



Office for Human Research Protections
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April 12, 2006

Seymour Mitchell, M.S.W.
CEO
Delta Health Center
702 Martin Luther King Road, P.O. Box 900
Mound Bayou, MS 38762

RE: Human Research Subject Protections Under Federalwide Assurance FWA- 2033

**Research Project: Phase III Randomized Study of Selenium and Vitamin E for the
Prevention of Prostate Cancer– SELECT
Project Number: SWOG-S0000**

Dear Mr. Mitchell:

The Office for Human Research Protections (OHRP) has reviewed the Delta Health Center's (DHC) December 20, 2005 report and Delta State University institutional review board's (DSU IRB's) January 16 and March 26, 2006 reports responding to allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46).

OHRP acknowledges that DHC has been notified by the Southwest Oncology Group that DHC's participation in the SELECT protocol has been permanently "suspended and closed." In addition, the DSU IRB has incorporated changes recommended by OHRP into their IRB Manual. Numerous other corrective actions taken by DHC and DSU have been described in OHRP's February 14, 2006 letter.

OHRP finds that the corrective actions taken adequately address the findings and are appropriate under the DHC FWA. As a result of this determination, 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 institutions to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

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

cc: Dr. J. Reid Jones, IRB Chairperson/Academic Research Coordinator, Delta State U
Dr. Suzette Hornsby-Odoi, MD, Dir. Clin. Services, Delta Health Center
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Lana Skirboll, Director, Office of Science Policy, NIH
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