



NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY AND INNOVATION

**GUIDELINES FOR ACCREDITATION OF INSTITUTIONAL SCIENTIFIC AND
ETHICS REVIEW COMMITTEES (ISERC) IN KENYA**

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ABBREVIATIONS/ACRONYMS

CV	Curriculum Vitae
ISERC	Institutional Scientific and Ethics Review Committee
M&E	Monitoring and Evaluation
NACOSTI	National Commission for Science, Technology and Innovation
NSEC	National Scientific and Ethics Committee
SOPs	Standard Operating Procedures
STI	Science, Technology and Innovation

DEFINITION OF TERMS

In these Guidelines, unless the context otherwise requires-

“Accreditation” means giving approval and delegated authority to an ISERC 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 Scientific and Ethics Review Committee (ISERC) 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 ISERC who is not:

- a. 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.
- b. Currently, or has recently been, a registered health practitioner or researcher (for example, a doctor, nurse, midwife, dentist or pharmacist);
- c. An officer of, or someone otherwise employed by, any health board, health authority, the ministry of Health or medical school;
- d. Involved in conducting health research or employed by a health research agency or a sector that undertakes health research; or

1.0 INTRODUCTION

The National Commission for Science, Technology and Innovation (NACOSTI) is established by the Science, Technology and Innovation Act, No. 28 of 2013 (STI Act) as a State Corporation. NACOSTI regulates and assures quality in Science, Technology and Innovation Sector and advises the Government in matters related thereto. The STI Act assigns NACOSTI seventeen (17) functions as outlined under section 6 (1). These functions can be broadly summarised as **Regulatory, Advisory, Coordination and Promotion as pertains to STI.**

The Guidelines for Accreditation of Institutional Scientific and Ethics Review Committees in Kenya (hereinafter referred to as Guidelines) provide Institutional 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. In so doing, 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 Scientific and Ethics Review Committees (ISERCs). 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 ISERCs 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 National Scientific and Ethics Committee

The National Scientific and Ethics Committee herein referred to as NSEC, is recognized to advise NACOSTI on ethical matters. The mandate of NSEC is within the greater objective of the Commission to regulate and assure quality in the science, technology and innovation sector and advise the Government in matters related thereto. Specifically, NSEC's functions fall within the Commission's functions of:

- i. Accrediting research institutions and approving all scientific research in Kenya; and
- ii. Assuring relevance and quality of research programmes in research institutions.

1.1.1 Functions of NSEC

The specific functions of NSEC are to:

- i. Ensure that ethical standards are maintained in research;
- ii. Consider and review accreditation applications for ISERCs;
- iii. Undertake monitoring and evaluation of ISERCs;
- iv. Address ethical dilemmas in research;
- v. Review protocols referred to it by the NACOSTI;
- vi. Maintain linkages and partnerships with other scientific organizations; and
- vii. Develop and review instruments to support research ethics.

1.1.2 Constitution and Membership of the Committee

The Committee draws members from various Institutions across the Country:

- i. NSEC is composed of eleven (11) members;
- ii. It is multi-disciplinary and multi-institutional;
- iii. During appointment, gender and regional balance is taken into consideration;
- iv. It includes Chairperson, lawyer and layperson;
- v. Eight (8) experts drawn from any of the following disciplines:

- a. Health Sciences,
- b. Biomedical Sciences,
- c. Biological sciences,
- d. Social sciences
- e. Environmental sciences.
- f. Animal sciences

1.2 Types of Scientific and Ethics Review Committees

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

2.0 OBJECTIVES OF ACCREDITATION GUIDELINES

The main objective of the Guidelines is to standardize the constitution and operations of ISERCs.

