



NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY AND
INNOVATION

GUIDELINES FOR ACCREDITATION OF INSTITUTIONAL
ETHICS REVIEW COMMITTEES IN KENYA

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ABBREVIATIONS/ACRONYMS

IERC	Institutional Ethics Review Committee
NACOSTI	National Commission for Science, Technology and Innovation
M&E	Monitoring and Evaluation
MMUST	Masinde Muliro University of Science and Technology
ST&I	Science, Technology and Innovation
SOP	Standard Operating Procedure
CVs	Curriculum Vitae

DEFINITION OF TERMS

Accreditation means giving approval and delegated authority to an IERC to conduct ethics review on behalf of NACOSTI.

Host Institution means an institution which takes responsibility and administers the assets and liabilities of a certain research.

Principal Investigator means the individual who is answerable / in-charge over a certain research.

Institutional Ethics Review Committee (IERC) means a committee accredited by NACOSTI and is responsible for ethical review of research proposal in an institution.

Lay member means a member of an IERC who is not:

- a. Currently, or has recently been, a registered health practitioner or researcher (for example, a doctor, nurse, midwife, dentist or pharmacist);
- b. An officer of, or someone otherwise employed by, any health board, health authority, the Ministry of Health or medical school;
- c. Involved in conducting health research or employed by a health research agency or a sector that undertakes health research; or
- d. Construed by virtue of their employment, profession or relationship, to have a potential conflict of interest or professional bias in a majority of research proposals reviewed.

1.0 INTRODUCTION

The Guidelines for Accreditation of Ethics Review Committees in Kenya (hereinafter referred to as Guidelines) provide Institutional Ethics Review Committees (IERCs) and the respective appointing authorities with the minimum requirements for accreditation by the National Commission for Science, Technology and Innovation (NACOSTI).

NACOSTI, in fulfilling its mandate of assuring quality in matters of research, science and technology, appreciates the need to delegate some of its tasks in accordance with section 27 of the Science, Technology and Innovation Act, 2013 (ST&I Act). The Guidelines will further provide a framework for operationalization of paragraph 7 of the ST&I (Relevance and Quality Assurance in Research) Regulations, 2014.

One of the key functions of NACOSTI is to consider applications for the grant of research licenses. The Commission receives and reviews all submitted research proposals before issuance of research licenses. However, there are proposals that require ethical review before consideration of application for a research license. The number of applications received for research licensing has steadily increased following growth in the national research and innovation system. NACOSTI has delegated the task of reviewing research proposals for ethical clearance to accredited Institutional Ethics Review Committees (IERCs). This is to ensure that research conducted in the country observes high standards research ethics.

The Guidelines provide for the composition, processes and procedures for the conduct of business for the IERCs and the standards that the committees are expected to observe and maintain. The Guidelines also provide a basis for Monitoring and Evaluation (M&E) and standardization of ethics review in the country.

1.1 Types of Ethics Review Committees

Institutional Ethics Review Committees, hereinafter referred to as IERC, are recognized for the purposes of accreditation. These may be defined according to the subject area of the research, which include health sciences, biomedical, biological, social sciences and environmental sciences.

1.2 Objectives of Accreditation Guidelines

The main objective of the Guidelines is to standardize the constitution and

operations of IERCs.

Accreditation will ensure the following:

- i. Upholding of the standard of ethics review in the country;
- ii. Development of public confidence and trust in the national research system;
- iii. Facilitation equitable access to research and human health records in health facilities;
- iv. Facilitating coordination and collaboration among IERCs in ethics review; and
- v. That animal welfare is taken into consideration during research and training.

2.0 REQUIREMENTS FOR ACCREDITATION

2.1 Application Requirements

- i. Duly completed Application Form (Annex III)
- ii. Copy of the Standard Operating Procedures (SOPs)
- iii. Copies of abridged CVs (Max 4 pages) for each member of the proposed IERC (to include the training attended)
- iv. Profile of the Organization/Institution detailing the areas of competence (Max. 4 pages)

2.2 Membership and requirements for IERC

2.2.1 Membership

The IERC membership shall consist of the following members:

- i. A Chairperson, who must have some basic training and/or experience in research ethics and leadership;
- ii. At least seven members and if more, the total membership must be an odd number;
- iii. At least one member who possesses knowledge and understanding of the Kenyan Law

2.2.2 Requirements for Appointment

The following requirements shall apply in the appointment of the Members of the IERC:

- i. Appointments to an IERC shall be the responsibility of the administrative

- head of the institution;
- ii. Where a committee serves more than one institution, the institution providing office space for the secretariat shall be the Host Institution for the functioning of the IERC in all aspects. Where multiple institutions are involved, the appointing authority shall make the appointments upon recommendation and in consultation with the Heads of the relevant institutions.
 - iii. At least one third of the members of the committee shall be of either gender;
 - iv. At least one of the members shall be from outside the institution;
 - v. At least two members shall have research expertise and experience;
 - vi. At least one member shall be a lay person; and
 - vii. The composition of the IERC shall reflect the regional and ethnic diversity of the people of Kenya.

2.2.3 Quorum

The quorum for IERC meetings shall be as follows:

- i. At least 50 per cent of the membership shall form the quorum;
- ii. A lay person must be present in all meetings; and
- iii. For ethics committees reviewing clinical research, at least two members shall be clinicians, one of whom is currently in active practice or clinical research.

