DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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July 28, 2005

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

John Fletcher
Chief Administrative Officer
Providence Health System
1235 N.E. 47th Avenue, Suite 299
Portland, OR 97213-2100

RE: Human Research Subject Protections Under Federalwide Assurances FWA-161 and FWA-1033

Research Project:	**Echocardiographic and Historical Screening for Familial Dilated Cardiomyopathy**
Principal Investigator:	**Ray Hershberger, M.D.**
OHSU Protocol #:	**3457**
HHS Award #:	**R01HL58626-01**

Dear Dr. Kohler and Mr. Fletcher:

The Office for Human Research Protections (OHRP) has reviewed the May 4, 2005 report submitted by Providence Health System (PHS) and the June 7, 2005 report submitted by Oregon Health and Science University (OHSU) in response to OHRP's letter of April 8, 2005. Based upon our review of these reports and OHSU's June 22, 2004 report, OHRP makes the following determinations:

(1) Department of Health and Human Services (HHS) regulations at 45 CFR 46.117(a) require that informed consent shall be documented by the use of a written consent form

approved by the institutional review board (IRB) and signed by the subject or the subject's legally authorized representative. OHRP finds that a blood sample was procured for research purposes from the complainant's mother without informed consent being obtained using a written consent form.

(2) HHS regulations at 45 CFR 46.103(b)(4)(iii) and 108(a) require that the IRB follow written procedures for ensuring prompt reporting to the IRB of proposed changes to a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB approval except when necessary to eliminate apparent immediate hazards to the subject. OHRP finds that informed consent was to be obtained by someone other than the research staff after the investigators faxed the consent document to PHS, and this procedure was not first approved by the OHSU IRB.

Corrective Action: OHSU has provided education for the principal investigator and his team on the requirement of having changes in the informed consent process for this study approved in advance by the IRB. OHSU has also provided guidance to its investigators via the IRB website on this topic. In addition, the topic of informed consent has been added to the OHSU on-line responsible conduct of research education module.

OHRP notes that OHSU has requested clarification as to whether Providence-St. Vincent Hospital was engaged in the above-referenced research. OHRP believes that since Providence-St. Vincent Hospital's involvement with the research was limited to (i) collection of the blood sample and (ii) providing the complainant a copy of the OHSU informed consent document, Providence-St. Vincent Hospital could be considered not to be engaged in the research.

OHRP finds that the corrective actions described above adequately address OHRP's determinations. In addition, OHSU has adequately addressed the additional allegations and questions raised in OHRP's letters of May 26, 2004 and April 8, 2005. As a result, there should be no need for further involvement of OHRP in this matter. OHRP appreciates the continued commitment of your institutions 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: Dr. Gary Chiodo, OHSU
Dr. Ray Hershberger, OHSU
Ms. Claudia Haywood, Providence Health System

Dr. Lana Skirboll, NIH
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Ms. Shirley Hicks, OHRP
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