Accreditation will ensure the following:

- i. Upholdingof the standard of ethics review in the country;
- ii. Development of public confidence and trust in the national research system;
- iii. ISERCs have qualified, experienced members who are knowledgeable in bioethics, research ethics and rules & regulations for conducting research involving human participants
- iv. Ensure compliance to national and international standards
- v. Facilitation equitable access to research and human health records in health facilities;
- vi. Facilitating coordination and collaboration among ISERCs in ethics review; and
- vii. That animal welfare is taken into consideration during research and training

3.0 REQUIREMENTS FOR ACCREDITATION

3.1 Application Requirements

The institution applying for accreditation shall be required to adhere to the requirements of the First Schedule of the Guidelines.

3.2 Process of Accreditation

The Institution seeking accreditation shall be assessed per the following procedures:

a) Application procedure

The application procedure for accreditation of an ISERC shall be as follows:

- i. An application for accreditation shall be in the format prescribed in the Second Schedule of the Guidelines; and
- ii. The application shall be addressed and submitted to the Director General together with the required documents specified in the First Schedule of the Guidelines.

b) Assessment Procedure

The assessment procedure for accreditation of an ISERC shall be as follows:

- i. If the application complies with the set criteria, NSEC shall subject it to evaluation and schedule an assessment visit;
- ii. The assessment visit will comprise of team of five people consisting of experts (NSEC) and secretariat;
- iii. The Institution will be notified at least two (2) weeks before the assessment visit;
- iv. If not compliant, the Institution shall be informed to make amendments as appropriate;
- v. Where necessary, the assessment team may make a brief tour of the facilities; and
- vi. During the assessment visit, the team shall examine the human, infrastructure and financial capabilities of the institution.

c) Submission of Assessment Report

The assessment team shall compile a report and submit to the full NSEC

d) Mentorship of the ISERC

- i) NSEC will advise the applicant to undergo mentorship of the Committee by an established IERC with similar mandate;
- ii) at least two members of ISERC sit in the meetings of the chosen IERC.
- iii) The selected members should sit in at least three meetings. Upon completion of the three meetings, the mentor should send copies of the minutes of the meetings and mentorship report to NACOSTI to confirm attendance.

e) Approval for Accreditation

If the Institution complies with the Guidelines, NSEC shall advise the Director General to accredit the ISERC.

- i. If not compliant, NSEC shall prepare a detailed report for the Director General on the non-conformities.
- ii. Where the ISERC is not recommended for accreditation, the Director General will advise the applicant in writing on the corrective measures to be undertaken.
- iii. If the institution does not act on the non-conformities within one year, the application will lapse, and the institution will be required to re-apply.

f) Issuance of Accreditation Certificate

If approved, the Institution shall be issued with the Accreditation Certificate for the ISERC for three (3) years.

4.0 MEMBERSHIP AND REQUIREMENTS FOR ISERC

4.1 Membership

The ISERC 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
- iv. At least one technical member from outside the institution;
- v. At least one member shall be a layperson: and
- vi. At least five members shall have research expertise and experience.

4.2 Requirements for Appointment

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

- i. Appointments to an ISERC 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 ISERC 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. The composition of the ISERC shall reflect the regional and ethnic diversity of the people of Kenya.

4.3 Quorum

The quorum for ISERC 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.

5.0 DURATION AND RENEWAL FOR ACCREDITATION

5.1 Duration of Accreditation

The duration of accreditation shall be three (3) years from the date of approval.

5.2 Procedure for Renewal of Accreditation

An institution due for accreditation renewal shall apply to the Commission at least six (6) months before the expiry of the accreditation period. The Commission will review the documentation provided and communicate its decision to the institution.

The provisions relating to the process for accreditation set out in 3.2 shall apply *mutatis mutandis* to the procedure for renewal of accreditation.

5.3 Failure to Renew Accreditation

Failure to apply for renewal for accreditation within the prescribed period may lead to the lapse of the accreditation at the end of the accreditation period.

5.4 Termination of Accreditation

Accreditation shall be terminated if, in the opinion of the Commission, the institution fails to maintain the required standards for the accredited ISERC. Upon termination, the Commission shall revoke the accreditation certificate.

5.5 Annual Reporting

All accredited research institutions shall submit their annual reports by the 31st July each year for review and monitoring. The report shall be as prescribed in the given template in the third schedule

5.6 Accredited ISERC

A list of accredited committees is available in NACOSTI website.

