DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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September 16, 2004

Alfred B. Knight, M.D.
President & CEO
Scott & White Memorial Hospital
& Scott, Sherwood & Brindley Foundation
2401 South 31st Street
Temple, TX 76508

RE: Human Research Subject Protections Under Federalwide Assurance FWA- 3358

Dear Dr. Knight:

The Office for Human Research Protections (OHRP) has reviewed the documents related to the above-referenced research that were submitted with your report of July 29, 2004, in response to OHRP's letter of June 24, 2004.

> It was alleged that the institutional review board (IRB) failed to have diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, as required by Department of Health and Human Services (HHS) regulations at 45 CFR 46.107(a).
>
> **Corrective Action:** OHRP acknowledges Scott & White's (S&W) statement that, while the S&W IRB members are sensitive to cultural issues across various subject populations, S&W has not yet been successful in recruiting members of diverse ethnicity. S&W has recently appointed several new members to its IRB to enhance its cultural diversity and satisfy the requirements of HHS regulations at 45 CFR 46.107(a), and such efforts will continue. OHRP finds that these corrective actions adequately address the allegation. OHRP encourages S&W's efforts to further increase the diversity of its IRB.

As a result of the above 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.

At this time, OHRP offers the following additional guidance:

Written IRB policies and procedures should provide a step-by-step description with key operational details for each of the procedures required by HHS regulations at 45 CFR 46.103(b)(4) and (5). Please see OHRP's Guidance on Written IRB Procedures at http://www.dhhs.gov/ohrp/humansubjects/guidance/irbgd702.htm.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

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

cc: Ms. Carrice E. Dunnahoo, Director, Research Compliance, Scott & White Mem Hosp
Dr. Thomas J. Wincek, Chairperson, Scott & White Mem Hosp/SS&BF IRB #1
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Ms. Shirley Hicks, OHRP
Ms Patricia El-Hinnawy, OHRP
Ms. Melinda Hill, OHRP