DEPARTMENT OF HEALTH & HUMAN SERVICE

Office of the Secretary
Office of Public Health and Science

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September 26, 2008

Murray G. Ramsden, HBA, DHA, CHE
Chief Executive Officer
Interior Health Authority
Kelowna, British Columbia V1Y 4N7
CANADA

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 10352

Dear Dr. Ramsden:

Thank you for your August 26, 2008 report responding to our June 23, 2008 letter regarding compliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46).

In our December 18, 2007 letter, we made the following determinations, among others:

> (1) We determined that the Interior Health Authority (IHA) did not have written institutional review board (IRB) procedures that adequately described the following activities, as required by HHS regulations at 45 CFR 46.103(a) and 46.103(b)(4) and (5): The procedures for ensuring prompt reporting to any department or agency head, and the Office for Human Research Protections (OHRP) of: (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval.
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> **Corrective Action:** We acknowledge that IHA has developed written IRB procedures to address the procedures for ensuring prompt reporting to any department or agency head and OHRP of: (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval.
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> (2) HHS regulations at 45 CFR 46.115(a)(2) require that minutes of IRB meetings be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written

summary of the discussion of controverted issues and their resolution. We determined that IHA and Penticton IRB minutes failed to include the vote on actions including the number of members voting for, against, and abstaining.

Corrective Action: OHRP acknowledges that in the revised Terms of Reference, the requirement for recording of voting has been made explicit. We also acknowledge that the role statement of the secretary has been revised to ensure that minutes of IRB meetings include documentation of the votes on all actions including the number of members voting for, against, and abstaining.

In our June 23, 2008 letter, we made the following additional determination:

(3) 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. We determined that the IHA IRB failed to conduct continuing review of research at least once per year for the protocol "Albumin in Acute Stroke: ALIAS." We noted that the study was initially approved November 6, 2006 and was not reviewed and approved again until February 7, 2008.

Corrective Action: OHRP acknowledges that the Guidelines for Principal Investigators have been revised to provide additional information regarding responsibility for continuing review. We also acknowledge that the addition of an electronic tracking system for research activities will allow the IRB to more easily identify those studies for which approval is ending and remind the research staff of this.

We determine that these corrective actions adequately address our determinations and are appropriate under the IHA 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 the continued commitment of your institution to the protection of human research subjects. Please feel free to contact me should you have any questions.

Sincerely,

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

cc: Dr. Anne-Marie Broemeling, Director, Research & Evaluation, Strategic Information & Planning, IHA
Ms. Susan Valley, Chairperson, Penticton Regional Hospital IRB
Ms. Beryl A, Ferguson, Chairperson, IHA IRB
Commissioner, FDA
Dr. Joanne Less, FDA

Ms. Lou Valdez, OGHA
Dr. Sherry Mills, NIH
Dr. Joe Ellis, NIH