DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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November 3, 2004

Theodore G. Krontiris, M.D., Ph.D.
Executive Vice President for Medical
and Scientific Affairs
City of Hope National Medical Center
and Beckman Research Institute
Administrative Offices
Needleman Building
1500 East Duarte Road
Duarte, CA 91010-3000

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 692

Research Project:	**Prostate Cancer Prevention Trial**
Principal Investigator:	**Timothy Wilson, M.D.**
Protocol Number:	**93090**

Dear Dr. Krontiris:

The Office for Human Research Protections (OHRP) has reviewed the City of Hope National Medical Center and Beckman Research Institute's (COH) October 5, 2004 report, which was submitted in response to OHRP's August 23, 2004 letter.

In its August 23, 2004 letter, OHRP made the following determination:

> OHRP found that the COH institutional review board (IRB)-approved informed consent document for the research failed to describe adequately the risk of serious infection associated with prostate biopsy, which may require hospitalization and could result in death, as required by Department of Health and Human Services (HHS) regulations at 45 CFR 46.116(a)(2).
>
> OHRP acknowledges that the above-referenced research has been closed and all research-related procedures and follow-up have been completed. As a result, OHRP's required

action that the informed consent process for the above-referenced research be amended for any subjects scheduled to undergo prostate biopsy is unnecessary. In addition, COH has adequately addressed the additional concern noted in OHRP's August 23, 2004 letter. As a result of these determinations, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects.

Sincerely,

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

cc: Ms. Gwen Oki, Director, Research Subject Protection, COH
Dr. John Zaia, Chair, COH IRB
Dr. Timothy Wilson, COH
Dr. Lana Skirboll, Director, Office of Science Policy, NIH
Dr. Andrew von Eschenbach, Director, NCI, NIH
Ms. Joan Mauer, NCI, NIH
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Bernard Schwetz, OHRP
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Ms. Shirley Hicks, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Janet Fant, OHRP