Standard Operating Procedures

Document Reference:	Busara ISERC-SOP-001
Version:	1.0
Effective Date:	25th March 2026
Review Date:	25th March 2029
Approved By:	Francis Meyo, Chief Executive Officer
Classification:	Public

Glossary of Terms and Acronyms

Term / Acronym	Definition
Busara ISERC	Busara Institutional Scientific and Ethics Review Committee - Busara's independent body responsible for ethical oversight of research protocols.
NACOSTI	National Commission for Science, Technology and Innovation. The statutory body in Kenya responsible for the regulation of research and development.
ISERC	Institutional Scientific and Ethics Review Committee - An ethics committee that reviews and monitors research involving human participants.
SOP	Standard Operating Procedure - A set of step-by-step instructions to ensure consistency and compliance in processes.
PI	Principal Investigator - The lead researcher responsible for the conduct of a study.
COI	Conflict of Interest - A situation where personal, financial, or professional interests may compromise judgment.
Minimal Risk	Research where the probability and magnitude of harm or discomfort are no greater than those ordinarily encountered in daily life.
Informed Consent	A process by which a prospective research participant voluntarily confirms willingness to participate in a particular study, after having been informed of all aspects relevant to participation.
Vulnerable Population	Individuals whose willingness to volunteer in research may be unduly influenced by their situation, including but not limited to children, prisoners, pregnant women, and economically disadvantaged persons.

Expedited Review	A faster review process for studies that involve minimal risk and meet specific regulatory criteria.
Exempt Review	A category of ethical review for very low-risk studies that fit defined regulatory exemptions.
Full Committee Review	A review of a research protocol by the convened quorum of the Busara ISERC.
Continuing Review	Mandated re-evaluation of an approved study that is required to be conducted by an ISERC at least once per year
Quorum	The minimum number of committee members required to validate meeting proceedings and decisions. For Busara ISERC the quorum shall be defined as 50 % of Busara ISERC membership + 1 member
Ethics Approval	The affirmative decision of the Busara ISERC that a research protocol is ethically acceptable and may proceed, subject to any stated conditions.
Amendment	Any proposed change to a research protocol that has previously received ethics approval.
Protocol Deviation	A minor unplanned departure from the approved study protocol that does not significantly affect participant safety or data integrity.
Protocol Violation	A major deviation from the approved protocol that may impact participant safety or the validity of the study.
Adverse Event	An adverse event is any injury, problem or unfavorable occurrence experienced by human participants or others during conduct of research activities. Adverse events may or may not be caused by the research protocol.
SAE	Serious Adverse Event - An unexpected occurrence during the conduct of research activities that results in death, hospitalization, or serious harm.

CAPA	Corrective and Preventive Action - A plan outlining steps to correct and prevent protocol violations or deviations.
Research Misconduct	Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
RHinnO	This is a cloud-based digital platform that Busara ISERC uses to manage the entire ethical review

Background

Busara's mission of advancing and applying behavioral science in the pursuit of poverty alleviation can only be achieved if global human development activities respond to people's lived experience, value knowledge generated in the context in which it is applied, and promote culturally appropriate and inclusive practices.

Busara ISERC helps propel Busara's broader objective of promoting culturally appropriate, equitable, and inclusive development in the Global South. Busara ISERC seeks to enhance efficiency, contextual adaptation, and community engagement in research through the incorporation of participants' voices and a focus on local contexts. We aim to build trust, promote equity, and contribute to transformative change

These Standard Operating Procedures (SOPs) govern the operations of the Busara Scientific and Ethics Review Committee (Busara ISERC). They have been developed in accordance with the Science, Technology and Innovation Act (No. 28 of 2013), the Research Institutions Regulations of 2014 by NACOSTI, which provide procedures for registration of research institutions, the Data Protection Act No. 24 of 2019 which governs the processing of personal data in Kenya, and applicable international ethical frameworks including the Declaration of Helsinki, the Belmont Report, and the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines.

