



Office for Human Research Protections
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May 28, 2004

Peter O. Kohler, M.D.
President
Oregon Health & Science University
3181 S.W. Sam Jackson Park Rd. L101
Portland, OR 97201-3098

RE: Human Research Protections Under Federalwide Assurance FWA-161

Research Project: Student Athlete Drug Surveillance Trial (SATURN)
Principal Investigator: Linn Goldberg, M.D.
OHSU IRB Number: 4682
HHS Protocol Number: R01DA012018

Dear Dr. Kohler:

The Office for Human Research Protections (OHRP) has reviewed Oregon Health & Science University's (OHSU) May 12, 2004 letter regarding the above-referenced research project that was submitted by the OHSU in response to OHRP's January 15, 2004 letter.

OHRP acknowledges OHSU's statement that the above-referenced research project (the SATURN study) has been permanently closed to enrollment of human subjects and any direct interactions with human subjects. The study is only active for analysis of data that has been permanently stripped of all identifiers and can never be linked to identifiable private information.

Given OHSU's statements, OHRP notes that the restriction placed on the OHSU Assurance (FWA-161) is no longer necessary.

As a result, OHRP hereby has removed the restriction on the OHSU FWA, effective immediately, and is closing its investigation into the SATURN study. OHRP anticipates no need for further involvement with OHSU related to this matter. Please note that OHRP should be notified immediately in the event OHSU decides to reopen the SATURN study in a manner that involves human subjects.

OHRP notes that analysis of data that has been permanently stripped of all identifiers and can never be linked to identifiable private information would not be considered human subjects research and therefore does not require continued oversight by the OHSU Institutional Review Board.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Do not hesitate to contact me should you have any questions.

Sincerely,

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

cc: Dr. Gary T. Chiodo, OHSU IRB#1 & #3 Chair
Dr. Susan Hansen, OHSU IRB#2 Chair
Dr. William C. Jacobs, Western IRB Chair
Dr. Charlotte Shupert, Compliance Manager, OHSU
Dr. Lana Skirboll, Director, Office of Science Policy, NIH
Dr. Nora Volkow, Director, NIDA
Dr. Bernard Schwetz, OHRP
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Ms. Shirley Hicks, OHRP
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Ms. Melinda Hill, OHRP
Ms. Patricia El-Hinnawy, OHRP