DEPARTMENT OF HEALTH & HUMAN SERVICE

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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April 28, 2008

Thomas Van Osdol
Chief Executive Officer
Saint John's Health System
2015 Jackson Street
Anderson, IN 46016

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 1780

Dear Mr. Van Osdol:

Thank you for your December 13, 2007 email and April 7, 2008 report regarding research conducted under the above-referenced Federalwide Assurance (FWA) which were submitted by Saint John's Health System (Saint John's) in response to our November 28, 2007 letter.

In our September 14, 2007 letter we found that the suspension of institutional review board (IRB) approval for Radiation Therapy Oncology Group (RTOG) 0615, which was documented in the June 13, 2007 IRB meeting minutes, was not reported to appropriate institutional officials, the Office for Human Research Protections (OHRP), or the head of the sponsoring federal department or agency as required by Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(a) and 46.103(b)(5).

Corrective Action: We acknowledge receipt of a Saint John's Health System Policy and Procedure entitled Interactions with Institutional Review Boards (revised November 30, 2007). We determine that this policy adequately address the finding noted above. In specific, we determine that this policy addresses the reporting of unanticipated problems involving risks to subjects or others, any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB, and any suspension or termination of institutional review board (IRB) approval as required by HHS regulations at 45 CFR 46.103(a) and (b)(5).

In addition, we acknowledge Saint John's confirmation that all HHS supported non-exempt human subjects research that was previously suspended has been re-reviewed and approved by the New England Institutional Review Board, an IRB designated under the Saint John's FWA in accordance with HHS regulations at 45 CFR 46.103(b).

As a result, we have removed the restriction on the Saint John's FWA, effective immediately, and are closing our investigation into research conducted under the above-referenced FWA. At this time, there should be no need for further involvement by our office in this matter.

We appreciate your institution's continued commitment to the protection of human research subjects. Please contact me should you have any questions.

Sincerely,

Lisa A. Rooney, J.D.
Compliance Oversight Coordinator

cc: Dr. Sugar, IRB Chair, New England IRB #1 & #2
Ms. Mary Oster, IRB Chair, New England IRB #3
Dr. Gary Brazel, Saint John's Health System
Ms. Laura Sylvester, IRB Manager, Saint John's Health System
Dr. Andrew C. von Eschenbach, Commissioner, FDA
Dr. Joanne Less, FDA
Dr. Sherry Mills, OER, NIH
Mr. Joe Ellis, OER, NIH