



Office for Human Research Protections  
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April 29, 2003

Greg Dell'Omo, Ph.D.  
Vice President for External Affairs  
Saint Joseph's University  
5600 City Avenue  
Philadelphia, PA 19131

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

Dear Dr. Dell'Omo:

The Office for Human Research Protections (OHRP) has reviewed the Saint Joseph's University's (SJU) March 31, 2003 and April 17, 2003 reports submitted in response to OHRP's February 25, 2003 letter regarding the human subject protections program at SJU.

Based on the review of SJU's reports, OHRP finds that the SJU has developed satisfactory written IRB procedures and adequately addressed the additional concerns set forth in OHRP's February 25, 2003 letter.

As a result of the above determination, there should be no need for further involvement of OHRP in the above referenced matter. However, SJU must notify OHRP promptly of any new information that might alter this determination.

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. Phillip Schatz, IRB Chair, SJU  
Mr. Christopher Meussner, IRB Administrator, SJU  
Commissioner, FDA  
Dr. David Lepad, FDA  
Dr. Bernard Schwetz, OHRP  
Dr. Melody H. Lin, OHRP  
Dr. Michael Carome, OHRP  
Dr. Kristina Borrer, OHRP  
Mr. George Gasparis, OHRP  
Ms. Shirley Hicks, OHRP  
Dr. Harold Blatt, OHRP  
Ms. Melinda Hill, OHRP