NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY AND INNOVATION

GUIDELINES FOR ACCREDITATION OF INSTITUTIONAL SCIENTIFIC AND ETHICS REVIEW COMMITTEES IN KENYA

2026

FOREWORD

The National Commission for Science, Technology and Innovation (NACOSTI) is mandated under the Science, Technology and Innovation Act, Cap 511, to regulate and assure quality in the science, technology and innovation sector in Kenya, including accrediting research institutions and approving all scientific research conducted in the country. In fulfillment of this mandate, the Commission has developed these Guidelines for Accreditation of Institutional Scientific and Ethics Review Committees (ISERCs) in Kenya to strengthen research ethics governance and to promote high standards of scientific and ethical review nationwide.

These Guidelines offer a clear and harmonized framework for establishing, accrediting and overseeing ISERCs. They set out practical requirements for institutional commitment, committee composition, competencies and day-to-day operations, and clarify the respective roles of NACOSTI and the National Scientific and Ethics Committee (NSEC). By standardizing the application, assessment, mentorship and accreditation processes, the Guidelines aim to ensure that ethics review is competent, independent, consistent and timely, and that it aligns with institutional policies, national laws and internationally recognized ethical standards.

At their core, these guidelines are about protecting people. They are central to safeguarding the dignity, rights, safety and welfare of research participants, while also supporting researchers and institutions to conduct responsible, high-quality research. In rapidly evolving scientific fields, robust and trusted ethics review systems are essential for sustaining public confidence in research and ensuring that innovation benefits communities across Kenya.

NACOSTI appreciates the efforts of universities, research institutes, teaching and research hospitals and other organizations that have invested in establishing ISERCs and embedding ethical review in their governance structures. We also acknowledge the commitment of ISERC members, secretariats and mentors, whose expertise and dedication underpin ethical and scientifically sound research in the country. Through systematic accreditation, mentorship and ongoing monitoring and evaluation, these Guidelines seek to support them in a journey of continuous learning and quality improvement.

All stakeholders are expected to use these Guidelines as a practical tool for creating, strengthening and managing ISERCs, and for fostering collaboration among committees across the scheduled sciences and specialized areas such as clinical and animal research. It is my hope that they will contribute to a more robust, transparent and accountable system of research ethics governance in Kenya, advancing knowledge while respecting and protecting the communities and environments that make research possible.

The Guidelines for Accreditation of ISERCs in Kenya, hereinafter referred to as the Guidelines, aim to standardize scientific and ethical review of research in the country. They guide the composition, processes and procedures for conducting ISERC business, set out the standards that Committees are expected to observe and maintain, and provide a basis for monitoring and evaluation of approved research activities.

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Ag. Director General

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To all who contributed in one way or another to this important undertaking, the Commission conveys its heartfelt gratitude.

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ABBREVIATIONS/ACRONYMS

AE	Adverse Event
CAP	Chapter (as used in Cap 511 of the Laws of Kenya)
COI	Conflict of Interest
CVs	Curriculum Vitae
DG	Director General
FY	Financial Year
GCP	Good Clinical Practice
ISERC	Institutional Scientific and Ethics Review Committee
M&E	Monitoring and Evaluation
NACOSTI	National Commission for Science, Technology and Innovation
NEMA	National Environment Management Authority
NSEC	National Scientific and Ethics Committee
PI	Principal Investigator
PPB	Pharmacy and Poisons Board
SOPs	Standard Operating Procedures
STI	Science, Technology and Innovation
ToR	Terms of Reference
TRACE	Trial Regulation and Clinical Ethics (Optimization) Project

DEFINITION OF TERMS

Accreditation means granting approval and delegated authority to an Institutional Scientific and Ethics Review Committee to conduct Scientific and Ethical review within a given mandate on behalf of NACOSTI.

Animal Research means any scientific investigation and testing activity that involves the use of animal subjects to generate knowledge or evaluate interventions, products or technologies. It also includes research involving animal-derived materials or products, such as tissues, organs, blood, body fluids, cells, embryos, excreta, and other biological specimens collected from animals.

Clinical Trial means any systematic study on pharmaceutical products involving human subjects, whether in patients or other volunteers, to discover or verify the effects of, identify any adverse reactions to investigational products, to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety.

Host Institution means an institution that takes responsibility for the establishment and housing of an Institutional Scientific and Ethics Review Committee (ISERC), provides resources for the review and oversight of research activities approved by the committee, and administers associated assets and liabilities.

Institutional Scientific and Ethics Review Committee means a committee established by an Institution and accredited by NACOSTI to review scientific and ethical aspects of research proposals.

Layperson means a member of an ISERC who is:

a) A member of the local community and understands their priorities and needs;
b) In possession of at least Secondary Education and not higher than a Bachelor's degree;
c) Not 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;
d) Not affiliated with the host institution; and
e) Not involved in conducting research or employed by a research agency or a sector that undertakes research.

f) Not possessing formal training or primary professional expertise in the research disciplines under review

g) In addition, a layperson in health research is a member who is not: a health practitioner, an officer of, or someone otherwise employed by, any health board, health authority, Ministry of Health, health research agency, or medical school, or involved in conducting health research.

Mentorship means a formal, structured support relationship in which a more experienced, accredited ISERC within a given scope guides a less experienced ISERC to help it meet that scope's standards and move toward accreditation and high-quality ethical review practice.

National Scientific and Ethics Committee (NSEC) means a national expert committee established by NACOSTI in accordance with the STI Act, CAP 511, section 27.

Principal Investigator means a qualified individual who is in charge of a research project/program.

Research Ethics means the standards of conduct that guide scientific research and protect the dignity, rights, and welfare of research participants.

Scheduled Science means any of the groups of sciences listed in the Second Schedule of the Science, Technology and Innovation (STI) Act CAP 511.

Secretariat means an administrative unit composed of the Chairperson, Secretary, and administrator that supports ISERC's operations by handling day-to-day coordination, documentation, communication, and record-keeping, enabling the Committee to carry out its functions effectively.

