JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

FWA #00000287

Institutional Review Board Office

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ADMINISTRATIVE CHANGES REQUIRED FOR RELEASE OF APPROVAL DOCUMENTS NEW APPLICATION

Date: August 20, 2010

To: Sara Bennett, PhD
Department of International Health

From: Elizabeth A. Skinner
Chair, IRB-X

Re: Study Title: "Assessing the Long-term impacts of research training programs supported by the John E. Fogarty International Center "

IRB No: IRB00003099
Study Expiration Date: August 18, 2011

PLEASE NOTE: If you change any study document in ways other than those required by the IRB, your documentation will be returned to you to remove those changes. The changes required below are the only ones that you may make. Other changes to your study must be made separately via amendment after receiving your approval documents.

The JHSPH IRB-X made a determination of "Approved with Administrative Changes" for the above referenced study on **August 19, 2010**. This determination means that the following action must take place before your IRB approval is finalized and stamped IRB approved documents are released to you.

Please make the following changes or submit the following additional documents:

1. Please reconcile the difference in sample size numbers provided in the research plan pp.4-5 and the table summarizing the sample on pp. 6-8.

2. Please revise the consent form using JHSPH IRB template.

3. Please consistently state that FGDs & IDIs will be audio recorded.

4. Please add the total sample size as given in PHIRST (i.e., 167) to the research plan.

5. In section 5 of the research plan, “Data Security”, you have marked “X” to an option that states “No identifiers will be collected”, although you are asking for participants‘ names and signatures in the consent forms. Please select the correct option.

6. In section 14 of the research plan, “Oversight plan”, please provide information about the local co-investigator (i.e. name and affiliation). Also provide brief details about how the PI will be kept informed by the local investigator from the local site.

7. Please append the recruitment email and telephone script documents in PHIRST.

8. Please provide consent forms in the local languages (s) along with a certificate of translation (if applicable).

9. Please add the local co-investigator in PHIRST.

10. Please provide letters of support from the University of Nairobi and Makerere University.

11. Please provide local IRB approval letters from Uganda and Kenya.

12. Please provide a human subjects training certificate for Ligia Paina Bergman.

13. The study document identification (i.e., **study title, version number and/or date, and assigned IRB number**) needs to be added to or completed in the footer or header of all the study documents

Please upload your response as a separate document in the “**Miscellaneous**” section of PHIRST and any revised documents in their respective sections. Provide clearly labeled tracked changed and clean copies of any documents that have been revised. When you have completed your response, please click the “**Respond to Concerns**” link under “**My Activities**” and follow the instructions to return the application to the IRB. Upon receipt of your response, the review will continue.

We encourage you to respond quickly. The sooner you submit your response to this letter, the sooner your approved documents will be released. You may not start your study until the approved documents are released by the JHSPH IRB Office. If you need consent documents labeled “Do Not Use for Enrollment” to show to other IRBs or to your sponsor with this letter, please contact the IRB office.

If you have any questions regarding this action, please contact the JHSPH IRB Office at (410) 955-3193 or via email at irboffice@jhsph.edu.

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