EMORY UNIVERSITY | Institutional Review Board

TO: Susan Allen, MD, MPH
Principal Investigator
*SOM: Pathology: Admin

DATE: September 7th, 2016

RE: **Continuing Review Expedited Approval**
CR1_IRB00083001

IRB00083001
A randomized control study to evaluate a novel intervention to reduce risk factors associated with HIV acquisition from concurrent partners among HIV concordant negative couples in Zambia

Thank you for submitting a renewal application for this protocol. The Emory IRB reviewed it by the expedited process on **September 7th, 2016**, per 45 CFR 46.110, the Federal Register expeditable categories F2, F3, and F7 , and/or 21 CFR 56.110. This reapproval is effective from **September 9th, 2016** through **September 8th, 2017**. Thereafter, continuation of human subjects research activities requires the submission of another renewal application, which must be reviewed and approved by the IRB prior to the expiration date noted above. Please note carefully the following items with respect to this reapproval:

- OneLove_Aim3_Protocol_v1.3_28Mar2016_clean.docx

Any reportable events (e.g., unanticipated problems involving risk to subjects or others, noncompliance, breaches of confidentiality, HIPAA violations, protocol deviations) must be reported to the IRB according to our Policies & Procedures at www.irb.emory.edu, immediately, promptly, or periodically. Be sure to check the reporting guidance and contact us if you have questions. Terms and conditions of sponsors, if any, also apply to reporting.

Before implementing any change to this protocol (including but not limited to sample size, informed consent, and study design), you must submit an amendment request and secure IRB approval.

In future correspondence about this matter, please refer to the IRB file ID, name of the Principal Investigator, and study title. Thank you.

Sincerely,

Parul Reddy
Analyst Assistant
This letter has been digitally signed

CC:

Drakes	Janeen	*SOM: Pathology: Admin
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