1.0 INTRODUCTION

Background

The National Commission for Science, Technology and Innovation, herein referred to as the Commission, is established by the Science, Technology and Innovation Act (CAP 511) as a State Corporation. The Commission regulates and assures quality in the Science, Technology, and Innovation Sector and advises the Government in matters related thereto. The functions of the Commission are as outlined in section 6(1) of the STI Act.

One of the Commission's core functions is to accredit research institutions and approve all scientific research conducted in Kenya. As part of this role, the Commission receives and reviews research proposals prior to issuing research licenses. The approval process for scientific research generally occurs in two stages: initial ethical review and approval by an accredited ISERC, followed by regulatory review and licensing by the Commission. For clinical trials, however, the second stage consists of review and approval by the Pharmacy and Poisons Board, after which the proposal is submitted to the Commission for review and issuance of a research license.

The Guidelines for Accreditation of ISERCs in Kenya aim to standardize scientific and ethical review of research in the country. They guide the composition, processes, and procedures for the conduct of business for ISERCs, as well as the standards that the Committees are expected to observe and maintain. These Guidelines also provide a basis for Monitoring and Evaluation (M&E) of approved research activities.

Objectives of the Guidelines

The objective of these guidelines is to establish a standardized framework for accrediting ISERCs to ensure that ethical reviews are conducted in a consistent, competent, independent, and timely manner, while ensuring compliance with national and international ethical benchmarks.

2.0 FRAMEWORK FOR ESTABLISHMENT OF INSTITUTIONAL SCIENTIFIC AND ETHICS REVIEW COMMITTEES

In Kenya, ISERCs are established and operate within a legal and regulatory framework anchored in the STI Act Cap 511, and its associated regulations. The regulations provide the framework for accreditation and oversight of all ISERCs responsible for approving research activities, including clinical trials. ISERCs are established through institutional governance mechanisms such as university senates, hospitals, and research institute boards. These committees can serve as a national function once accredited by NACOSTI. All studies must undergo scientific and ethics review and obtain approval before they are initiated. Although ISERCs provide ethical approval, research projects must also secure additional regulatory clearances prior to implementation depending on the nature of the research. For example, approval from the Pharmacy and Poisons Board (PPB) for clinical trials and the National Environment Management Authority (NEMA) for studies with environmental impact, among others. However, the overall research regulatory mandate rests with the Commission, which provides approval by registering research institutions, accrediting ISERCs, and issuing research licenses.

2.1 National Scientific and Ethics Committee

The Commission, in exercising its mandate to establish expert and advisory bodies, has constituted the National Scientific and Ethics Committee (NSEC). The NSEC is a committee of experts and community representatives consisting of individuals with diverse expertise and experience. This Committee is tasked with advising the Commission on matters of research ethics and scientific quality, aligning with the Commission's broader mandate to regulate and assure quality within the research, science, technology, and innovation sector, as well as to advise the Government on related matters.

Functions of NSEC

The specific functions of NSEC are to:

i. Ensure scientific and ethical standards are maintained in research;
ii. Provide expert input on the review of applications for accreditation of ISERCs;
iii. Participate in the monitoring and evaluation of ISERCs;
iv. Address ethical dilemmas in research referred by NACOSTI;
v. Review protocols referred to it by NACOSTI;

vi. Provide a forum for consultation and informed debate on ethical issues of public concern;
vii. Maintain linkages and partnerships with other scientific organizations including ISERCs;
viii. Provide expert input on the formulation, review, and application of tools and instruments that strengthen and support research ethics' governance.

2.1.1 Constitution and Membership of the NSEC Committee

The constitution of the Committee shall be as follows:

i. Composed of at least eleven (11) members, including the chairperson, a lawyer, and layperson (s);
ii. Multi-institutional and multi-disciplinary, with at least 3 members drawn from health disciplines
iii. The Chairperson and committee members shall serve for a term of four years, renewable once. To maintain continuity, at least 50% of members shall be retained.
iv. The appointment of members should adhere to the principles of gender and regional balance as provided for in the Constitution of Kenya;
v. Membership shall be drawn from across the Scheduled Science disciplines.

2.2 Objectives of the Accreditation of ISERCs

The main objective of accrediting ISERCs is to standardize their operations and ensure consistent, high-quality, scientific, and ethically sound research review. Specifically, the accreditation of ISERCs will ensure:

i. Upholding standards and consistent quality of ethics review in the country;
ii. Development of public confidence and trust in the national research system;
iii. Compliance with national and international standards;
iv. Coordination and collaboration among ISERCs in the review of research protocols;
v. Safeguarding the autonomy and welfare of research participants;
vi. Harmonizing the composition and functioning of ISERCs;
vii. Protecting researchers and related personnel from harm, abuse, or exploitation.

2.3 Accreditation Categories

Institutional Scientific and Ethics Review Committees (ISERCs) may be accredited in one or more categories. Six categories are provided under the Second Schedule of the Science,

Technology and Innovation Act, Cap. 511, with two additional categories introduced for Clinical Trials and Animal Research.

The scheduled sciences provide a framework for categorizing research activities in line with institutional mandates, ensuring that each ISERC possesses domain-specific expertise needed to protect participants and the environment across the full spectrum of scientific inquiry.

