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> I.R.B. No. 00005948 F.W.A. No. 00011697

15<sup>th</sup> June, 2016

## Ref. No. 2016-May-003

The Principle Investigator
Dr. Michael Mulimansenga Chanda & Dr. Till Barnighaussen
John Snow Inc. Company Limited
P.O. Box RW 51185,
LUSAKA.

Dear Dr's Mulimansenga & Barnighaussen,

## RE: ZAMBIAN PEER EDUCATORS FOR HIV SELF- TESTING (ZEST) STUDY.

Reference is made to your resubmission dated June 9, 2016. The IRB resolved to approve this study and your participation as Principal Investigator for a period of one year.

| Review Type                                | Ordinary                                      | Approval No. 2016-May-003                |
|--|---|--|
| Approval and Expiry Date                   | Approval Date:<br>15 <sup>th</sup> June, 2016 | Expiry Date: 14 <sup>th</sup> June, 2017 |
| Protocol Version and Date                  | Version-Nil                                   | 14 <sup>th</sup> June, 2017              |
| Information Sheet, Consent Forms and Dates | • English.                                    | 14 <sup>th</sup> June, 2017              |
| Consent form ID and Date                   | Version September 17, 2015                    | 14 <sup>th</sup> June, 2017              |
| Recruitment Materials                      | Nil   | 14 <sup>th</sup> June, 2017              |
| Other Study Documents                      | Baseline Quantitative Questionnaire.          | 14 <sup>th</sup> June, 2017              |
| Number of participants approved for study  | -   | 14 <sup>th</sup> June, 2017              |

Specific conditions will apply to this approval. As Principal Investigator it is your responsibility to ensure that the contents of this letter are adhered to. If these are not adhered to, the approval may be suspended. Should the study be suspended, study sponsors and other regulatory authorities will be informed.

## **Conditions of Approval**

- No participant may be involved in any study procedure prior to the study approval
  or after the expiration date.
- All unanticipated or Serious Adverse Events (SAEs) must be reported to the IRB within 5 days.
- All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk (but must still be reported for approval).
   Modifications will include any change of investigator/s or site address.
- All protocol deviations must be reported to the IRB within 5 working days.
- All recruitment materials must be approved by the IRB prior to being used.
- Principal investigators are responsible for initiating Continuing Review
  proceedings. Documents must be received by the IRB at least 30 days before the
  expiry date. This is for the purpose of facilitating the review process. Any
  documents received less than 30 days before expiry will be labelled "late
  submissions" and will incur a penalty.
- Every 6 (six) months a progress report form supplied by ERES IRB must be filled in and submitted to us.
- ERES Converge IRB does not "stamp" approval letters, consent forms or study documents unless requested for in writing. This is because the approval letter clearly indicates the documents approved by the IRB as well as other elements and conditions of approval.

Should you have any questions regarding anything indicated in this letter, please do not hesitate to get in touch with us at the above indicated address.

On behalf of ERES Converge IRB, we would like to wish you all the success as you carry out your study.

Yours faithfully,

**ERES CONVERGE IRB** 

Dr. E. Munalula-Nkandu

BSc (Hons), MSc, MA Bioethics, PgD R/Ethics, PhD

CHAIRPERSON