



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

Telephone: 301-435-8072
FAX: 301-402-2071
email: kberrorr@osophs.dhhs.gov

January 15, 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 your September 26, 2003 report regarding the above-referenced research project that was submitted by the Oregon Health & Science University (OHSU) in response to OHRP's October 24, 2002 and April 17, 2003 letters.

In its October 24, 2002 letter, OHRP made the following determinations regarding the SATURN study.

- (1) OHRP found that mandatory drug testing of student athletes is an integral part of the design of the SATURN research protocol.
- (2) Department of Health and Human Services (HHS) regulations at 45 CFR 46.116 require, among other things, that the investigator shall seek informed consent only under circumstances that minimize the possibility of coercion or undue influence. OHRP found that the circumstances under which subjects were enrolled and the study was conducted failed to meet this requirement.
- (3) HHS regulations at 45 CFR 46.103(a) require that each institution "engaged" in human subjects research that is conducted or supported by HHS provide OHRP with a satisfactory assurance of compliance with the regulations, unless the research is exempt under 45 CFR 46.101(b). (Please see OHRP guidance at

<http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm>.)

An institution becomes "engaged" in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)].

OHRP found that (a) all of the participating SATURN high schools were engaged in human subjects research funded by HHS and (b) none of these sites obtained an OHRP-approved assurance for this research.

OHRP Findings and Action

In its October 24, 2002 letter, OHRP restricted the OHSU Assurance (FWA-161), and OHRP's April 17, 2003 letter upheld that restriction. Under this restriction, the applicability of FWA-161 to the above-referenced research project (the SATURN study) was suspended until OHSU developed a satisfactory corrective action plan to address all deficiencies and concerns described above as a condition for OHRP consideration of removal of the restriction on the OHSU FWA.

OHRP finds that the OHSU September 26, 2003 letter fails to add any substantive information to previous reports and that the OHSU corrective action plan still fails to adequately address the findings made by OHRP in its October 24, 2002 letter. In specific, OHRP finds that the plan fails to adequately address the finding that the informed consent of the subjects is not being sought under circumstances that minimize the possibility of coercion or undue influence, as required by HHS regulations at 45 CFR 46.116. As a result, the OHRP restriction on the OHSU FWA remains in effect and the SATURN study must remain suspended until OHSU develops a satisfactory corrective action plan to address these findings. OHRP notes again that the findings noted in paragraphs (1), (2), and (3) above may be impossible to address under the current protocol and that a satisfactory corrective action plan most likely will have to include (i) termination of the current study; and (ii) designing a new study that provides for an informed consent procedure which minimizes the possibility of coercion or undue influence.

OHRP acknowledges that the OHSU IRB has approved the SATURN study for analysis of existing data and publication of the results of the first two years of the study. Please note that the restriction states that the applicability of FWA-161 to the above-referenced research project (the SATURN study) is suspended. This means that no human subjects research may be conducted for the SATURN study. HHS regulations at 45 CFR 46.102(f) define a human subject as a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. OHRP has interpreted "obtain" to include analysis. Therefore, no analysis of identifiable private information may be conducted in the SATURN study under this restriction. 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 could continue under OHRP's restriction.

OHRP encourages OHSU to develop its revised corrective action plan expeditiously, and forward it to OHRP for review as soon as possible. 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
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Ms. Shirley Hicks, OHRP
Ms. Janice Walden, OHRP
Ms. Melinda Hill, OHRP
Ms. Patricia El-Hinnawy, OHRP