Against 0, Abstain 0)." (See also December 20, 1999 IRB meeting minutes, Section VII, B 2). Please respond.

(4) HHS regulations at 45 CFR 46.109(e) require that continuing review of research be conducted by the IRB at intervals appropriate to the degree of risk and not less than once per year. The regulations make no provision for any grace period extending the conduct of the research beyond the expiration date of IRB approval. Additionally, where the convened IRB specifies conditions for approval of a protocol that are to be verified as being satisfied by the IRB Chair or another IRB member designated by the Chair, the approval period must begin on the date the protocol was reviewed by the convened IRB, not on the date the IRB Chair or his or her designee verifies that IRB-specified conditions for approval have been satisfied. OHRP is concerned that some protocols, such as the NSABP protocols, may not have been reviewed at least once per year.

(5) HHS regulations at 45 CFR 46.107(e) stipulate that no IRB member may participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB.

OHRP notes instances in which an IRB member abstained from the vote regarding continuing review of research protocols in which he had a conflicting interest (see June 21, 1999 IRB meeting minutes, protocols CV 137-012 and CV137-018). However, it is unclear whether the member was absent from the room at the time of the vote. Please clarify.

OHRP strongly recommends that IRB members absent themselves from the meeting room when the IRB votes on research in which they have a conflicting interest, and such should be noted in the IRB meeting minutes.

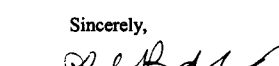
(6) OHRP recommends that the SMH IRB Policies and Procedures be revised to reference the current categories of research that may be reviewed by the IRB through an expedited review procedure as published in the Federal Register at 63 FR 60364-60367.

(7) OHRP recommends that the SMH IRB Policies and Procedures be revised to address the additional safeguards to protect the rights and welfare of vulnerable subjects as described HHS regulations at 45 CFR Part 46, Subparts B, C, and D.

Please submit to OHRP your response to the above determinations, questions and concerns no later than July 31, 2001.

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

Enclosure: Guidance for Formulating Written IRB policies and Procedures (1/01).

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. Freda Yoder, OHRP
Mr. Barry Bowman, OHRP
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA