STANDARD OPERATING PROCEDURES
FOR
INSTITUTIONAL RESEARCH &
ETHICS COMMITTEE

Foreword

In any biomedical research involving human beings, the study participants are the most vulnerable of the partners. They are at risk of physical and emotional exploitation. This is largely due to the high esteem in which health professionals and researchers are held by the lay public, which can easily be abused. In addition, there are special groups such as minors, refugees and mentally unsound who are even more prone to exploitation in research.

With increasing collaborative research involving external institutions/organizations of diverse societal backgrounds, there will be different interpretations of ethical issues. There is need therefore for regulation of research activities through establishment of Institutional Review Committees or Boards.

Moi University College of Health Sciences (CHS) and Moi Teaching and Referral Hospital (MTRH) have therefore jointly constituted an Institutional Research and Ethics Committee (IREC) to oversee research, work. The activities of IREC especially in review of research proposals may be prone to various forms of abuse that can inhibit rather than foster a research culture. It is therefore important that the systems and procedure for receiving, reviewing and approving research proposals are put in place. These systems should be standardized so as to allow expeditious, objective and reproducible review of proposals. The development and dissemination of the Standard Operating Procedures (SOPs) of IREC must therefore be viewed as an important step in fostering an ethical and humane research culture in our institutions. It is understood that, new ethical issues in health related research will keep emerging and hence there will be need for regular revisions of these SOPs to maintain their relevance to contemporary trends.

Prof. H.N.K Arap Mengech,
Director, MTRH, Eldoret.
1.0 Role of IREC

The Institutional Research and Ethics Committee (IREC), hereinafter called The Committee, was constituted jointly by Moi University College of Health Sciences (MU/CHS) and Moi Teaching & Referral Hospital (MT&RH). IREC shall serve as the regulatory entity for research at the MU/CHS and MT&RH and as an independent representative and competent body to review, evaluate and decide on the scientific and ethical merits of research proposals. It is committed to ensuring and guaranteeing the rights, dignity, safety and protection of actual or potential individuals and communities who participate in research. This respect for human participants should extend to non-human subjects, plants and environment. The Committee governs health research as guided by applicable laws and regulations of the Kenyan government and relevant international bodies. IREC reviews and approves research proposals for and on behalf of the National Council for Science.
and Technology which is the legal entity authorized to review and approve research in Kenya under Cap 250 of the Laws of Kenya.

2.0 MEMBERSHIP.

The Committee shall be composed of core members from various disciplines including Biomedical, Clinical and Social Sciences, Biostatistics, Law and a lay person. The District Medical Officer of Health of Uasin Gishu District shall also be an ex-officio member.

2.1. Co-option
The Committee shall co-opt a maximum of (2) member at any one time for independent expertise as and when required. The committee shall determine the duration of the co-option.

2.2. Appointments
The Committee members shall be appointed by the Director, MTRH, hereinafter referred to as the Appointing Authority. The appointing authority shall make the appointments in consultation with
the deans of the School of Medicine and the School of Public Health.

2.3. Tenure and conditions of appointment
IREC shall have Chair, Vice-Chair, Secretary, Administrator and other members. Members shall be appointed initially for a period of three (3) years, renewable once. To maintain continuity in the operations of the Committee, at least $\frac{1}{3}$ of the membership shall be retained. The outgoing Chairman shall be an ex-officio member in the incoming Committee. At appointment, members shall commit themselves to providing their updated resumes, avoidance of any scientific misconduct and upholding confidentiality of the committee’s proceedings.

Absence of a member for three consecutive meetings without valid reasons shall lead to a suspension or replacement.

2.4 Resignation
A member may resign after giving at least one month’s
notice to the appointing authority.

The Committee may recommend to the appointing authority the replacement.

2.5. Allowances.
Honoraria for IREC membership may be considered by the appointing authority on recommendation of the Committee.

2.6. Review Fees
The Committee may recommend/levy fees to cover administrative costs of research proposal review. The recommended amount for students is Kshs. 500=.

2.7 Contact Information for IREC
IREC shall have a designated physical address, telephone contact and E-mail address. The IREC Administrator shall also be the contact person.

3.0. TERMS OF REFERENCE (TOR)

Broad Terms Of Reference for the Committee are as follows:

3.1 Review And Approvals Of Research Proposals

The Committee shall provide independent, competent and ethical review of research proposals.

3.1.1 The Committee shall review research proposals submitted to it within a reasonable time and document its views in writing to the applicant(s).

3.1.2 The Committee shall safeguard the dignity, rights, safety, and well being of all study participants and communities paying special attention to investigations that may involve vulnerable participants.

3.1.3 The Committee may request the investigator(s) to explain any aspect of the study that may require personal appearance at its Committee meeting.

3.1.4 The committee will make available acceptable standard format accepted by for submissions of
research proposals.

3.1.5 The Committee meeting shall obtain relevant documents including but not limited to the following:-
- Summary of proposal.
- Study protocol(s) and /or amendments(s)
- Written informed consent forms(s) and questionnaires update(s) that the investigator proposes for use in the study
- Available safety information
- Information about benefits available to participants before deciding on any protocol
- Any other relevant documents desired.

3.1.6 The Committee shall consider the suitability of the investigator(s) for the proposed study with respect to relevant qualification, training and experience, as documented by current curriculum vitae and/or by any other relevant documentation.

3.1.7 The Committee shall review both the amount and type of benefit to participants to ensure that neither presents problems, coercion or undue influence on the study participants.

3.1.8 Submitted proposals that have been reviewed elsewhere shall be reviewed afresh by the Committee and the decision of IREC will be final.

3.1.9 The SOPs shall be reviewed and revised from time to time not exceeding 3 years.

3.2. Provide Leadership In Research And Development Through:

3.2.1 Setting out research policy
3.2.2 Providing research guidelines
3.2.4 Developing and maintaining an institutional research database
3.2.4 Providing training on research proposal
writing and critical appraisal of scientific literature

3.2.5 IREC shall maintain a database of its activities.

4.0 THE SECRETARIAT

The Secretariat shall consist of the Secretary, an Administrator and support staff.

5.0 FUNCTIONS AND RESPONSIBILITIES

5.1 Chair:
Shall:
• conduct meetings in accordance with the regulations
• Facilitate provision of training of new Committee members and continuing education for older members.
• Oversee the functions and activities of the Secretariat.
• Assign responsibilities and duties to any
• Member of the Committee.
• Sign the minutes of the committee meetings
• Sign approval letters for research proposals on the recommendation of the committee
• Provide liaison with the National Council for Research and other IRBs.

5.2 The Vice Chair
Shall:
• Perform all the functions and duties of the Chair whenever the Chair is absent
• Perform any other duties as assigned by the Committee or the Chair.

5.3 Secretary
Shall:
• Call meetings in consultation with the Chair
• Dispatch proposals to reviewers for scientific review
• Identify suitable reviewers in collaboration with the
Scientific Committee

- Receive reviewed proposals and comments from reviewers within the stipulated period.
- Prepare proposal review documents for discussion at regular Committee meetings.
- Oversee the functions and activities of the Administrator and the support staff.
- Take process and circulate the minutes of the IREC meetings.
- The Committee Secretariat shall keep and archive all original copies of the Committee minutes.

5.4 Administrator

Shall:
- Perform day to day running of the IREC secretariat including financial management with approval of the IREC.
- Receive and ensure that submissions of research proposals adhere to IREC SOPs.
- Provide general logistical support to the secretariat to ensure prompt execution of IREC mandate.
- Undertakes all other administrative duties as assigned.

5.5 Other Members of IREC

Shall:
- Review ALL proposals presented to IREC and circulate to members and submit types comments to the IREC office.
- Attend IREC meetings regularly and contribute constructively to the deliberations.
- Offer other technical support to uphold the integrity of IREC as and when needed.

6.0. REGULAR IREC MEETINGS

6.1 Frequency

The Committee shall convene a meeting once every last Thursday of the month at 8.30 am.
6.2 Quorum
At least half (½) of the IREC membership shall constitute a quorum for a regular meeting.

6.3 Decision Making
Except when an expedited review procedure is used, the committee shall review and act upon proposed research at convened meetings at which a quorum is present. In order for the research to be approved, it shall receive the approval of the majority of those members present at the meeting.

7.0 CONDUCT OF THE MEETING

7.1 IREC Meeting Schedule and Distribution of Agenda
7.1.1 The Secretary shall notify and circulate the agenda for the next meeting to all committee members at least one week in advance.

7.1.2 The Secretary shall notify all committee members of any changes of the meeting time, date or agenda within 24 hours

7.2 Meeting Procedure
7.2.1 The Chair shall call the meeting to order
7.2.2 The Chair shall request for adoption of the agenda

7.2.3 The Standard agenda shall be as follows;
- Apologies
- Communication from the chair
- Consideration of actions taken by the Chair on behalf of the Committee
- Confirmation of minutes

- Matters arising
- Receive and Consider Research Proposals
- Any Other Business (A.O.B)

7.2.4 Committee members with interests in any research proposal shall declare the same and shall leave the meeting for the duration of the deliberations on the proposal.
7.2.5 IREC may where necessary invite the Principal Investigator to the meeting to clarify certain issues relating to their proposal.

7.2.6 Decision making of the Committee shall be by consensus.

7.3 Meeting Minutes

7.3.1 The Chair shall review the minutes for accuracy and completeness then sign/approve for circulation.

7.3.2 The minutes of each meeting shall be distributed to members within a period of not more than one week after every meeting.

7.3.3 The minutes shall be confirmed at the next meeting.

7.3.4 The confirmed minutes shall be distributed to the Vice-Chancellor, the Director MTRH, the Dean School of Public Health, the Dean School of Medicine, and the National Council for Science and Technology.

8.0 SPECIAL MEETINGS

Special meetings shall be called as deemed necessary, and the specific agenda shall be circulated in the meeting notice. The conduct of such meetings shall be same as for the regular meeting.

9.0 SUBMISSION OF A RESEARCH PROPOSAL

The Committee shall issue an application form to the Principal Investigator at a prescribed fee. Four (4) hard copies and a soft copy of the study proposal that conform to the Committee guidelines shall be submitted. These copies shall be distributed as follows:

- Two (2) to reviewers
- One (1) to circulate among the Committee members
- One (1) to be archived
- Soft copy to be saved into IREC database.

The Principal Investigator shall submit a Curriculum Vitae (CV) including copies for Co-investigators when making first application to the IREC.

10.0 TYPES OF REVIEW

There shall be four types of review, namely;
1) Expedited Review
2) Full Review
3) Continuing Review
4) Review of Amendments to a previously approved Proposal.

10.1 Expedited Review

An expedited review shall be conducted jointly by the IREC Chairman, Secretary and one other reviewer designated by the Chairman.

The following categories of research proposal shall qualify for an expedited review and approval:

- Research investigations that present no more than minimal risk to the study participants.

- Minor amendment in previously approved research during the period for which approval was granted.

Definitions of “minimal risk” and “minor amendment” will be based upon accepted guidelines/categories.

10.2 Full Review

10.2.1 All other research proposals submitted for review and which do not meet the criteria for expedited review shall undergo the process of a full review.

10.2.2 The Secretary of IREC shall identify at least two suitable experts within and/or outside the institution to review the proposal.

10.2.3 The administrator shall provide each reviewer a copy of the proposal and a reviewer’s standard form to assist them in reporting their review findings.

10.2.4 Simultaneously, the administrator shall circulate copies of the proposal to all IREC members.

10.2.5 The reviewer shall return the reviewer form, the proposal and any other comments to the administrator within 2 weeks.