In recognition of the evolving research landscape, the Clinical Trials and Animal Research accreditation categories have been established to address the unique ethical and scientific considerations associated with these areas. ISERCs seeking accreditation in these categories must demonstrate the requisite technical expertise, infrastructure, and oversight mechanisms to ensure the ethical conduct of research and the protection of human participants and animal subjects involved in experimental studies.

i. **Agricultural and Natural Resource Sciences**

This category encompasses research dedicated to the sustainable production of food, fiber, and fuel. The primary focus is on enhancing productivity while ensuring environmental stewardship, biodiversity conservation, and the ethical management of land, water resources and other related fields.

ii. **Physical, Industrial and Energy Sciences**

This category focuses on the inanimate world and the mechanics of production. Research in this category ranges from developing new materials and chemical processes to optimizing renewable energy sources and industrial automation, often requiring rigorous safety and environmental impact assessments and other related fields.

iii. **Biological and Health Sciences**

This category deals with living organisms, their biological materials and constituents. It includes research with human participants who may become individually identifiable through a researcher's collection, preparation, or use of biological materials, medical records, or other personal data. The accreditation focus is heavily weighted toward clinical ethics, patient safety, access benefit-sharing procedures, and the moral implications of biotechnological advancements.

iv. **Infrastructure, Information, and Communication Sciences**

This category bridges the physical and digital worlds and focuses on the integrity of physical structures and the ethics of the digital landscape, such as data privacy, cybersecurity, and the societal impact of automation and other related fields.

v. **Humanities and Social Sciences**

This category covers human experience and societal structures, and includes sociology, psychology, economics, and anthropology among other disciplines. Accreditation in this area focuses on the cultural sensitivities of social experimentation.

vi. **Earth and Space Sciences**

Research in this domain investigates geology, climate change, marine science, natural disaster mitigation, and space exploration, among others, focusing on long-term survival and the preservation of both terrestrial and extraterrestrial environments.

vii. **Clinical Trials**

Clinical Trials Accreditation recognizes ISERCs that demonstrate excellence in the review and oversight of clinical trials. This accreditation affirms compliance with internationally accepted ethical principles, regulatory requirements, Good Clinical Practice (GCP) standards, and participant safety measures. It provides assurance that clinical trials are conducted with scientific rigor, integrity, transparency, and respect for the rights, safety, and well-being of research participants, thereby strengthening public trust and advancing high-quality health research. Application for Accreditation in clinical trials review shall only become available upon successful completion of the initial three-year accreditation cycle.

viii. **Animal Research**

Accreditation in this area recognizes ISERCs that have capacity to review protocols to ensure highest ethical standards, responsible care and use of animals in research and testing activities. ISERCs that are accredited under this category must demonstrate the capacity to oversee and ensure robust animal care and use in research.

2.4 Establishment and Accreditation of Institutional Scientific and Ethics Review Committees

2.4.1 Requirements for Accreditation

a) Institutional Requirements and Obligations

Institutions intending to establish ISERCs are expected to meet the following requirements for effective and credible ethics oversight. These include**:**

i. Formally constitute the ISERC through an official institutional document, such as a research policy where the committee is anchored.

ii. Guarantee the committee's independence and autonomy, as articulated in its policy or Standard Operating Procedures (SOPs), allowing it to conduct ethics reviews and make decisions free from undue influence or retaliation, including

the independent assessment of the scientific validity of research. To further safeguard independence, institutional managers must not serve in the ISERC.

iii. Provide adequate and sustainable resources (financial, human, training, and logistical support including office space, boardroom, and relevant equipment) to support continuous functioning of the ISERC.

iv. Institutions will not constitute other organs or parallel committees to review, oversee or approve the work of the ISERC, as this constitutes undue influence and interference.

v. Formally approve SOPs that guide ISERC governance and day-to-day activities, ensuring consistency, accountability, and compliance with accreditation standards, and file these SOPs with NACOSTI.

vi. Institutions should be in good standing as required by Kenyan laws.

vii. 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.

viii. ISERC Secretariat: Every accredited ISERC shall le expected to have a dedicated secretariat and equipped office space that will assist in the operations of the committee.

b) Application Requirements

Applicants are required and expected to submit the documents listed below:

i. Duly filled application form (Appendix II).

ii. Application cover letter from the Head of the Institution on the institution's letterhead.

iii. Instrument of establishment for the host institution

iv. Institutional research policy

v. List and abridged curriculum vitae (CV) of the proposed Committee members, indicating areas of expertise and experience for each member.

vi. Individual appointment letters indicating the date of appointment.

vii. Professional/institutional affiliation (if any) of each member.

viii. ISERC’s Standard Operating Procedures (see Section 5.0)

ix. Except for the lay member, copies of certificates of research ethics training.

x. For ISERCs who are to review health research, a certificate of training in the protection of human subjects is required, and for clinical trials, additional proof of GCP training.

xi. A brief profile of the Institution highlighting background information, areas of mandate and competence.

xii. Evidence of payment of the prescribed fee

c) Membership Requirements

The ISERC membership shall consist of the following members:

i. At least seven members, and if more, the total membership must be an odd number;

ii. A member of an ISERC, except the layperson(s) and a lawyer, should have at least a master's degree.

iii. The Chairperson must be trained in research ethics, possess leadership skills, and have experience in a relevant research area, with specialized experience required for committees reviewing health research, clinical trials, or animal research.

iv. The composition of the ISERC shall reflect age, regional and ethnic diversity of the people of Kenya and a third of the members should be of either gender.

v. At least one member who is a lawyer by profession and an advocate of the High Court of Kenya

vi. At least one technical member from outside the institution;

vii. At least one member shall be a layperson who is a Kenyan citizen and not an employee of the institution where the ISERC is hosted; however, two lay members are recommended to ensure the required quorum for ISERC meetings;

viii. At least two members shall have research expertise and experience in areas relevant to the categories of ISERC accreditation.

ix. For ISERCs reviewing health research, one member must be a licensed clinician in active practice, and another
must have active involvement in clinical research; committees reviewing clinical trials require an additional member who should be a pharmacist.

x. For Animal Research ISERCs, the two members should be animal specialists, one of whom must be a practicing Veterinarian, and the other an animal scientist.

d) Requirements for ISERC Administrators

In line with international good practice for research ethics committee secretariats, the following requirements shall apply to the appointment of ISERC Administrators:

i. Shall not be a member of an ISERC but is an officer responsible for the day-to-day management of an ISERC
ii. Is directly answerable to the ISERC Chairperson.
iii. Shall hold at least a bachelor's degree in a relevant field and have relevant training or demonstrable experience in general administration, records management, or a related field.
iv. Administrators supporting ISERCs accredited to review health sciences and clinical trials should have a bachelor's degree in biomedical fields.
v. Should have training in research ethics, animal science for Animal research ISERCs and GCP for health sciences and clinical trial ISERCs
vi. The Administrator shall be appointed in writing by the administrative head of the institution, or, where the ISERC serves more than one institution, by the head of the host institutions.