In addition, the Committee shall be guided by internationally recognised best practices for protocol development and reporting, including the WHO Recommended Format for Research Protocols and, where applicable, the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) Guidelines. These frameworks shall inform expectations for protocol completeness, scientific rigor, and transparency.

These procedures shall apply to all research activities involving human participants, personally identifiable data, and any research that may have significant ethical implications, conducted under the auspices of the Busara Center, and all investigators seeking to submit their research proposals for review by the Busara Scientific and Ethics Review Committee.

Mandate and Objectives of Busara ISERC

Introduction

The Busara Scientific and Ethics Review Committee (Busara ISERC) is constituted as the primary institutional body responsible for the independent, competent, and timely review of the ethical acceptability of research involving human participants and related activities. Busara ISERC operates with full independence from institutional management, funding bodies, and researchers, and its decisions shall not be subject to override by any other institutional body.

Regulatory Authority

1. Accreditation

- Accredited by NACOSTI (*accreditation number: NACOSTI/NSEC/AC/05426*) to review, approve, and monitor all research within its jurisdiction.
- The committee issues ethical approval certificates, while research licensing remains under NACOSTI to ensure alignment with national laws and guidelines

2. Mandate

- The committee's area of accreditation is ***humanities and social sciences***

3. Regulatory and Governance Frameworks

- Innovation Act (No. 28 of 2013) and its subsidiary legislation;
- NACOSTI's Guidelines for Ethics Review Committees in Kenya;
- The institutional charter and governance framework of the parent institution;
- International ethical standards and guidelines as adopted and referenced herein.

Objectives of the Committee

Busara ISERC shall be guided by the following core objectives:

Streamlining Review of Research Proposals

- To establish clear, efficient, and transparent procedures for the review and approval of research protocols;
- To provide timely and constructive feedback to researchers to facilitate the advancement of scientifically and ethically sound research;

- To harmonise institutional review processes with national and international standards to eliminate duplication and reduce administrative burden;
- To maintain an institutional environment that supports and encourages high-quality, ethical research.

Safeguarding the Dignity and Rights of Research Participants

- To ensure that all research involving human participants is conducted in accordance with the principles of respect for persons, beneficence, non-maleficence, and justice;
- To verify that informed consent processes are appropriate, voluntary, and comprehensible;
- To ensure that the rights, welfare, and privacy of research participants are adequately protected throughout the research process;
- To give special attention to the protection of vulnerable populations, including children, pregnant women, prisoners, persons with diminished autonomy, and economically or socially disadvantaged groups;
- To ensure equitable distribution of the burdens and benefits of research participation.
- To ensure all participant protection protocols reflect the lived experience of research participants
- To ensure that all research reviewed demonstrates clear social and scientific value, including relevance to local contexts and a feasible plan for dissemination and use of findings.

Facilitating Correction and Ethics Approval of Research Protocols

- To provide clear, written, and reasoned feedback to principal investigators regarding deficiencies in submitted research protocols;
- To establish a structured process for the revision and resubmission of research protocols that require modification;
- To issue formal ethics approvals for protocols that satisfy all scientific and ethical criteria;
- To monitor approved research to ensure continuing compliance with the approved protocol and ethical standards;

- To facilitate the amendment review process for approved protocols requiring significant modifications.
- To ensure continuous improvement in the review process to align with emerging ethical challenges in research.

Terms of Reference

In fulfillment of its mandate and objectives, Busara ISERC shall perform the following functions:

- Review, recommend, and adjudicate submitted research proposals as they pertain to relevant ethical, legal, scientific, and social issues specified in the Science, Technology, and Innovation (STI) Act of 2013;
- Issue, withhold, suspend, or revoke ethics approvals for research protocols;
- Ensure that all research promotes meaningful and positive change, reflects participants' lived experiences, and safeguards the dignity, respect, and autonomy of all individuals involved in research;
- Identify and evaluate risks and benefits, including social harms, and ensure provisions are in place to address them;
- Develop, review, and update institutional policies, guidelines, and standard operating procedures related to research ethics;
- Provide education and training to researchers, research staff, and students on research ethics principles and institutional requirements;
- Monitor ongoing research to ensure compliance with approved protocols, including review of progress reports, adverse event reports, and protocol amendments;
- Investigate and adjudicate complaints and allegations of research misconduct, unethical conduct of research, or violations of approved protocols;
- Maintain comprehensive and confidential records of all committee activities, correspondence, and decisions;
- Establish and maintain linkages with NACOSTI, relevant national ethics bodies, and other institutional ethics review committees;
- Report to NACOSTI and other relevant authorities as required by law and regulation;

