DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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September 15, 2008

Suniti Solomon
Managing Trustee
YR Gaitonde Center for AIDS Research and Education
YRG CARE
#7, Krishna Street
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Chennai 600017 India

Re: Human Research Subject Protections under Federalwide Assurance FWA-00000672

Dear Mr. Solomon:

Thank you for your responses to the Office for Human Research Protection's (OHRP) request (dated May 1, 2008) for information to conduct an evaluation of the YR Gaitonde Center for AIDS Research and Education's system for protecting human subjects. The evaluation was conducted as part of our program to evaluate human subjects protection programs of institutions that receive Department of Health and Human Services (HHS) support for research in compliance with 45 CFR part 46. Based on the documentation provided in your June 16 and 20, 2008 correspondence, we have determined the following:

A. Determinations regarding your institution's system for protecting human subjects:

(1) HHS regulations at 45 CFR 46.108 require that, "…the [institutional review board (IRB)] review proposed research at convened meetings at which a majority of the members of the IRB are present." We have determined that the IRB failed to meet this requirement at the May 24, 2008 IRB meeting, when the IRB meeting convened and conducted business with only 7 of 15 IRB members in attendance. Further, we have noted that IRB Policies and Procedures state that "…no fewer than five (5) voting members will constitute a quorum for the transaction of business." This number is inadequate, as the IRB currently consists of 15 members.

Required Action: Please provide a corrective action plan to address the findings above. In your plan, please provide the procedures the IRB will use to ensure that all HHS-

supported research will be reviewed and approved at convened meetings at which a majority of the members of the IRB are present.

(2) HHS regulations at 45 CFR 46.115(a)(2) require that minutes of IRB meetings be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on each of these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research. We have determined that the May 24, 2008 IRB meeting minutes failed to indicate the number of members voting for, against, and abstaining. Additionally, the IRB Policies and Procedures, Section C.1 The Review Process, state that "[i]f the IRB is unable…to reach consensus…a decision may be made by vote of a simple majority." This statement suggests that votes may not be taken for each IRB action.

Required Action: Please provide a corrective action plan to address the findings above. In your plan, please provide the procedures that the IRB will use to ensure that IRB meeting minutes for HHS-supported research include the detail outlined in 45 CFR 46.115(a)(2).

B. Questions and Concerns:

[Redacted]

C. Recommendation:

(1) We have reviewed the YRG CARE IRB Policies and Procedures, and recommend that more operational details be included for some procedures required by HHS regulations at 45 CFR 46.103(b)(4 and 5); specifically:

- procedures which the IRB will follow for determining which projects require review more often than annually;
- 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;

- procedures which the IRB will follow for prompt reporting to 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.

We recommend reassessing the IRB Policies and Procedures for the information listed above. Please refer to OHRP Guidance on Written IRB Procedures http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.htm, for additional guidance to ensure that IRB Policies and Procedures are in sufficient detail of processes required by HHS regulations at 45 CFR 46.103.

(2) The document titled "YRG Care Program for Education in Protection of Human Participants" does not include HHS regulations training for IRB members, staff or research investigators. We recommend incorporating a plan to train IRB members, staff and research investigators on HHS regulations (45 CFR part 46).

Please provide us with responses to the above determinations, questions and concerns by October 30, 2008, including a corrective action plan for each of our determinations. Feel free to contact me if you would like guidance in developing a corrective action plan.

We appreciate your institution's continued commitment to the protection of human research subjects.

Sincerely,

Lisa R. Buchanan, MAOM, CIP
Compliance Oversight Coordinator
Division of Compliance Oversight

cc:
Dr. Swarnalakshmi, IRB Regulatory Coordinator, YRG CARE
Dr. Ganapathy Murugan, IRB Chairperson/Dean, Meenakshi Medical College & Research Institute
Dr. Andrew C. von Eschenbach, FDA Commissioner
Dr. Joanne Less, FDA