DEPARTMENT OF HEALTH & HUMAN SERVICES

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OFFICE OF PUBLIC HEALTH AND SCIENCE

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August 21, 2001

Mr. Murray Ramsden, CEO
Okanagan Similkameen Health Region – Corporate
2180 Ethel Street
Kelowna, BC
V1Y 3AI

RE: Human Research Subject Protections Under Cooperative Project Assurance (CPA) T-4165

Dear Mr. Ramsden:

The Office for Human Research Protections (OHRP) has reviewed Penticton Regional Hospital's (PRH's) June 21 and July 25, 2000 responses to concerns expressed in OHRP's letters of June 6, 2000 and May 31, 2001. OHRP has determined that PRH's corrective actions substantially address the issues raised, with the following caveats:

(1) PRH has developed written IRB policies and procedures ("Standard Operating Procedures – Clinical Trials") describing operational activities set forth in the U. S. Department of Health and Human Services (HHS) regulations for the protection of human research subjects at 45 CFR 46.103(b)(4) and (5). However, OHRP notes that PRH's reporting policies should include the obligation to report unanticipated problems involving risks to subjects or others involved in HHS-supported research to OHRP.

(2) HHS regulations at 45 CFR 46.109(e) and 46.103(b)(4) require IRBs to determine which protocols require continuing review more often than annually, based upon the degree of risk. OHRP notes that although the PCH IRB has made the determination to review protocols more often than annually, PCH's Standard Operating Procedures describe continuing review as "Annual Renewal" and indicate that all IRB approvals expire in one year. OHRP recommends that PCH clarify its Standard Operating Procedures to state that continuing review is to be conducted at intervals appropriate to the degree of risk and not less than once per year.

(3) HHS regulations at 45 CFR 46.115(a)(2) require that minutes of IRB meetings be in sufficient detail to show 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. OHRP notes that while PRH has complied with most of these requirements, IRB minutes do not describe the number of members voting upon actions. OHRP recommends that IRB minutes reflect the actual number of votes rather than a designation of "unanimous" or that "all members approved" of an action.

Presuming resolution of the issues set forth above, there should be no need for further OHRP involvement, and we are therefore closing this matter. Please do not hesitate to contact me should you have any questions. OHRP appreciates PRH's continued commitment to the protection of human research subjects.

Sincerely,

Carol J. Weil, J.D.
Division of Compliance Oversight

cc: Ms. Susan Marlin, Msc, NCIC
Ms. Lorraine Ferguson, Administrator, Penticton Regional Hospital
Mr. John Mowry, IRB Chair, Penticton Regional Hospital
Ms. Pat Lawrence, Ethics/Research Committee, Penticton Regional Hospital
Dr. Kristina Borror, OHRP
Dr. Michael Carome, OHRP
Ms. Helen Gordon, OHRP
Dr. Greg Koski, OHRP
Dr. Melody Lin, OHRP
Dr. Jeffrey Cohen, OHRP
Dr. Cliff Scharke OHRP
Mr. Barry Bowman, OHRP
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James McCormack, FDA