10.2.6 If after 4 weeks there shall be no response from the reviewer the proposal shall be withdrawn.
10.2.7 The administrator shall pool all the reviewers’ comments, remove any reviewer identifiers and hand them over to the PI.

10.2.8 Once the PI addresses all the reviewers’ comments, a copy of the amended proposal shall be returned to the reviewer.

10.2.9 Once satisfied, the reviewer shall communicate the decision in writing to the secretary, who shall then advice the Chair to consider granting provisional approval to the PI to begin the research work, if it is urgent.

10.2.10 Provisional approval will only be used by the PI to commence investigations when the two reviewers, the Chair, Secretary and two other IREC members have given a go ahead and under special circumstances.

10.2.11 Normally, the reviewed proposal shall be presented, discussed taking cognizance of the reviewers’ comments at the next regular IREC meeting.

10.3 Continuing Review

10.3.1 All approvals shall be valid for a period of 1 year.

10.3.2 Studies that last for more 1 year shall apply for a fresh approval.

10.3.3 A Standard Form for application for Continuing Review shall be developed.

10.3.4 For all research studies that are likely to run for more than a year, the IREC administrator shall send all PIs an alert notice reminding them to apply for continuing review two months before the expiry of the IREC approval for their study. The alert notice shall be accompanied by the standard form for application for Continuing Review.

10.3.5 A copy of the application form for Continuing Review submitted by the PI shall be circulated to all IREC members and will be discussed at the next regular IREC meeting.

10.4 Review of Study Amendments

10.4.1 All amendments to the study proposal shall be communicated to the IREC members.

10.4.2 The PI shall submit 4 copies of the amended proposal with detailed highlights of all changes made on the original approved version together
with a cover letter detailing the amendments.

10.4.3 All amendments on methodology shall undergo full review process, if possible, by the original primary reviewers.

10.4.4 No methodological amendments shall undergo expedited review process.

11.0 COMMUNICATION OF REVIEW DECISIONS

11.1 The Chair shall communicate to the Principal Investigator all review decisions through standardized IREC documents, within 2 weeks of the date of the decision.

11.2 The review decision shall be in the following format;

- Formal Approval
- Provisional Approval
- Deferred Approval
- Not Approved.

When the decision is deferred or Not Approved, the reasons shall be given to the Principal Investigator in writing.

11.3 The approvals shall be for one year period, renewable on application for continuing review approval.

12.0 RESPONSIBILITY OF THE PRINCIPAL INVESTIGATOR IN THE REVIEW PROCESS

The Principal Investigator shall be responsible for prompt response to reviewers comments, usually within one month of receiving the comments.

12.1 The administrator shall remind the PI to respond to the reviewer comments after the month grace period elapses.

12.2 If after being reminded, the PI does not respond to the reviewer comments within a further period of one month, the reviewer shall be considered to have lapsed and the PI shall be required to make a fresh submission for IREC review.

13.0 FINAL REPORT

The Principal Investigator shall submit a final report resulting from the study; in hard and soft copies.
14.0 ACKNOWLEDGEMENTS

1. The Appointing Authority is acknowledged for its foresight in recognizing the need for streamlining the functions and procedures of the committee. The initial groundwork and drafting of the SOPS was the effort of the task group led by Dr E. Were, under the direction of Prof A.K. Chemtai. The members of the task group were: Prof A.J. Oloo, Dr. M. Nangami, Dr. R. Kakai, Dr. K.K. Kamar, Ms V. Yebei, Mr. Sitti and Mr. Muttai. Their efforts are deeply appreciated. The 2nd edition of the SOPs was fully deliberated on by the members of the IREC and their individual and collective contribution towards the 3rd edition is greatly appreciated. Lastly Ms A. Rotich is also thanked for her tireless secretarial effort during the revision of the SOP’s.

15.0 REFERENCES:


4. The ENGAGE Guidelines for Good Clinical Practice Compliance and Quality Systems Auditing in Conforming to the Note for Guidance on Good Clinical Practice.

