DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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January 3, 2007

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 October 25, 2006 (received via e-mail on November 29, 2006). OHRP acknowledges your clarifying remarks and corrective actions.

Based upon its review, OHRP makes the following determinations:

> Department of Health and Human Services (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, but 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 chairperson or another IRB member designated by the chairperson, continuing review must occur no later than one year after the date the protocol was reviewed by the convened IRB, not on the anniversary of the date the IRB chairperson or his or her designee verifies that IRB-specified conditions for approval have been satisfied.
>
> OHRP finds that for numerous protocols, the U of U IRB failed to conduct continuing review of research at least once per year.
>
> OHRP notes your response to our questions of October 11, 2006 concerning the 73 protocols for which there appeared to be continuing review renewal dates that were

separated by 13 or more months.

OHRP previously supplied a listing of the 73 protocols and the example of protocol IRB_00008533 that received continuing review on 3/2/2005 and that was apparently not reviewed again until 4/10/2006.

OHRP notes that your October 25, 2006 response states, "The convened IRB approved the majority of these studies within the twelve month approval period. In the past however, our procedure was to assign the approval and expiration dates based on the date the Chair signed the application to acknowledge that the convened board had approved study."

Corrective Action: OHRP notes that the U of U IRB has revised its procedure to associate the approval and expiration dates with the date of the meeting of the convened IRB review of the protocol. For protocols where this was the reason for the apparent lapse in IRB approval, OHRP finds that this corrective action adequately addresses this issue and is appropriate under the U of U FWA.

As a result, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which 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,

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

cc: Ms Lori Kedington, Administrator, IRB, University of Utah
Dr. Gerald S. Treiman, Chair IRBs, University of Utah
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