3.0 APPEAL PROCESS

The IERC shall have specific procedures and mechanisms for appealing against its decisions. Where the applicant is dissatisfied with the appeal decision of the IERC, he/she may appeal to NACOSTI. The appeal to NACOSTI should be made within one (1) month of the outcome of the decision by the same IERC.

4.0 PROCEDURES FOR ACCREDITATION AND RENEWAL

Institutions undertaking research shall apply for accreditation of their IERC as prescribed in Annex 1. Accredited IERC shall be issued with Certificate of Accreditation.

4.1 Duration of Accreditation

The duration of accreditation shall be three (3) years from the date of notification by NACOSTI.

4.2 Annual Reporting

All accredited IERCs shall submit their annual reports by the 31st July each year for review and monitoring.

The report should comprise the following:

1. A list of all research proposals reviewed during the year containing the following information:-
 - Research title,
 - Principal Investigator and his/her qualifications,
 - Co-investigators and their qualifications,
 - Institution where the research is to be/has been undertaken,
 - Date of approval,
 - Proposed duration of the project
2. Any changes in the IERC membership or guidelines for operation, or other substantive changes, which, in the opinion of the committee or its Chair, should be noted.
3. A summary of other activities of the committee including training, monitoring and evaluation of approved research projects.
4. Any areas of review, which caused difficulty for the committee in making a decision on any particular research proposal.
5. Any other information on policy or other matters which the committee may wish to bring to the attention NACOSTI.

4.3 Procedures for Renewal of accreditation

Applications for renewal of accreditation should be made six (6) months before expiry of accreditation period. NACOSTI will review the documentation provided and communicate its decision to the Institution. The renewal of accreditation shall not be provided retrospectively.

Applicants will submit all documents listed in 2.1, including the latest report.

4.4 Failure to Renew Accreditation

Failure to renew accreditation or failure to maintain the appropriate standards for continuity of accreditation will mean that the accredited status of the ethics committee will lapse at the end of the current accreditation period and the committee shall cease to function henceforth.

4.5 Termination of Accreditation

Accreditation shall be terminated if, in the opinion of the NBC, the accredited committee fails to maintain the required standards.

4.6 Accredited Committees

A list of accredited committees is available from NACOSTI.

ANNEX I

Guidelines for Development of Standard Operation Procedures for IERCs.

For accreditation review purposes, ethics committees shall provide the Standard Operating Procedures (SOPs) under which the ethics committee will operate.

The SOPs are not required as part of the annual reporting process, unless they have been amended, but are required to be stated/included for the three-yearly reaccreditation review process.

The NBC will explicitly approve the SOPs and may request revisions if necessary for accreditation to proceed.

The NBC recommends that SOPs should include but will not be limited to the following:

- a) Scope and responsibility of the IERC;
- b) Institutions served;
- c) Objectives of the committee; streamlining research, safeguarding dignity and rights of research participants, facilitating correction and registration of research protocols;
- d) Functions of the committee;
- e) Appointment and terms of appointment for members, the appointing authority, responsibility to the authority;
- f) Conduct of business; procedures, decision making, notification, types of review, meetings, confidentiality
- g) Documentation; record keeping, archiving
- h) Responsibility of the principal investigator;
- i) Complaints; handling procedures, dispute resolution, appeals and reports to the NBC;
- j) Application procedures;
- k) Monitoring of approved procedures;
- l) Linkages with other ethics review committees.

ANNEX II

Summary and Checklist

Summary

- a) All ethics committees wishing to provide ethical approval for research protocols must be accredited. Only those ethics committees, which are accredited, can provide ethical approval for clinical trials, and research involving human subjects and/or animals. Approval by an accredited ethics committee is also required for research authorization where the methodology includes access to health data.
- b) Accreditation is for three years, from the date of notification. The provision of ethical approvals as an accredited committee commences from the date of notification by the NBC and is not retrospective.
- c) Annual reports are required by the NBC by 31st July of each year.
- d) Requests for renewal of accreditation are required six (6) months before the expiry date.
- e) The role of the NBC is policy development, guidelines, accreditation, dispute resolution, monitoring and evaluation.

Checklist of attachments for accreditation

The following documentation is required for accreditation review:

- a) A list of members of the committee, descriptions of their responsibilities in the committee, areas of categorization (Chair, lay and their respective responsibilities.), professional affiliation (if any), areas of expertise, gender, and nominating body and others.
- b) Any Amendments and/or Extensions to the Standard Operational Procedures where applicable.
- c) Relevant additional documents, such as a description of the committee's complaints procedure and a summary of other activities of the committee including monitoring and training.

ANNEX III

Application Form for Institutional Ethics Review Committee Accreditation/ Renewal of Accreditation

1. Name of Institution

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2. Name of Institutional Ethics Review Committee (IERC)

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3. Institutional Ethics Review Committee Address

Physical:
E-mail:
Website:

4. IERC Contact Officer

Name:
Position:
E-mail:
Phone:

5. IERC Chairperson

Name:
Position:
E-mail:
Phone:

6. IERC Secretary

Name:

11. (a) If yes to above, attach the Standard Operating Procedures
(b) If no, explain

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12. Has the IERC been accredited by the NACOSTI in the Past?

13. If yes in 12 above, indicate the date of notification and number (NACOSTI/

14. Declaration (to be signed by the Appointing Authority of the institution referred to in 1 above)

I hereby declare that the information given in this form and any attachments are correct;

Name of IERC:

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Name of Institution:

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Name and Designation

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Signature: _____ Date: _____

Official Stamp of Institution:

For Official Use

Date Received: _____

Decision: _____

Notification Date: _____

