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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 (MU/CHS) and Moi Teaching and Referral Hospital (MT&RH) 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 for an 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 twin 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.

Principal, CHS, Moi University
And Director, MT&RH, Eldoret

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IREC STANDARD OPERATING PROCEDURES

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 the environment. The Committee governs health research as guided by applicable laws and regulations of the Kenyan government and relevant international bodies.

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 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 two (2) members 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, MT&RH/ Principal CHS, Moi University, hereafter referred to as the Appointing Authority.

2.3 Tenure and conditions of appointment

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 Chairperson shall be an ex-officio member in the incoming Committee.

Absence of a member for three consecutive meetings without valid reasons may lead to a suspension or replacement by the Appointing Authority.

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 a replacement.

2.5 Allowances

Allowances for IREC membership may be considered by the appointing authority.

2.6 Review Fees

The Committee may recommend levy fees to cover administrative costs of research proposal review.

3.0 TERMS OF REFERENCE

Broad Terms of Reference for the Committee were identified 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 health 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 the committee 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 proposal(s) and /or amendment(s)
 - Written informed consent form(s) and questionnaires updates 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.

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

3.2 Provide Leadership in Research Development Through:

3.2.1 Setting out research policy

3.2.2 Providing research guidelines

3.2.3 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 Facilitation of establishment of research infrastructure such as biomedical complex and literature search facilities

3.2.6 Development of linkages with industry.

3.3 Facilitate Sourcing And Coordinate Approval Of Research Grants / Funds

3.4 Coordinate The Dissemination And Publicity Of Research Information And Findings

4.0 THE EXECUTIVE COMMITTEE

There shall be an Executive Committee consisting of the Chairperson, the Secretary and a maximum of three (3) experts.

5.0 THE IREC SECRETARIAT

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

6.0 FUNCTIONS AND RESPONSIBILITIES

6.1 Chairperson

- To conduct meetings in accordance with the regulations
- To facilitate provision of training of new Committee members and continuing education for older members.
- To oversee the functions and activities of the Secretariat.
- To assign responsibilities and duties to any member of the Committee.

6.2 Secretary

- To call meetings in consultation with the Chair
- To dispatch proposals for scientific review
- To identify suitable reviewers in collaboration with the Scientific Committee
- To prepare proposal review documents for discussion at regular Committee meetings.
- To oversee the functions and activities of the Administrator and the support staff.

6.3 Administrator

- To receive proposals and fees
- To document proposals and make dispatches to the Secretary
- To receive names of reviewers from the Secretary and dispatch proposals to them
- Undertakes all other administrative duties as assigned.

7.0 REGULAR IREC MEETING

7.1 Frequency

The Committee shall convene a meeting once every two months or when deemed necessary.

7.2 Quorum

At least half ($1/2$) of the IREC membership shall constitute a quorum for a regular meeting.

7.3 Operation

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 a majority of those members present at the meeting.

8.0 CONDUCT OF THE MEETING

8.1 IREC Meeting Schedule and Distribution of Agenda

- 8.1.1 Except for emergency or special meeting the Committee shall meet on last Thursday of the month at 8.30 a.m.
- 8.1.2 The Secretary shall notify all committee members of an upcoming meeting at least one week in advance.
- 8.1.3 The Committee Secretary shall notify all committee members of any changes of the meeting time, date or agenda within 24 hours.
- 8.1.4 The Committee Secretariat shall keep and archive all original copies of the Committee documents.

8.2 Meeting Procedure

- 8.2.1 The Chair shall call the meeting to order.
- 8.2.2 The Chair shall request for adoption of the agenda.
- 8.2.3 The standard agenda shall be as follows:
- Apologies
 - Communication from the chair
 - Ratification of actions taken by the Executive Committee.
 - Confirmation of minutes
 - Matters Arising
 - Receive and Consider Research Proposals
 - Any Other Business (AOB)
- 8.2.4 Committee members with interests in any research proposal shall declare the same and shall not participate in the deliberations on the proposal.

8.3 Meeting Minutes

8.3.1 The chair shall review the minutes for accuracy and completeness and approve for circulation.

8.3.2 The minutes shall be confirmed at the next meeting.

8.3.3 The Appointing Authority shall be given copies of confirmed minutes.

9.0 SUBMISSION OF A RESEARCH PROPOSAL

The Committee shall issue an application form to the Principal Investigator at a fee. Four (4) copies 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

The Principal Investigator shall submit a Curriculum Vitae (CV) including copies for co-investigators when making first application to the IREC or at the discretion of the Secretariat.

10.0 COMMUNICATION OF REVIEW DECISIONS

The Secretariat shall communicate to the Principal Investigator all review decisions through standardized IREC documents. Three such forms currently exist: “approval”, “provisional approval” and “not approved”. Reviewer comments shall be attached as part of communication of the reviewer decisions where a research proposal requires adjustments or revision. These documents shall be reviewed and revised at the discretion of the Secretariat.

11.0 EXPEDITED REVIEW

An expedited review shall be conducted 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 and/or at the discretion of the Secretariat.

12.0 MONITORING AND EVALUATION OF RESEARCH

12.1 The Committee shall monitor and evaluate all approved research studies at a frequency deemed necessary but at a frequency no greater than once yearly for all active proposals.

12.2 The principal investigator shall submit a progress report as stipulated by the Committee. Violation of this code shall lead to the following steps:

- The Committee shall remind principal investigator (PI) of the responsibility to send progress reports.
- If no positive response is received from the PI, the Committee shall terminate approval to undertake research activities.

- 12.3 The PI shall be expected to hand in a final report resulting from the study.
- 12.4 The Committee shall develop mechanisms of networking with other Research and Ethics Committees within the region and internationally.
- 12.5 The Committee shall endeavor to establish formal and informal linkages with other national, regional and international committees to facilitate networking and monitoring of research projects.

13.0 ACKNOWLEDGEMENTS

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