DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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February 25, 2003

Daniel J. Curran, Ph.D.
Executive Vice President
Saint Joseph's University
Regis Hall
5600 City Avenue
Philadelphia, PA 19131

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) FWA-0064

Dear Dr. Curran:

The Office for Human Research Protections (OHRP) has reviewed the Saint Joseph's University's (SJU) December 19, 2001 report submitted in response to OHRP's October 19, 2001 letter regarding the human subject protections program at SJU.

Based on the review of SJU's report, OHRP makes the following determinations:

(1) OHRP finds that SJU does not have written institutional review board (IRB) procedures that adequately describe the following activities, as required by Department of Health and Human Services (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 which the IRB will follow for conducting its continuing review of research.

(c) The procedures which the IRB will follow for determining which projects require review more often than annually.

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

(e) The procedures for ensuring prompt reporting to the appropriate institutional officials, any Department or Agency head, and OHRP of: (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval.

OHRP is particularly concerned because SJU's December 19, 2001 report stated "The IRB of St. Joseph's University understands that the policies and procedures must be followed to ensure that research is being undertaken in the appropriate manner and that the findings, conclusions and actions of the investigator are reported appropriately. Moreover, these rules are always followed to determine which projects require review more often than annually; which projects need verification from sources other than the investigators to determine that no material changes have occurred since previous IRB review; and to ensure prompt reporting to the IRB of any change in the research activity, and for ensuring that any change in approved research not be initiated without IRB approval." Based on the material in SJU's report and located on SJU's current website, OHRP could find no evidence that SJU has written IRB procedures which describe many of these activities.

OHRP notes that the IRB policies and procedures submitted with SJU's report provide a detailed and thorough description of how investigators should prepare and submit protocols for IRB review. OHRP further notes that, in general, these procedures do not provide an adequate description of the procedures which **the IRB will follow** to conduct its activities.

Required Action: By March 31, 2003, SJU must submit revised written IRB policies and procedures that adequately describe the operational details for each of the above referenced procedures. In order to assist SJU in revising its IRB procedures, please see OHRP's guidance at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/irbgd702.htm.

(2) In its October 19, 2001 letter, OHRP presented an allegation that the SJU IRB failed to review proposed research at a convened meeting at which a majority of members were present, as required by HHS regulations at 45 CFR 46.108(b). OHRP finds that this allegation could not be substantiated.

(3) In its October 19, 2001 letter, OHRP presented an allegation that the SJU IRB failed to

review and approve human subjects research, as required by HHS regulations at 45 CFR 46.109(a). OHRP finds that this allegation could not be substantiated.

(4) In its October 19, 2001 letter, OHRP presented an allegation that the SJU IRB failed to be sufficiently qualified through the expertise of its members, and the diversity of its members to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects, as required by HHS regulations at 45 CFR 46.107(a). OHRP finds that this allegation could not be substantiated.

OHRP has the following questions and concerns regarding SJU's December 19, 2001 report:

(5) [Redacted]

(6)[Redacted]

Please respond to the above concerns and questions above no later than April 18, 2003.

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,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Michelle Rowe, IRB Chair, SJU
Dr. Thomas Kaeo, Director, Office of Research Services, SJU
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Mr. George Gasparis, OHRP
Ms. Shirley Hicks, OHRP
Dr. Harold Blatt, OHRP
Mr. Barry Bowman, OHRP