

Ref: AMREF-ESRC P71/2013

17th July 2013

Caroline W Kabiru, PhD (Principal Investigator),
Research Scientist, APHRC,
Mobile: 0722 205933/ 0720 098388
Email: ckabiru@aphrc.org

Dear Caroline,

RESEARCH PROTOCOL: UNDERSTANDING POTENTIAL SOCIAL HARMS AND ABUSES OF ORAL HIV SELF-TESTING IN KENYA.

Thank you for submitting your research protocol to the AMREF Ethics and Scientific Review Committee (ESRC).

This is to inform you that the ESRC has reviewed and approved your above protocol. The approval period is from 17th July 2013 to 17th July 2014.

The approval is subject to compliance with the following requirements:

- a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- b) All changes (amendments, deviations, violations etc) are submitted for review and approval by AMREF ESRC before implementation.
- c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the ESRC immediately.
- d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to AMREF ESRC immediately.
- e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period (attach a comprehensive progress report to support the renewal).
- f) Clearance for export of biological specimens must be obtained from AMREF ESRC for each batch of shipment.
- g) Submission of an executive summary report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

Please do not hesitate to contact the ESRC Secretariat (esrc.kenya@amref.org) for any clarification or query.

Yours faithfully,



Dr. Mohamed Karama
Chair, AMREF ESRC

Cc. Dr. Meshack Ndirangu, Deputy Country Director, AMREF in Kenya and Vice Chair AMREF ESRC
Dr. David Ojaka, Programme Manager Research Advocacy and Business Development