- Collaborate with research sponsors, regulatory authorities, and other oversight bodies as necessary;
- Periodically review and assess the effectiveness of the Busara ISERC's own operations and procedures.
- Promote sensitization and awareness by engaging the public, research participants, and other research stakeholders on research ethics, rights, and responsibilities

SOP 1: Membership, Roles, and Responsibilities

1.1 Purpose

To define the structure, roles, and responsibilities of the Busara ISERC membership, ensuring the efficient operation and integrity of the committee.

1.2 Definitions

The appointing authority for Busara ISERC members shall be the Chief Executive Officer of the Busara Center (hereinafter "the Appointing Authority").

The hosting institution shall be the Busara Center (hereinafter "the hosting Institution").

External member refers to a member of Busara ISERC who is not an employee of the the hosting institution

Internal member refers to a member of Busara ISERC who is an employee of the the hosting institution

1.3 Scope

This SOP applies to all members, secretariat, prospective members, and the appointing authorities of the Busara ISERC.

1.4 Committee Composition

The Busara ISERC shall be constituted to ensure a multidisciplinary and balanced composition capable of reviewing the full range of research protocols in humanities and social sciences. The Committee shall comprise 11 members, including:

- A Chairperson with demonstrated expertise in research ethics, bioethics, or a related field;

- A Vice Chairperson;
- A minimum of two (2) scientists with relevant expertise in the primary research domains of the institution;
- A legal expert or person with expertise in law, human rights, or regulatory affairs;
- A community representative who is not affiliated with the institution and can represent the interests of potential research participants;
- A bioethicist or philosopher with expertise in applied ethics;
- A statistician or epidemiologist;
- A gender and social equity expert;
- Additional members may be co-opted for specific review purposes.

The Committee shall at all times maintain gender balance, with no gender comprising less than 30% of the total membership.

1.4.1 Appointing Authority

The Appointing Authority shall be responsible for:

- Establishing and publishing clear criteria and processes for the recruitment and nomination of Busara ISERC members;
- Appoint Busara ISERC members in accordance with established criteria and procedures;
- Ensuring that the Busara ISERC at all times maintains a composition adequate for its functions;
- Providing adequate resources, administrative support, and infrastructure for the effective operation of the Busara ISERC;
- Taking appropriate action in cases of misconduct, conflict of interest, or incapacity of Busara ISERC members;
- Approving and publishing the Busara ISERC's Standard Operating Procedures;
- Ensuring that the Busara ISERC operates with full independence from institutional management and funding bodies.

- The Appointing Authority shall not participate in protocol review, deliberation, or decision-making processes.

1.4.2 Role of the Hosting Institution

- Establish and support the Busara ISERC as an independent ethics review body;
- Provide adequate resources, including financial, administrative, and infrastructure support for the effective functioning of the Busara ISERC;
- Ensure availability of a qualified Secretariat to support Busara ISERC operations;
- Facilitate training and capacity building for Busara ISERC members and staff;
- Ensure that all research conducted under its auspices undergoes prior ethical review and approval by a competent ethics committee;
- Support compliance with national regulations and applicable ethical guidelines;
- Respect and uphold the independence of the Busara ISERC in its deliberations and decision-making.

1.4.3 Member Training Requirements

All members will review research proposals. To ensure competency and compliance, members must fulfill the following training obligations:

- Mandatory onboarding Training:
    - New members must complete onboarding training within 30 days of appointment.
    - The training will cover ethical principles, regulatory frameworks, Busara ISERC SOPs, and RHinnO (ethics review management platform)
- Annual Refresher Training:
    - All members must participate in annual refresher training sessions.
    - The topics covered include changes to review guidelines and emerging issues in research
- **Format:** Workshops, e-learning modules, webinars, or mentorship.
- Documentation:
    - The Secretariat will maintain a record of training completion.