2.4.2 Appointment of ISERC Members

The following shall apply in the appointment of the members of the ISERCs:

i. Appointment of ISERC members shall be the responsibility of the administrative head of the institution;
ii. Where an ISERC is serving more than one institution, all the heads of the involved institutions should be consulted in the appointment of ISERC members;
iii. There should be individual appointments of members.
iv. Members of the ISERC shall be appointed to serve for a period of three years, open to renewal based on performance and the need to balance members' continued experience and expertise with the contribution of new perspectives and approaches.
v. Appointments to the ISERC should be made through a transparent and impartial process based on the established criteria to avoid conflicts of interest.
vi. All prospective members must disclose any potential or perceived conflict of interest.

2.4.3 Functions of ISERCs

i. The committee conducts ethical review of research protocols to ensure studies meet established standards before approval.
ii. It ensures the protection and safety of research participants throughout the study.

iii. It undertakes monitoring and oversight of approved studies to ensure ongoing compliance.
iv. It ensures compliance with applicable ethical and regulatory standards.
v. It ensures its members continuously enhance knowledge and competence in research ethics through training and professional development.

3.0 PROCESS OF ACCREDITATION

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

3.1 Application procedure

i. An application shall comprise of the documents provided in **Appendix I**
ii. An application shall be in the format prescribed in **Appendix II**; and
iii. The application shall be addressed and submitted to the Director General of the Commission together with the required documents specified in **Appendix I**.

3.2 Review of Application Documents

i. Pre- screening of the application by the Commission's division in charge of ISERCs accreditation.
ii. The submitted documents are assessed for completeness.
iii. Recommendation for assessment visit or further action by the applicant.
iv. If the application complies with the set criteria, the Commission shall consolidate application documents in readiness for physical assessment.

3.3 Assessment procedure

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

i. The Commission shall constitute an expert assessment committee which will comprise of relevant experts;
ii. The institution to be assessed will be notified at least two (2) weeks before the scheduled assessment visit;
iii. During the assessment visit, the Committee shall make a courtesy call to senior institutional leadership.
iv. The Committee will meet and engage the proposed ISERC members to examine the tools, human resources, infrastructure, and financial capabilities of the institution to support the proposed ISERC.
v. Applicants who meet accreditation requirements shall be advised to proceed with mentorship before accreditation can be finalized.
vi. Institutions that are not compliant, shall be required to make amendments as appropriate and update the Commission on the changes effected within one year, failure to which the application shall lapse, and the institution required to re-apply.

3.4 Mentorship of the ISERC

i. The assessment committee shall advise the proposed ISERC to undergo mentorship by an established ISERC that has a similar mandate;
ii. The proposed ISERC and the secretariat shall be expected to undergo mentorship on core processes of the mentoring ISERC, including mock reviews, communication, documentation, and other standard operating procedures related to ethics review and oversight;
iii. Upon completion of the mentorship, the mentor shall submit a mentorship report to the Commission that not only confirms completion of the mentorship process but also assesses the capacity and readiness of the mentees to perform the functions and responsibilities of an accredited ISERC.
iv. The mentor ISERC shall submit the report within a month after completion of the mentorship programme.

3.5 Approval for Accreditation

Upon receipt of the mentorship report, the expert committee prepares and presents a comprehensive report comprising the physical assessment and mentorship, which provides recommendations for consideration by the Director General

3.6 Issuance of an accreditation certificate

The Director General, upon consideration of the recommendations of the expert committee, and where satisfied that the proposed ISERC meets the prescribed accreditation standards, shall issue an Accreditation Certificate for a period of three (3) years.

4.0 ACCREDITATION LIFECYCLE MANAGEMENT

4.1 Duration of Accreditation

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

4.2 Annual Reporting

All accredited ISERCs shall submit their annual reports (1st July - 30th June) by the 31st of July of each year.

The report shall be in the format prescribed in **Appendix IV**.

Failure to submit annual reports shall be considered non-compliance and may result in the Commission suspending ISERC's accreditation status.

4.3 Expansion of Scope of Accreditation

Where there are changes in the research area/scope of the host institution, an accredited ISERC may apply to expand the scope of its mandate. The process of expanding the scope of accreditation mirrors the initial accreditation process, including payment of the prescribed fees

4.4 Renewal of Accreditation

i. An institution due for accreditation renewal shall apply to the Commission at least six (6) months before the expiry of the accreditation period.

ii. The process and requirements for renewal of accreditation shall mirror those of the initial accreditation process.

4.5 Failure to Renew Accreditation

Failure to renew accreditation within the prescribed period will result in the accreditation status expiring at the end of the current period.

4.6 Termination and Withdrawal of Accreditation

Accreditation shall be terminated or withheld if, in the opinion of the Commission:

i. The institution fails to maintain the required standards for an accredited ISERC.

ii. If the institution usurps the powers of the ISERC or there is demonstrable evidence of interference with the work of the ISERC by the institution.

iii. If more than half of the members of the approved ISERC committee resign or are arbitrarily removed from the committee by the institution’s leadership without the approval of the Commission.

iv. If the Commission establishes that the ISERC failed in its review and oversight functions in safeguarding rights and safety of participants and protecting the sovereignty of Kenya.

Upon termination of accreditation, the Commission shall revoke the ISERC's accreditation certificate, remove it from the online list of accredited ISERCs, and the committee shall immediately cease reviewing or approving research protocols. The institution shall refer

researchers to NACOSTI, which shall assume oversight of ongoing studies in collaboration with other accredited ISERCs. The ISERC shall remain suspended and shall not resume operations until the Commission resolves the issues that led to the withdrawal of accreditation.

4.7 Appeal Against Termination

If the ISERC is not satisfied with the Commission's decision, the arbitration mechanism shall involve the ISERC presenting an appeal (in form of a letter) to the Director General for consideration.

4.8 Monitoring and Evaluation

i. The Commission shall monitor and evaluate the accredited ISERCs, at least once every three years or on a need basis, to ensure compliance and provide supportive supervision.

ii. The assessment procedure outlined in section 3.3 will apply.

iii. Accredited ISERCs shall be required to conduct annual self-assessments for continued quality improvement.

4.9 List of Accredited ISERCs

An updated list of accredited ISERCs shall be available on the Commission's website.

5.0 GUIDELINES FOR DEVELOPMENT OF STANDARD OPERATING PROCEDURES FOR ISERCS.

For review for accreditation purposes, ISERCs shall provide the Standard Operating Procedures (SOPs) which shall guide the committee.

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 Commission will explicitly approve the SOPs and may request revisions, if necessary, to allow accreditation to proceed.

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

i. Scope and responsibility of the ISERC
ii. The mandate of the ISERC
iii. Objectives of the committee; streamlining research, safeguarding dignity and rights of research participants, facilitating correction and ethics approval of research protocols
iv. Functions, roles and responsibilities of the committee
v. Mechanism of appointment/renewal/removal, terms of appointment, including committee structure (e.g. Chair, Secretary), need to balance committees' continued experience and expertise with the contribution of new perspectives.
vi. Induction of committee members
vii. Conduct of business: meetings, communication, notification, quorum, confidentiality of information, handling conflicts of interest, code of conduct for members and the committee
viii. Protocol submission: mechanism for submission, required documentation for review, format of protocols;
ix. For clinical trials SOPs to specify requirements for investigator brochure, insurance policy, GCP training for principal investigator and research team depending on study responsibilities; commitment by PI to adhere to GCP principles; and registration/authorization status of study facility/research centre.
x. Review of protocols; types of review (exempt, expedited, full review), review procedures, mechanisms of review, procedures for convening external experts, principal Investigators to have research ethics training.
xi. Indication that ethics review and monitoring shall be in line with national and internationally recognized standards and principles; handling confidentiality of protocols and committee deliberations, managing conflict of interest

xii. Decision-making: Mechanisms for decision-making (consensus/voting), type of decisions (approve, disapprove, request modifications, suspend, terminate etc.), communication of decision,

xiii. Service charter: published with set timelines for conducting the review, communication of decisions to researchers and responding to ISERCs queries/requests, charges for protocol reviews etc.

xiv. Monitoring and oversight of ongoing research: renewal of approval (extension), protocol amendments, reports on adverse events, notifications to relevant authorities in case of any breaches, study progress reports, and end-of-study reports;

xv. For Clinical Trials, mention procedures and timelines for receiving and review of safety reports, corrective actions and deadlines for notifying ISERCs of amendments necessary for the protection of participants.

xvi. Capacity building of members by NACOSTI or other trainers approved by NACOSTI.

xvii. Documentation; record keeping including members' CVs, statements of confidentiality and conflict of interest records; protocols including support documents, record of communication with researchers, ISERC decisions and documents on study monitoring; ISERC meeting minutes.

xviii. Archiving procedures and duration.

xix. Responsibility of the principal investigator;

xx. Complaints: handling procedures, dispute resolution, appeals and reports to the NACOSTI;

xxi. Linkages with other ethics review committees and researchers, relevant authorities, mechanisms for communication with the public, and how to be reached by study participants.

xxii. Procedures for review during emergencies (health or others) should specify expedited procedures for review and monitoring.

xxiii. Operations and funding for the ISERC; budgetary allocation, funding sources devoid of conflict of interest, training and capacity building of members and administrative staff, compensation for members and reviewers, service charge, a functional and easily accessible website or domiciled in the institutional website.

xxiv. Reliance with other ISERCs.

xxv. Other relevant operations

6.0 SUMMARY GUIDANCE ON ISERC MEMBERSHIP AND ACCREDITATION CRITERIA BY CATEGORY

Requirement	Scheduled Sciences	Clinical Trials	Animal Research
Institutional Requirements	• An institution must be in good standing with Kenyan law • Formal constitution of the committee: have research policy/SOPs guaranteeing ISERC independence and autonomy in the conduct of proposal reviews and decision-making • Provide adequate human and financial resources for the operations of the ISERC • Senior management staff, for example, CEOs, Deputy CEOs, VCs, Directors, should not be appointed as members of the ISERC • Clinical trials accreditation may be applied for only after successful completion of the initial three-year accreditation cycle.		
Infrastructure Required	• Office space equipped with computers, internet connectivity, lockable cabinet, furniture • Meeting rooms/board room • Storage and backup facility • Website (accessible) • A digitized system for applications, reviews and communication • For animal research ISERCs, the institution must have standard animal facilities to support animal welfare		
Minimum Membership	At least 7 members, (maintain an odd number if more)	At least 7 members (odd number if more); additional specialist requirements	At least 7 members (odd number if more); additional specialist requirements
Chairperson	Trained in bioethics/research ethics, experience in leadership and a relevant research area	Trained in bioethics/research ethics; experience in leadership and **experience in clinical trials** required	Trained in bioethics/research ethics, experience in leadership, **experience in animal research** required
Gender balance and Diversity	At least one-third of members must be of either gender. Ensure age and regional balance		
Lawyer	At least one member should be an advocate of the High Court of Kenya		
External member	At least one technical member from outside the institution		
Layperson	• One public member. • Representing public/community interests • Holds at most a Bachelor's degree, have no professional bias • Not affiliated with the institution • Not actively involved in research.	• One public member • Representing public/community interest • Primary expertise is outside the scientific, medical field • Not a healthcare professional • Not affiliated to the institution • Not involved in research	• One public member representing community interests • Independent of the science and care of animals • Holds at most a Bachelors degree, have no professional bias • Not affiliated to the institution • Not involved in the care and use of animals for scientific purposes
Research / Scientific	At least 2 members with research expertise and experience in the relevant	At least 3 members with specialized expertise:	At least 2 members with specialized expertise:

experts	scheduled science discipline	• One licensed clinician in active practice • One member actively involved in clinical research • One additional member with pharmaceutical expertise • Need-based co-option of trial specific expertise	• One veterinarian • One Animal scientist
Training / certification	Research ethics certificate for all members (except layperson)	All ISERC members except the lay member should have training in: • Research ethics • Human participants protection • Good Clinical Practice (GCP)	All ISERC members except the lay member should have training in: • Research ethics • Lab animal management/animal welfare • Animal research ethics
Administrator	• A dedicated administrative staff deployed to the committee • At least a bachelor's in a relevant field • Training or experience in general administration, records management or a related field	• A dedicated administrative staff deployed to the committee • Bachelor's in a biomedical field • Training in research ethics and GCP	• A dedicated administrative staff deployed to the committee • At least a Bachelor's in a biomedical field • Training in animal research ethics and animal science
Appointing authority	Administrative head of the host institution		
SOP requirements	SOPs to be numbered and named (refer to guidelines of development of SOPs 5.0) • Scope and responsibility of the ISERC. • Mandate of the ISERC. • Objectives of the committee, including streamlining research, safeguarding the dignity and rights of participants, and facilitating ethics approval of protocols. • Functions, roles and responsibilities of the committee. • Appointment, renewal, removal and structure of committee members, and responsibilities of the appointing authority. • Induction of committee members. • Conduct of business, including meetings, communication, quorum, confidentiality and handling of conflicts of interest. • Protocol submission requirements, including clinical trial-specific documentation. • Review of protocols, including types, procedures, use of external experts, and alignment with national and	All standard SOPs plus: • Procedures for community engagement • Post-approval monitoring of active clinical trials; procedure for receiving and reviewing safety reports and required corrective action, deadline for notifying ISERC on any amendments. • Trial risk categorisation • A service charter with a comprehensive outline of timelines • Requirement for investigator brochure, insurance policy, GCP training for PI and the research team, commitment to adhere to GCP, registration status of study centre/facility	All standard SOPs plus: • Procedures for animal care and use in research • Review procedures: requirements for Procedure for Replacement, Reduction and Refinement • Post–approval monitoring of active animal research activities • A service charter with a comprehensive outline of timelines

	international ethical standards. • Decision-making mechanisms and communication of decisions. • Service charter setting timelines, communication of decisions and charges for protocol review. • Monitoring and oversight of approved and ongoing research, including renewals, amendments, adverse event reporting, breach notifications, and progress and end-of-study reports. • Capacity building of committee members. • Documentation and record-keeping. • Archiving procedures. • Responsibilities of the principal investigator. • Complaints handling, dispute resolution, appeals and reporting to NACOSTI. • Linkages with other ethics review committees, researchers, relevant authorities and the public. • Procedures for expedited review and monitoring during emergencies. • Operations and funding of the ISERC, including budgetary allocation, funding sources, member compensation and administrative requirements. • Reliance • Other relevant operations.		

APPENDICES

APPENDIX I: APPLICATION INSTRUCTIONS

1. The application shall comprise of the following documents:
    i. Duly completed Application Form
    ii. A copy of the institutional instrument of establishment e.g. registration certificate or other
    iii. A copy of the institutional research policy.
    iv. Copy of the SOPs
    v. Copies of abridged CVs (Max 4 pages) for each member of the proposed ISERC (to include the Research Ethics and/or related training attended)
    vi. Individual appointment letters by the Head of the institution
    vii. Profile of the host Organization/Institution detailing the areas of competence (Max. 4 pages)
    viii. Evidence of payment of the prescribed fee.
2. The application shall be addressed and submitted to the Director General using email dg@nacosti.go.ke or the provided online portal.

APPENDIX II – APPLICATION FORM

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

1. Name of Institution

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

3. Indicate type of accreditation being sought (Tick as appropriate)

Initial	
Renewal	
Mandate expansion	

4. Has the ISERC been accredited by the Commission in the past? Put a tick as appropriate

Yes	No

5. If yes in 4 above, indicate the certificate number

6. Institutional Scientific and Ethics Review Committee Address

Physical:
Email:
Website:

7. ISERC Contact Officer

Name:
Position:
E-mail:
Phone:

8. ISERC Chairperson

Name:
Position:
E-mail:
Phone:

9. ISERC Secretary

Name:
Position:
E-mail:
Phone:

10. Scope of Accreditation (Tick where applicable)

S/No	Area of Accreditation	Tick
1.	Agricultural and natural resource sciences	
2.	Physical, industrial and energy sciences	
3.	Biological and health sciences	
4.	Infrastructure, information and communication sciences	
5.	Humanities and social sciences	
6.	Earth and space sciences	
7.	Clinical Trials	
8.	Animal Research	

11. List the Institution (s) constituting the ISERC

12. Please indicate how the membership of your proposed ISERC is constituted (The Table below can be converted to landscape)

S/N	Name	Gender	Age Bracket (Years) ≤35; 36 - 55; ≥56	Role (e.g. Chair, layperson, member)	Academic Qualifications	Membership to Professional body (Name)	Area of specialization	Affiliation (Institution)	Evidence of Research Ethics, HPP, GCP, animal science/Welfare training
1.									
2.									
3.									
4.									

Add rows as necessary.

