DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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December 1, 2008

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

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

Dear Dr. Solomon:

Thank you for your October 30, 2008 report in response to our May 1, 2008 request that YRG CARE conduct an evaluation of its system for protecting human research subjects to ensure that it is in compliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46).

We reviewed the materials you provided in response to our May 1, 2008 request and made the following determinations in our September 15, 2008 letter:

(1) We determined that the YRG CARE institutional review board (IRB) failed to meet HHS regulation 45 CFR 46.108 that requires that, "…the [IRB] review proposed research at convened meetings at which a majority of the members of the IRB are present" during its May 24, 2008 IRB meeting, when the IRB meeting convened and conducted business with only 7 of 15 IRB members in attendance. And we noted that the IRB Policies and Procedures stated that "…no fewer than five (5) voting members will constitute a quorum for the transaction of business"—which was an inadequate number to establish quorum per your IRB roster which consisted of 15 members.

Corrective Action: We acknowledge that YRG CARE's IRB procedures have been revised to ensure that IRB meeting are conducted in compliance with HHS regulations found at 45 CFR 46.108.

(2) We also 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, stated that, "[i]f the IRB is unable…to reach consensus…a decision may be made by vote of a simple majority," and noted that this statement seemed to imply that a vote may not be taken for each IRB action as required by HHS regulations found at 45 CFR 46.115(a)(2) which 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.

Corrective Action: We acknowledge that YRG CARE's IRB procedures have been revised to ensure that IRB meeting minutes for HHS-supported research include the details outlined in HHS regulations found at 45 CFR 46.115(a)(2).

Lastly, we note that additional modifications and clarifications have been made to the YRG CARE IRB procedures and adequately address the questions, concerns and recommendations outlined in our September 15, 2008 letter.

We determine that the corrective actions outlined above adequately address our determinations and are appropriate under the YRB CARE FWA. At this time, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

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

Sincerely,

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

cc:
Dr. Swarna Swarnalakshmi, HPA, IRB Regulatory Coordinator, YRG CARE
Dr. Ganapathy Murugan, IRB Chairperson/Dean, Meenakshi Medical College & Research Institute
Dr. Andrew C. von Eschenbach, Commissioner, U.S. Food and Drug Administration (FDA)
Dr. Joanne Less, FDA