- The Secretariat will maintain a copy of the most recent curriculum vitae from all members. Members are required to update their CVs annually.
- The Secretariat will collect and file certificates of any training in research methodology, research ethics (CITI, TTREE,...etc), or Good Clinical Practice.

1.4.4 Criteria for the Selection of Busara ISERC Members

- Members will be selected in their personal capacities based on their qualifications, experience in their domain, interest, ethical and/or scientific expertise, and their commitment to volunteer the necessary time and effort for the committee.
- Except for the community and the legal representatives they should all have at least a Masters Degree or an equivalent and at least three years of experience in their domain after obtaining the Masters degree or its equivalent.
- A community representative should be a literate person from the community, familiar with local language, culture, and norms, and not affiliated with Busara
- The Legal Expert must hold a basic law degree from a recognized university with a minimum of three years' experience in the legal field.
- They should not have any known record of professional misconduct.

1.5 Confidentiality Agreement

- Members must sign a confidentiality agreement at the commencement of their initial term. This agreement remains binding beyond the duration of their membership.
- Re-signing will be required only if confidentiality policies are substantively updated or if a member's role changes in ways that warrant renewed acknowledgment.
- Research protocols, data, and related materials submitted for review shall be treated as confidential and shall not be disclosed to any third party without the consent of the principal investigator, except as required by law or for audit and accreditation.
- Breach of confidentiality shall constitute grounds for removal from the Committee and may be subject to disciplinary action.

1.6 Co-option of Members

- Busara ISERC may co-opt external expertise as required.

- The duration of any co-option will be determined by the Busara ISERC.

1.7 Appointments

- Appointments will be made by the Appointing Authority
- No gender shall comprise less than 30% of the total membership.

1.7.1 Tenure

Members of Busara ISERC shall be appointed for a term of three (3) years, renewable once, for a maximum of two (2) consecutive terms. To ensure continuity, the terms of members shall be staggered such that no more than half of the Committee's members shall be replaced at any given time.

New members are appointed under these circumstances:

a) Tenure: A regular member completes their tenure.

b) Vacancies: Casual vacancies arising from resignation, incapacity, death, or removal shall be filled by the Appointing Authority within sixty (60) days. A person appointed to fill a casual vacancy shall serve the remainder of the unexpired term.

c) Resignation: A member wishing to resign shall give thirty (30) days' written notice to the Appointing Authority through the Chairperson.

d) Removal: A member may be removed by the Appointing Authority for misconduct, incapacity, conflict of interest, or failure to attend three (3) consecutive meetings or more than 25% of meetings annually without satisfactory explanation, following due process and natural justice.

- The Chair, in consultation with the Busara ISERC will identify potential new members based on the membership requirements.
- Voluntary proposals for consideration may be submitted by the Secretariat. These are proposals by external reviewers, or other qualified individuals who are not members of the Committee but have expressed an interest in contributing to its work. All submissions must fall within the Committee's mandate and will be subject to the Committee's standard review and approval processes.

- The Chair will then submit the suggested names to the appointing authority for final approval
- The final decision on appointment is taken by the Appointing Authority

1.8 Resignation and Termination of Membership

1.8.1 Resignation

- Members may resign by submitting a written letter of resignation at least 30 days in advance to the Appointing Authority through the Chairperson.
- The Secretary shall arrange an exit meeting to discuss pending tasks and gather feedback.
- The chair shall send an acknowledgment, confirming the resignation date and transition steps.
- Transition: Pending tasks shall be reallocated to remaining members.

1.8.2 Termination

Membership may be terminated due to:

- Resignation
- Death
- Persistent absenteeism: Absence from three consecutive meetings without prior notification or missing more than 25% of meetings annually without valid justification.
- Conflict of Interest Violations: Failing to disclose or manage conflicts of interest.
- Breach of Confidentiality: Unauthorized sharing of committee information.
- Ethics Violations: Any action undermining the ethical integrity of Busara ISERC.

