DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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April 27, 2005

John R. Sladek, Jr., Ph.D.
Vice Chancellor for Research
University of Colorado Health Sciences Center
Office of the Chancellor
4200 East Ninth Avenue
Campus Box A095
Denver, Colorado 80262

**RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 5070**

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|---|---|
| **Research Project:** | **The Joint Outcomes Study** |
| **Principal Investigator:** | **Marilyn Manco-Johnson, M.D.** |
| **Protocol Number:** | **95-011** |

Dear Dr. Sladek:

The Office for Human Research Protections (OHRP) has reviewed the University of Colorado Health Sciences Center's (UCHSC) March 30, 2005 letter, which was submitted in response to OHRP's letter of March 1, 2005.

After reviewing your report, OHRP notes the following additional corrective actions taken by UCHSC:

(1) The UCHSC institutional review board (IRB) has made continued progress on its review of exempt protocols.

(2) The UCHSC IRB has reviewed the informed consent documents for certain protocols noted in OHRP's December 15, 2005 letter, and has made changes to these documents as appropriate.

(3) The UCHSC has provided additional training opportunities to its IRB members and research investigators regarding human subjects protections.

(4) The UCHSC has made appropriate changes to its standard operating procedures for

conducting IRB meetings and for reporting suspensions and terminations of research.

As a result of these corrective actions, as well as those noted in OHRP's letter of March 1, 2005, OHRP finds that UCHSC has adequately addressed the determinations made in OHRP's letter of December 15, 2004. Therefore, there should be no need for further involvement of OHRP in this matter.

At this time OHRP has the following additional guidance:

> OHRP recommends that UCHSC consider revising its standard operating procedure for reporting suspensions and terminations (SOP# IR-070) to include a list of corrective actions being taken by UCHSC as part of its report to OHRP. In addition, OHRP notes that reports submitted to OHRP should be sent to the attention of the Division of Compliance Oversight.

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,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Ms. Lisa Jensen, Director, COMIRB
Mr. Ken Easterday, Chair, IRB Panel A, UCHSC
Dr. Norman Stoller, Chair, IRB Panel B, UCHSC
Dr. Doug Ford, Chair, IRB Panel C, UCHSC
Mr. Stephen Bartlett, Chair, IRB Panel D, UCHSC
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Lana Skirboll, NIH
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Ms. Shirley Hicks, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP