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 6, 2004

John R. Raymond, M.D.
Vice President for Academic Affairs and Provost
Medical University of South Carolina
171 Ashley Avenue
P.O. Box 250002
Charleston, SC 29425

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 00001888

Research Activity:	**Alpha-1 Research Registry**
Principal Investigator:	**Dr. Charles Strange**
Project Number:	**HR #9059**

Dear Dr. Raymond:

The Office for Human Research Protections (OHRP) has reviewed the Medical University of South Carolina's (MUSC) reports dated May 25 and June 9, 2004, in response to allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) in the above-referenced research.

In its April 21, 2004 letter, OHRP found that the informed consent document reviewed and approved by the MUSC institutional review board (IRB) for the above-referenced research failed to include several specific elements of informed consent required by HHS regulations at 45 CFR 46.116(a). OHRP also determined that the MUSC IRB did not find and document the criteria necessary to waive these elements of informed consent, as required by HHS regulations at 45 CFR 46.116(d). As a result, OHRP required MUSC to file a satisfactory corrective action plan to ensure that the IRB approves informed consent documents as required by HHS regulations.

OHRP acknowledges that MUSC has submitted to OHRP a corrective action plan that describes the following steps taken by the MUSC IRB to address these issues:

(1) The IRB has renewed efforts to ensure that the purpose of the research is clearly and concisely stated in the first paragraph of the informed consent document.

(2) In reviewing new protocols as well as evaluating applications for continuing review, the IRB has asked its community board members to be particularly vigilant regarding the presence and clarity of the purpose statement.

(3) The IRB has added a notation to the reviewer checklist reminding members to assess the adequacy of the purpose statement carefully.

(4) New paragraphs will be included in each IRB-approved informed consent document, stating (a) the process for seeking medical treatment for injuries as a result of participation in the research; (b) that participation is voluntary and that subjects may withdraw at any time; and (c) subjects should call the MUSC IRB if questions arise concerning the rights of a research subject.

(5) The MUSC IRB's corrective action plan will be used by the MUSC Office of Compliance to evaluate future research protocols.

(6) The MUSC Office of Compliance will request additional IRB review for research studies where the IRB has waived the elements of informed consent.

OHRP has determined that these corrective actions and those outlined in OHRP's letter of April 21, 2004 appropriately address the issues raised. As a result, 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 MUSC's continued commitment to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Rina Hakimian, J.D., M.P.H.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Raymond S. Greenberg, President, MUSC
Dr. Edward Conradi, MUSC Compliance Officer
Ms. Becky Roberts, IRB Administrator, MUSC
Dr. Patricia Arford, Chair, IRB I & II, MUSC
Dr. Robert Malcolm, Chair, IRB III, MUSC
Dr. Franklin Bolander, Chair, IRB #1, Univ. of South Carolina
Dr. Bernard Schwetz, OHRP
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Dr. Michael Carome, OHRP
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Ms. Shirley Hicks, OHRP
Ms. Jan Walden, OHRP
Ms. Melinda Hill, OHRP
Ms. Patricia El-Hinnawy, OHRP