The termination process shall involve the following:

- The chair or a subcommittee investigates and informs the member in writing, allowing a 14-day response.
- The chair reviews the response and issues a final decision within 7 days.

- All records related to termination are securely stored for a period of 10 years.

1.10 Roles and Responsibilities

1.10.1 The Chair

- The Chair shall preside over all committee meetings, ensuring that discussions are relevant, balanced, and in accordance with ethical guidelines.
- The Chair shall seek information on conflict of interest from members and ensure quorum and fair decision making
- The Chair shall sign approval letters for research proposals and minutes of meetings.
- The Chair shall ratify minutes of previous meetings.
- The Chair shall oversee the decision making process, ensuring each member's opinion is considered.
- The Chair shall ensure that protocols are reviewed thoroughly and decisions are communicated effectively.
- The Chair shall act as the primary liaison between Busara ISERC and the broader institutional administration on strategic and governance matters. Day-to-day administrative communication shall be coordinated by the Secretariat.
- The Chair shall address conflicts or disputes within the committee and ensure fair resolution.

1.10.2 The Vice Chair

- The Vice-Chair shall assume the Chair's responsibilities when the Chair is unavailable, ensuring continuity in leadership.

1.10.3 The Secretariat

The Committee shall be supported by a Secretariat comprising the Secretary, Regulatory Affairs Manager, who shall be the Busara ISERC Administrator, and Administrative Assistants. The Administrator shall be a full-time employee of the institution with appropriate qualifications and experience in research administration and ethics oversight. The Secretariat shall be responsible for the administrative operations of the Busara ISERC, including receiving and processing

applications, maintaining committee records, coordinating reviews, and communicating committee decisions to applicants. The specific responsibilities of the secretariat include:

- The Secretariat shall maintain records of all Busara ISERC activities, including protocol reviews, correspondence, and meeting outcomes.
- The Secretariat shall coordinate meeting schedules, rooms, teleconference arrangements, and other logistics.
- The Secretariat shall prepare an agenda for each meeting, listing protocols to be reviewed, ongoing issues, and pending actions.
    - Meetings shall be scheduled monthly, with additional meetings as required for urgent protocol reviews.
    - Meeting notifications and agendas shall be sent to all committee members at least 7 days before each meeting.
- The Secretariat shall record and securely store all protocol submissions, reviews, meeting minutes, and decision letters.
- The Secretariat shall log each protocol upon submission using its assigned unique tracking number recorded in the Busara ISERC database.
- The Secretariat shall compile meeting minutes, including decisions, attendance, and discussions, and share them with Busara ISERC members within 7 days for review.
- The Secretariat shall ensure that all information regarding protocols and committee deliberations is handled confidentially.
- The Secretariat shall maintain digital and physical copies of all records, including meeting minutes, signed letters, and approved protocols. Documents shall be retained in a secure repository for at least 5 years following study completion.
- The Secretariat shall prepare annual and periodic reports on committee activities and submit them to the Chair for review.

1.10.4 Members

- Members shall be assigned protocols based on their expertise and must review them thoroughly before each meeting. The protocol review will focus on scientific validity and ethical considerations such as participant safety, consent, and risk-benefit balance.

- Members shall be expected to attend all meetings, participate in discussions, and vote on each protocol.
- Members must declare any potential conflicts of interest at the beginning of each meeting and, if necessary, recuse themselves from discussions and voting.
- Members shall uphold the committee's ethical standards in every review and ensure that protocols protect participants' rights and welfare.

1.11 Contact Information

- **Physical Address:** 38 Apple Cross Road, Lavington Nairobi, First Floor, Room (Kampala).
- **Telephone Contact: WIP**
- **Email Addresses:** busara.iserc@busara.global
- **Website: WIP**

The Regulatory Affairs Manager shall be the primary contact person

SOP 2: Meeting Procedures

2.1 Purpose

This SOP outlines the procedures for conducting Busara ISERC meetings, ensuring meetings are conducted efficiently, transparently and in compliance with ethical and legal guidelines

2.2 Scope

This SOP applies to all members of Busara ISERC. It covers the scheduling, notification, conduct, and documentation of meetings.