6.0 EXPANSION OF SCOPE OF ACCREDITATION

Where necessary, an accredited ISERC may apply for expansion of scope of mandate giving a justification.

7.0 MONITORING AND EVALUATION

- i. The Commission shall monitor and evaluate accredited ISERC to ensure compliance.
- ii. Notwithstanding paragraph (i) above, accredited ISERC shall be required to annually carry out internal monitoring and evaluation of approved protocols and submit reports to the Commission.

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

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9.0 GUIDELINES FOR DEVELOPMENT OF STANDARD OPERATION PROCEDURES FOR ISERCs.

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

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

- a) Scope and responsibility of the ISERC;
- 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 NSEC;
- j) Application procedures;
- k) Monitoring of approved procedures;
- l) Linkages with other ethics review committees.

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 NSEC and is not retrospective.
- c) Annual reports are required by the NSEC 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 NSEC 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.

FIRST SCHEDULE

Application Instructions

1. An application for accreditation shall be in the form set out in the Second Schedule.
2. The duly filled application form shall be accompanied by the following required documents:
 - i) Duly completed Application Form
 - ii) Copy of the SOPs
 - iii) Copies of abridged CVs (Max 4 pages) for each member of the proposed ISERC (to include the training attended)
 - iv) Appointment letters
 - v) Profile of the Organization/Institution detailing the areas of competence (Max. 4 pages)
 - vi) One off payment of prescribed fee of two hundred and seventy five thousand (275,000/=) shillings only.
3. The application shall be addressed and submitted to the Director General using both email and postal address as follows:

Email: dg@nacosti.go.ke

Postal address: Director General, NACOSTI
off Waiyaki Way, Upper Kabete,
P. O. Box 30623, 00100.
Nairobi, KENYA.

SECOND SCHEDULE

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

1. Name of Institution

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2. Name of Institutional Scientific and Ethics Review Committee (ISERC)

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3. Institutional Scientific and Ethics Review Committee Address

Physical:
E-mail:
Website:

4. ISERC Contact Officer

Name:
Position:
E-mail:
Phone:

5. ISERC Chairperson

Name:
Position:
E-mail:
Phone:

6. ISERC Secretary

Name:
Position:
E-mail:
Phone:

Scope of Accreditation (eg Social, Biomedical, environmental)

7. List the organizations served by the ISERC

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8. Please indicate how the membership of your proposed ISERC is constituted

Name	Gender	Category (eg Chair, lay)	Academic Qualifications	Membership to Professional body (Name)	Area of Specialization	Affiliation (Institution)	Ethics Training (Yes/No)

9. Gender Composition

Number of Males	Number of Females

10. Has the ISERC developed Standard Operating Procedures?

Yes	No

11. (a) If yes to above, attach the Standard Operating Procedures

(b) If no, explain

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

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

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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 ISERC:

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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: _____

THIRD SCHEDULE

TEMPLATE FOR ANNUAL REPORT FOR IERC FY (specify the FY)

Name of IERC	
Date Submitted	

SECTION 1:

A list of all research proposals reviewed during the FY 2020/21						
NO.	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
1.						
2.						
3.						
4.						
5.						

SECTION 2:

Changes in the IERC membership or guidelines for operation, or other substantive changes.

- i. Changes in membership (New and those exited)
Please enclose appointment letters for the new members

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- ii. Changes in SOP (if any)

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SECTION 3

Summary of other activities of the committee including training, monitoring and evaluation of approved research projects.

- i. Training attended

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- ii. Monitoring and Evaluation of approved research projects

NO.	Research Project title	Area of research project	Date monitored
1.			

2.			
3.			
4.			
5.			

SECTION 4.

Areas of review, which caused difficulty for the committee in making a decision on any particular research proposal

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SECTION 5

Any other information on policy or other matters which the committee may wish to bring to the attention NACOSTI

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Chairperson/Secretary

Name.....Date.....Signature.....

Official stamp