13. Gender Composition (The committee is expected to meet the 'third' gender rule)

Number of Males	Number of Females

14. Has the institution set aside adequate staffing, facilities, infrastructure, and financial resources to support the ISERC carry out its responsibilities? Confirm availability of the following:

S/No	Item	Remarks/Notes
1	Permanent staff and Contract/temporary staff for the Secretariat support, including their academic qualifications and experience	
2	Does the administrator possess the requisite qualifications and experience?	
3	Adequate Infrastructure, office space(s), and equipment (computers, internet connectivity, stationery, telephones, photocopying machines) for ISERCs activities	
4	Proposed budgets (current budget in case of renewal or mandate expansion)	
6	Policies regarding public information disclosure (transparency) e.g service, newsletters, website etc	

15. Have the Standard Operating Procedures been approved by the institution?

Yes	No

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

(b) If no, explain

17. 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 true and correct;

Name	Designation

Signature:_____ Date: _____

Official Stamp of Institution:

For Official Use

Date Received:_____

Decision:_____
_____

Notification Date:_____

APPENDIX III: CRITERIA FOR ASSESSMENT OF ISERCs

Assessment Date: Day:……..…

Month:…….……Year:……..……. **Type of Assessment:**

Initial [ ] Expansion of Mandate [ ] Renewal [ ]

Name(s) of Assessment Team:

S/No	Name	Institution	Designation	Expertise	Email Address

PARTICULARS OF THE ISERC

i. Name of ISERC:
ii. Name of host institution:
iii. Date established:
iv. Physical location:
v. Postal address:
vi. Website:

Official Contact person and address: Chairperson/Secretary/Secretariat *(Circle appropriate)*

i. Postal address:
ii. Email:
iii. Phone No:

Section 1: Submission of Documents

An application for accreditation must contain all of the following:

S/No	Item	Remarks	MAX SCORE	SCORE
1.	Duly completed application form (Signed and stamped by the head of institution)		1	
2.	Copy of the SOPs (***See section 5.0 for details***)		1	
3.	Copy of Institutional Research Policy		2	
	Copies of abridged CVs (Including name, education level, current institution, position, research expertise)		1	
	Profile of the organization		1	
	Appointment letters		1	
	Evidence of budget allocation/Plan of budgetary support		2	
	Evidence of payment of the prescribed fee		1	
		Score out of 10		

Section 2: ISERC's Governance Structure

Section 2.1 Host Institution

Name of host institution:

……

Does the host institution have a valid registration/accreditation certificate from the relevant authority? Yes [ ] No [ ]
Registration Number:……

Institutional requirement in support of the ISERC operations: Confirm documented institutional policy on:

S/No	Item	Availability	MAX SCORE	SCORE
1.	Establishment of ISERC		2	
2.	ISERC independence and autonomy in the ethics review of research applications		2	
3.	Financial mechanisms to support ISERC operations		2	
4.	SOPs approved by the institution's governing body		1	
5.	ISERC administrator qualifications and roles		2	
	Score out of 09			

Section 2.2 ISERC Membership

The constituted list of members for the ISERC has adequate qualifications, experience, and expertise sufficient to manage the committee and ethics review of proposals in the area sought for accreditation and has received recommended training and orientation.

1	Item	Availability		MAX SCORE	SCORE
2	Terms of Reference for the Committee			3	
3	Appointing authority			1	
4	Dates of appointment			1	
5	Terms of appointment			1	
Membership structure		**Availability**	**Qualifications**		
6	Chair			2	
7	Secretary			2	
8	Lay member			2	

9	Lawyer			2	
10	Non-institutional technical member			2	
11	Members with relevant expertise			2	
12	Gender diversity			3	
13	Age Distribution			2	
14	Regional Balance			2	
	SCORE OUT OF 25			**25**	

Comments, if any;

……

……

…….....

Section 3: Fees and charges for Ethics Review

The ISERC has clear guidelines on the fees charged for ethics review of research protocols to investigators, as well as guidelines for the payment of reviewers for the review process.

No.		**REMARKS**	**MAX SCORE**	**SCORE**
1.	ISERC charges fees to applicants		2	
2.	Approval of ISERC fees by the host institution		2	
3.	Mechanism of reviewer compensation		2	
	SCORE OUT OF 06			

Comments, if any;

……

……

…….....

Section to be scored out of 06

Section 4: ISERC's SOPS

The ISERC developed SOPS that are in conformity with this guideline.

S/No	Item	Remarks (relevance and completeness)	MAX SCORE	SCORE
1.	Scope and responsibility of the ISERC		2	
2.	The mandate of the ISERC		2	
3.	Objectives of the committee		2	
4.	Functions of the committee		2	
5.	Appointment and terms of appointment for members, the appointing authority, and the responsibility of the authority		2	
6.	Submission procedures		2	
7.	Conduct of business			
	• Types of review and review procedures		1	
	• Decision making procedures		1	
	• Communication		1	
	• Conduct of meetings		1	
	• Confidentiality of information		1	
	• Conflict of interest management		1	
	• Service charter		1	
	• Post approval responsibilities		1	
8.	Capacity building of members, (induction and continuous training)		2	
9.	Documentation, record keeping, archiving		2	
10.	Responsibility of the principal investigator		2	
11.	Procedures for community engagement		2	
12.	Complaints handling procedures,dispute resolution, appeals		2	
13.	Monitoring of approved protocols		2	

14.	Reporting including to NACOSTI		2	
15.	Reliance with other ethics review committees, researchers, and relevant authorities		2	
16.	Data management and protection procedures		2	
17.	Guidelines and templates e.g Informed consent form, application form etc		2	
	Score out of 40			
	Additional for Clinical trials			
	i) Safety and adverse events tracking and reporting		2	
	ii) Post approval monitoring of approved protocols		2	
	iii) Trial-risk categorisation		2	
	iv) Requirements for investigators/investigator brochure, insurance, etc.		2	
	v) Registration status of study Centre/facility		2	
	Score out of 10			
	Additional for Animal research			
	i) Procedure for animal care and use in research		3	
	ii) Post-approval monitoring of active animal research activities		2	
Score out of 05				

Comments, if any;
……
……
……....