2.3 Responsibilities

- **Chair:** Opens and facilitates the meeting, ensures quorum, and reviews and approves minutes.
- **Secretary/Regulatory Affairs Manager:** Notifies members of meetings, circulates the agenda and minutes, and records attendance and the proceedings.
- **Committee Members:** Participate in discussions, review proposals, and contribute to decision-making.

2.4 Meeting procedures

2.4.1 Meeting Schedule and Distribution of Agenda

- The Busara ISERC shall convene a meeting once per month on the last Monday of every month, from 9:00 am to 3:00 pm. Where Monday falls on a weekend or public holiday, the meeting will be held on the next working day.
- Special meetings may be called as needed. The meeting day may be changed if there is a holiday or for any other reason that prevents the meeting from taking place.
- Busara ISERC members may summon Principal Investigators (PIs) to appear before the committee in cases of complex protocols requiring discussion.

Quorum verification

For a full committee meeting, the quorum shall be defined as:

- 50 % of Busara ISERC membership + 1 member
- Mandatory inclusion of at least one community representative. This is non-negotiable to ensure community representation in ethical deliberations.
- Apologies do NOT count toward quorum. Only physically or virtually present members should be included.
- If quorum is not met, the meeting shall be postponed or decisions deferred to the next convened meeting.

Notification and Distribution of Agenda

- The Secretariat shall notify and circulate the agenda, minutes, meeting time, venue, date, and virtual participation details (e.g., Zoom link, dial-in instructions) at least 7 days in advance.
- The Secretary shall notify all Committee members of changes to meeting time, venue, date, agenda, or format within 24 hours of the change.

Virtual meetings

- Full committee meetings shall be conducted synchronously to ensure robust deliberation and decision-making.
- Meetings shall be conducted using secure, encrypted virtual platforms (e.g., Zoom, Microsoft Teams, or Google Meet).
- Participants must join from a private, quiet location to ensure confidentiality.

- Members joining remotely must ensure stable internet connectivity and familiarity with the designated platform

2.4.2 Meeting Procedures

1. **Opening the meeting**
    - The Chair will open the meeting and verify that quorum is met
    - The Regulatory Affairs Manager will record in-person attendees, virtual participants, and apologies.
2. **Meeting flow**
    - The Secretary shall read out the agenda, which must include the meeting format (physical, hybrid, or virtual).
    - The chairperson will ask members to declare any potential COIs after the full review items on the agenda.
    - If a potential COI is identified, the chair shall determine whether a COI exists, and this determination shall be documented in the meeting minutes.
    - Members are required to protect sensitive and proprietary information and must not disclose or use such information outside their official duties. This obligation continues even after their role on the committee ends, and any breach may result in disciplinary action.
    - The Secretary shall read the minutes of the previous meeting and the committee shall confirm them before proceeding to new agenda items.
3. **Decision making**
    - Busara ISERC will adopt a structured and transparent decision-making process to ensure fairness, accountability, and protection of research participants.
    - All members (in-person or virtual) may discuss, deliberate, and decide.
    - Only members who are present for the full deliberation of a protocol and are free of conflicts of interest shall participate in decision-making.
    - Members who declare a conflict of interest shall recuse themselves from both deliberation and deciding on the affected protocol, and their recusal shall be

recorded. Members who recuse themselves will not count toward the quorum of the meeting.

Consensus based decision making

- The Committee shall, as far as possible, strive to reach decisions through consensus following thorough ethical deliberation.
- Consensus shall be understood as a decision that all members present find acceptable, even if it is not each member's preferred outcome.
- The Chairperson shall facilitate inclusive discussion, ensuring that all members have an opportunity to contribute their perspectives.

