



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower
Building
1101 Wootton Parkway, Suite 200
Rockville,
Maryland 20852

Telephone: 240-453-8132
FAX: 240-453-6909
E-mail: Kristina.Borrer@hhs.gov

March 29, 2010

Brent E. Wallace, M.D.
Vice President and Chief Medical Officer
Intermountain Health Care
36 S. State Street, 17th Floor
Salt Lake City, UT 84111

Re: Human Research Subject Protections Under Federalwide Assurance FWA-7905

Dear Dr. Wallace:

Thank you for your February 24, 2010 report in response to our January 28, 2010 request. We have evaluated the documentation provided by the Intermountain Health Care (IHC) to determine compliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46). Based on review of your response, we make the following determinations:

A. Corrective actions for determination regarding your institution's system for protecting human subjects made in our January 28, 2010 letter:

We determined that the written policies and procedures are not in sufficient detail to accurately describe the following institutional review board (IRB) activities, as required by HHS regulations at 45 CFR 46.103(b)(4) and (5):

- (a) reporting findings and actions to the institution;
- (b) ensuring prompt reporting to the IRB of proposed changes in a research activity;
- (c) ensuring prompt reporting to the appropriate institutional officials, the department or agency head and our office of any suspension or termination of IRB approval.

Corrective Action: We acknowledge that written procedures for these activities have been developed. We determine that these corrective actions adequately address our determination, and are appropriate under the IHC FWA.

B. Additional determination regarding your institution's system for protecting human subjects

We determine that the IHC IRBs sometimes approved research at convened meetings contingent upon substantive modifications or clarifications that were directly relevant to the determinations required by the IRB under HHS regulations at 45 CFR 46.111 without requiring additional review by IRB at a convened meeting. We note that when the IRB at a convened meeting requests substantive clarifications or modifications regarding the protocol or informed consent documents that the IRB needs in order to make the determinations required by the IRB under HHS regulations at 45 CFR 46.111, IRB approval of the proposed research must be deferred, pending subsequent review by the convened IRB of responsive material, unless the research is eligible for review under an expedited review procedure.

In specific, we note the following:

- (a) The minutes of the January 8, 2009 meeting of the Urban Central Region IRB indicate that the investigators on the protocol tagged with RMS ID # 1009617, which had been contingently approved October 9, 2008, had responded to the issues raised by the IRB. These issues included an explanation of how the participants were identified to be approached for the study, and an explanation of why a standard randomized, parallel, positive controlled study design with a prospective statistical plan is not used for this study. We determine that the IRB had insufficient information at its October 9, 2008 meeting to make the determinations required for approval of research under HHS regulations at 45 CFR 46.111. In particular, the IRB was unable to determine that risks to subjects were minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and that informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116, without first reviewing the information requested by the IRB at its October 9, 2008 meeting.
- (b) The minutes of the January 7, 2009 meeting of the Urban North Region IRB indicate that the investigators on the protocol tagged with RMS ID #'s 1009760, which had been contingently approved September 3, 2008, responded to the issues raised by the IRB. These issues included a clarification of the reimbursement amount given to the subjects over the duration of the study. We determine that the IRB had insufficient information at its September 3, 2008 meeting to make the determinations required for approval of research under HHS regulations at 45 CFR 46.111. In particular, the IRB was unable to determine that informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by HHS regulations at 45 CFR 46.116.

Corrective Action: We acknowledge that IHC will educate IRB members regarding the requirements for approval set forth in 45 CFR 46.111, and that minutes of IRB meetings will specifically state the evaluative criteria described in 45 CFR 46.111 and whether they are met. We determine that these corrective actions adequately address our determination and are appropriate under the IHC FWA.

At this time, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

We appreciate IHC's continued commitment to the protection of human research subjects.

Sincerely,

Kristina C. Borrer, Ph.D.
Director
Division of Compliance Oversight

cc: Dr. Shelby A. Moench, IRB Administrator, IHC
Dr. Steven A. VanNorman, Chairperson, IHC IRB #1 and IHC Southwest Region IRB #2
Dr. Anthony Musci, Chairperson, IHC Family LDS Hosp - Urban Central Region IRB #1
Dr. Richard White, Chairperson, McKay-Dee Hosp Ctr - Urban North Region IRB#1
Dr. Paul Urie, Chairperson, IHC - Urban South Region IRB
Dr. Margaret Hamburg, Commissioner, Food and Drug Administration (FDA)
Dr. Joanne Less, FDA
Ms. Sherry Mills, National Institutes of Health (NIH), Office of Extramural Research
Mr. Joe Ellis, NIH, Office of Extramural Research