



INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/1/2/3



MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
Tel: 33471/1/2/3
28th September, 2012

Reference: IREC/2012/118
Approval Number: 000903

Dr. N. Busakhala & Team,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Busakhala & Team,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee have reviewed your research proposal titled:

"Levels of Breast Cancer Awareness among Women Volunteering for Breast Cancer Screening in Western Kenya."

Your proposal has been granted a Formal Approval Number: **FAN: IREC 000903** on 28th September, 2012. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 27th September, 2013. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Yours Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE



| | | | |
|-----|-----------|---|------|
| cc: | Director | - | MTRH |
| | Principal | - | CHS |
| | Dean | - | SOM |
| | Dean | - | SPH |
| | Dean | - | SON |
| | Dean | - | SOD |



INDIANA UNIVERSITY
OFFICE OF RESEARCH ADMINISTRATION

To: THOMAS S INUI
GENERAL INTERNAL MEDICINE

From: IU Human Subjects Office
Office of Research Administration – Indiana University

Date: September 05, 2012

RE: NOTICE OF EXPEDITED APPROVAL

Protocol Title: AWARENESS OF BREAST CANCER AMONG MEN AND WOMEN IN WESTERN KENYA

Protocol #: 1208009290

Funding Agency/Sponsor: None

IRB: IRB-01, IRB00000220

Expiration Date: August 21, 2013

The above-referenced protocol was reviewed by the Institutional Review Board (IRB-01). The protocol meets the requirements for expedited review pursuant to §46.110, Category (7). The protocol is approved for a period of August 22, 2012 through August 21, 2013. This approval does not replace any departmental or other approvals that may be required.

If you submitted and/or are required to provide participants with an informed consent document, study information sheet, or other documentation, a copy of the enclosed approved stamped document is enclosed and must be used.

As the principal investigator (or faculty sponsor in the case of a student protocol) of this study, you assume the following responsibilities:

1. **CONTINUING REVIEW:** Federal regulations require that all research be reviewed at least annually. You may receive a “Continuation Renewal Reminder” approximately two months prior to the expiration date; however, it is the Principal Investigator’s responsibility to obtain review and continued approval *before* the expiration date. If continued approval is not received by the expiration date, the study will automatically expire, requiring all research activities, including enrollment of new subjects, interaction and intervention with current participants, and analysis of identified data to cease.
2. **AMENDMENTS:** Any proposed changes to the research study must be reported to the IRB prior to implementation. Only after approval has been granted by the IRB can these changes be implemented. An amendment form can be obtained at: http://researchadmin.iu.edu/HumanSubjects/hs_forms.html.
3. **UNANTICIPATED PROBLEMS AND NONCOMPLIANCE:** Unanticipated problems and noncompliance must be reported to the IRB according to the policy described in the Unanticipated Problems and Noncompliance SOP, which can be found at http://researchadmin.iu.edu/HumanSubjects/hs_policies.html. NOTE: If the study involves gene therapy and an event occurs which requires prompt reporting to the IRB, it must also be reported to the Institutional Biosafety Committee (IBC).
4. **ADVERTISEMENTS:** Only IRB-approved advertisements may be used to recruit participants for the study. If you submitted an advertisement with your study submission, an approved stamped copy is provided with the approval. To request approval of an advertisement in the future, please submit an amendment, explaining the mode of communication and information to be contained in the advertisement.
5. **COMPLETION:** Prompt notification must be made to the IRB when the study is completed (i.e. there is no further subject enrollment, no further interaction or intervention with current participants, including follow-up, and no further analysis of identified data). To notify the IRB of study closure, please obtain a close-out form at http://researchadmin.iu.edu/HumanSubjects/hs_forms.html.
6. **LEAVING THE INSTITUTION:** The IRB must be notified of the disposition of the study when the principal investigator (or faculty sponsor in the case of a student project) leaves the institution.
7. **VULNERABLE POPULATION:** Please note that there are special requirements for the inclusion of prisoners in research. You may not enroll or otherwise include an individual who is or becomes a prisoner while enrolled in the research. For additional information on the requirements for including prisoners in research, please refer to http://researchadmin.iu.edu/HumanSubjects/hs_policies.html.

Note: SOPs exist covering a variety of topics that may be relevant to the conduct of your research. For more information on the relevant policies and procedures, go to http://researchadmin.iu.edu/HumanSubjects/hs_policies.html.

You should retain a copy of this letter and any associated approved study documents (e.g. informed consent or information sheet) for your records. Please refer to the project title and number in future correspondence with our office. Additional information is available on our website at <http://researchadmin.iu.edu/HumanSubjects/index.html>. Please contact our office if you have questions or need further assistance.

Thank you.