Section 5: Infrastructure and office space for ISERC activities

Infrastructure verification

Sn.	Type of equipment/infrastructure	Remarks	MAX SCORE	SCORE
1.	ISERC Office		2	
2.	Boardroom		1	
3.	Computer (s)		1	

4.	Projector/Screen		1	
5.	Cabinets:		2	
6.	Office Furniture		1	
7.	Storage / Archive:		1	
8.	IT infrastructure (e-System) for submission of proposals available/ not available? If available, explain the status of the online system of submission:		1	
Score out of 10				

Explain if they are adequate and up to date:

……

……

……....

Summarized total score of the physical verification:

Section	Assessment Area	Maximum Score	Given Score
Section 1	Submission of Documents	10	
Section 2.1	Host Institution	9	
Section 2.2	ISERC Membership	25	
Section 3	Level of funding and financial management of fees for ethics review	06	
Section 4	SOPS	40	
Section 5	Infrastructure and office space of ISERC activities	10	
Total Score		**100**	
Clinical trials +10		**110**	
Animal research +5		**105**	

Note;

i. ISERCs scoring **90%** and above will be recommended for accreditation

ii. ISERCs scoring between **61% and 89%** must address all documentation gaps before they can be recommended for accreditation.

iii. A score of **60%** or below shall attract physical reassessment.

The following must be in place for an ISERC to be accredited, regardless of the score;

i. The host institution must be in good standing with the Kenyan laws.
ii. Must have an institutional research policy
iii. The SOPs of the Committee must be approved by the host institution
iv. The proposed membership must have relevant expertise in the selected categories
v. The institution must have a budget plan to support the ISERC

Remarks: (The assessment team should provide overall comments from the assessment and outline the next steps)

……
……
……....

ISERC Chair

Name: ……

Signature: ……

Date: ……..

Assessment Team Leader

Name: ……

Signature: ……..

Date: ……..

APPENDIX IV: TEMPLATE FOR ANNUAL REPORTING BY ISERCs

Name of ISERC	
Financial	
Reference	
Date Submitted	
Annual Budget	
Budget Raised	

Meetings Held by the ISERC

SECTION 1:

Table 1 - A list of all research proposals reviewed and approved during the FY									
No	**Research Title**	**Category of Research (clinical trial, animal research, social science, etc.)**	**Principal Investigator and his/her Title (Prof., Dr., Md etc.)**	**Citizenship of the Principal Investigator**	**Co-investigators and their Title (Prof., Dr., Md etc.)**	**Citizenship of the Co-Principal Investigator**	**Institution/site where the research is to be/ has been undertaken**	**Date of approval**	**Proposed duration of the project**
1.									
2.									
3.									
4.									

Table 2 - A list of research proposals rejected during the FY									
No.	**Research title**	**Category of Research (clinical trial, animal research, social science, etc.)**	**Principal Investigator and his/her qualification s**	**Citizenship of the Principal Investigator**	**Co-investigators and their qualifications**	**Citizenship of the Co-Principal Investigator**	**Institution/site where the research was to be undertaken**	**Date of rejection**	**Reason(s) for rejection**
1.									
2.									
3.									
4.									
5.									

SECTION 2:

Changes in the ISERC membership, SOPs, or other substantive changes.

i. Changes in membership (New and those exited)

Please enclose appointment letters for the new members

……
……
……....

ii. Changes in SOPs (if any) (The sections changed)

……
……
……....

SECTION 3

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

i. Capacity building (training(s) conducted; include date, area of training, venue and number of members trained)

……
……
……....

ii. Capacity Building Plans for the next year

……
……
……....

iii. Monitoring and Evaluation of approved research projects

No.	**Research project title**	**Category of research project**	**Site of Research Project**	**Date monitored**	**Findings**	**Recommendation(s) made**
1.						
2.						

3.						

SECTION 4.

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

……

……

……....

SECTION 5.

Complaints and Appeals Handling (Complaints received, Appeals received, Resolution of complaints and Appeals, and any pending complaints)

……

……

……....

SECTION 6.

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

……

……

……....

DECLARATION

This is to confirm that the information provided is true to the best of our knowledge

Chairperson

Name…….Date……Signature……

Secretary

Name…….Date……Signature……

Official stamp

APPENDIX V: LIST OF CONTRIBUTORS

No.	Name	Institution
1.	Dr. David Ngigi	NACOSTI
2.	Dr. Benson Mburu	NACOSTI
3.	Christine Apakoreng	NACOSTI
4.	Teresia Nyawira	NACOSTI
5.	Charity Musembi	NACOSTI
6.	Carolyne Nekesa	NACOSTI
7.	Eunita Ogindo	NACOSTI
8.	Ezekiah Gatheru	NACOSTI
9.	Harriet Kinya	NACOSTI
10.	Mitchell Gakii	NACOSTI
11.	Dr. Hastings Ozwara	KIPRE
12.	Dr. Ruth Nyakundi	KIPRE
13.	Prof. Violet Naanyu	Moi University
14.	Winnie Kanana	Aga Khan University
15.	Dr. Christopher Opio	Aga Khan University
16.	Dr. Samuel Kerama	Pharmacy and Poisons Board
17.	Dr. Benson Kanji	Pharmacy and Poisons Board
18.	Rosemary Njogu	Pharmacy and Poisons Board
19.	Alice Osiemo	Kijabe Hospital
20.	Enock Kebenei	KEMRI
21.	Dr. James Kimotho	KEMRI
22.	Mary Njoroge	Ministry of Defence
23.	Josephat Otieno	ILRI
24.	Prof. Omu Anzala	KAVI-UON
25.	Dr. Amos Mbugua	JKUAT
26.	Prof. Stephen Muhudhia	Bioethics Society of Kenya
27.	Prof. Beatrice Amugune	University of Nairobi