DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852
Telephone: 240 453-8297
FAX: 240 453-6909

January 25, 2006

John C. McDonald, M.D.
Chancellor/Dean
Louisiana State University Health Science Center Shreveport (LSUHSCS)
PO Box 33932
1501 Kings Hwy
Shreveport, LA 71130-3932

RE: Human Research Subject Protections Under Federalwide Assurance FWA-653

Research Project: Neoadjuvant Zoladex and Flutamide in Bulky and Non-Bulky Clinical Stage C Carcinoma of the Prostate, Phase II
Principal Investigator: Dennis Venable, M.D.
Project Number: SWOG 9109

Dear Dr. McDonald:

The Office for Human Research Protections (OHRP) has reviewed Louisiana State University Health Science Center Shreveport's (LSUHSCS) November 22 and November 30, 2005 responses to OHRP's letter of October 31, 2005 regarding the above-referenced research.

Based upon its review, OHRP makes the following determinations.

(1) Department of Health and Human Services (HHS) regulations at 45 CFR 46.116 prohibit any oral or written exculpatory language in the informed consent process, through which the subject is made to waive, or appear to waive, any legal rights. In its October 31, 2005 letter, OHRP found the following language in the IRB-approved informed consent document signed by the subject in the above research to be exculpatory:

> By your consent to participation in this research study, you give up your property rights that you may have in your bodily fluids, substances or tissues.

Corrective Action: OHRP acknowledges LSUHSCS's statement that the IRB approved an amendment to the above research on July 1, 2005, which deleted the exculpatory consent document language and provided a separate consent form (not containing exculpatory language) for the use of tissue in future research. The separate consent form for future use of tissue enables subjects to choose, separately from choosing whether to

participate in the research study, whether to permit tissue removed as a result of the research to be used in future research studies. The separate consent form also states that such removed tissue will not be sold but may help develop new products in the future which may have some economic value. OHRP finds that this corrective action adequately addresses the above finding and is appropriate under the LSUHSCS FWA.

(2) In its October 31, 2005 letter, OHRP found that LSUHSCS's Standard Operating Procedures (SOPs) dated 07/01/03 did not have written IRB procedures that adequately describe the following activities, as required by HHS regulations at 45 CFR 46.103(a) and 46.103(b)(4) and (5):

> (a) The procedures which the IRB will follow for conducting its initial review of research.
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> (b) The procedures which the IRB will follow for conducting its continuing review of research.
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> (c) The procedures which the IRB will follow for reporting its findings and actions to investigators and the institution.
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> (d) The procedures which the IRB will follow for determining which projects require review more often than annually.
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> (e) The procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.
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> (f) The procedures which the IRB will follow for ensuring prompt reporting to the IRB of proposed changes in 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 review and approval except when necessary to eliminate apparent immediate hazards to the subject.
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> (g) The procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any department or agency head, and OHRP of: (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval.

Corrective Action: LSUHSCS's current SOPs dated 09/09/05 include operational details for the written procedures required at 45 CFR 46.103(a) and 46.103(b)(4) and (5). OHRP finds that this corrective action adequately addresses the above finding and is appropriate under the LSUHSCS FWA.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Feel free to contact me should you have any questions.

Sincerely,

Carol J. Weil, J.D.
Compliance Oversight Coordinator
Division of Human Subject Protections

cc: Mr. Michael Manheimer, LSUHSCS, Director, Grants Administration, IRB Administrator
Dr. Steven A. Conrad, LSUHSCS IRB Chair
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Ms. Shirley Hicks, OHRP
Ms. Pat El-Hinnawy, OHRP
Ms. Janet Fant, OHRP
Commissioner, FDA
Dr. David Lepay, FDA

Rosenstein's address:

Office of the Clinical Director, NIMH
Building 10, Room 3N242
10 Center Drive
MSC 1277
Bethesda, MD 20892-1277

Insel's address:

Dr. Thomas Insel, Director, NIMH
6001 Executive Blvd., Room 8235
Rockville, MD 20852