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 11, 2006

Raymond F. Gesteland, Ph.D.
Vice President for Research
University of Utah
201 South President's Circle, Room 210
Salt Lake City, UT 84112

RE: Human Research Subject Protections Under Federal-wide Assurance (FWA)-3745

Dear Dr. Gesteland:

The Office for Human Research Protections (OHRP) is conducting an evaluation of the University of Utah (U of U) system for protecting human research subjects. OHRP has reviewed your submission dated August 15, 2006 (received via e-mail on September 22, 2006). OHRP acknowledges your clarifying remarks and corrective actions. OHRP makes the following determinations:

(1) In its August 8, 2006 letter, OHRP expressed concern that the U of U IRB, when reviewing protocol applications, often lacks sufficient information to make the determinations required for approval of research under HHS regulations at 45 CFR 46.111. OHRP notes the following from the U of U IRB minutes from June 7, 2006 meeting:

(a) Agenda item 16 noted that the investigator indicated that patients with incidental cranial aneurysm could enter the study. The committee asked to know what the standard of care was for these patients but still voted to approve the study.

(b) Agenda item 19 noted that clarification was needed on how subjects would be recruited using ICD-9 methodology but still approved the protocol.

(c) Agenda item 22 asked the investigator to describe the mechanism for ensuring that women were not pregnant when they were enrolled but still approved the

protocol.

Corrective Action: OHRP acknowledges that the U of U IRB has explicitly addressed this issue through education of the IRB members and chairpersons and U of U's plan to have the future minutes better reflect the U of U IRB deliberations. OHRP finds that this corrective action adequately addresses this concern and is appropriate under the U of U FWA.

(2) HHS regulations at 45 CFR 46.103(a) and (b)(5) require that institutions have written procedures by which they will promptly report unanticipated problems to OHRP. In its August 8, 2006 letter, OHRP expressed concern that SOP: QA 901 Section 4 seemed to focus only on medical events as unanticipated problems involving risk to subjects.

Corrective Action: OHRP notes the U of U IRB plan to update SOP: QA 901 to include a process to include non-medical adverse events such as a breach in database security or computer theft. Please note that not all unanticipated problems are adverse events (i.e. resulting in harm). Please see OHRP's draft guidance on reporting adverse events and unanticipated problems at http://www.hhs.gov/ohrp/requests/aerg.html.

OHRP has the following remaining concern:

(3) [Redacted]

[Redacted]

Please provide OHRP with a response to the above concern by November 30, 2006. 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,

Paul J. Andreason, MD
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Ms Lori Kedington, Administrator, IRB, University of Utah
Dr. John F. Hurdle, Chair IRBs, University of Utah
Dr David LePay, FDA
Dr Thomas Puglsi, OHRO, VA
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Ms. Patricia ElHinnawy, OHRP
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