Voting procedures

- Where consensus cannot be reached within a reasonable time, the Chairperson may call for a formal vote.
- Voting shall be by a show of hands, unless a secret ballot is requested by any member, or in such a form as the committee deems appropriate.
- Decisions shall be made by a simple majority of members present and eligible to vote at a quorate meeting.
- Members participating remotely must verbally confirm agreement during roll-call voting.
- In the event of a tie, the Chairperson shall have a casting vote.

Recording of decisions

- The outcome of each decision shall be clearly documented in the meeting minutes and decision records.
- The following shall be recorded for each protocol reviewed:
    - The final decision (e.g., approved, approved with modifications, deferred, or rejected);
    - The number of members voting in favor;
    - The number of members voting against;
    - The number of abstentions;
    - Any declared conflicts of interest and recusals.

- Members who disagree with the final decision shall have the right to have their dissenting opinions formally recorded in the meeting minutes.
- Where appropriate, dissenting members may submit a brief written statement outlining the basis of their position, which shall be appended to the decision record.
- The possible outcomes of a full Committee review are:
    - **Approved:** The protocol is approved as submitted, with or without minor conditions.
    - **Approved with Modifications:** The protocol is approved subject to specified modifications, which must be confirmed before research commences.
    - **Deferred:** Additional information or clarification is required before a decision can be made.
    - **Not approved:** The protocol is not approved on scientific or ethical grounds, with written reasons provided to the applicant.

2.4.3 Minutes of Meetings

The Busara ISERC Secretariat shall notify the principal investigator in writing of the Committee's decision within 48 weekday hours of the decision being made. The notification shall include:

- The Committee's decision and the date thereof;
- The unique Busara ISERC reference number and approved title of the study;
- The period of validity of the approval, typically one (1) year from the date of approval.
- Any conditions attached to the approval, including required modifications;
- Instructions for submission of progress reports and requests for continuing review;
- Specific concerns or recommendations of the Committee, where applicable.

2.4.4 Special Meetings

- The Chairperson, with recommendations from the Secretariat, may plan and hold an ad hoc meeting as necessary.
- The Chairperson may convene special meetings at any time upon reasonable notice or upon the request of at least one-third of the Committee's members.

- Special meetings may be conducted virtually or hybrid, provided a quorum (including a lay member) is met.

SOP 3: Handling Conflict of Interest (COI)

3.1 Purpose

This SOP describes the process of identifying and managing conflict of interest among Busara ISERC members

3.2 Scope

The SOP covers the policy on identification, declaration, and management of conflict of interest. It applies to all members of the Busara ISERC

3.3 Responsibility

All Busara ISERC members are responsible for disclosing any conflict of interest. However, the Chairperson of the Busara ISERC has the final responsibility of ensuring that all Busara ISERC members declare conflicts of interest when reviewing research proposals.

3.4 Types of Conflict of Interest (COI)

Conflicts of Interest are categorized into two types: Non-Financial and Financial conflicts of interest. COI will be determined based on members' disclosures regarding their relationships with study investigators, financial ties to the research, or other factors that could affect impartiality. Additionally, all members of the committee, including reviewers and trainees, will be required to sign a conflict of interest declaration prior to the start of any committee meeting.

The Busara ISERC is committed to mitigating any possible financial and nonfinancial COIs of its members, experts, and research staff to ensure that the rights and welfare of research participants are not compromised.

It is the responsibility of the Secretariat and the entire Busara ISERC to ensure that members and experts reviewing research protocols have no conflicts of interest.

3.4.1 Non-Financial Conflict of Interest

- **Personal relationships:** When a committee member has a personal relationship (e.g., immediate family member or close friend) with the principal investigator or key personnel of a research protocol under review.

- **Relationship to the research study:** When a committee member is involved in the design, implementation, or reporting of a research protocol under review.

- **Professional affiliation:** When a committee member (or his/her spouse, or immediate family member) serves as a trustee, director, officer, owner, or partner of a for-profit entity that could be affected by the outcome of a research protocol under review.

3.4.2 Financial Conflict of Interest

This occurs:

- when a Busara ISERC member (or his/her spouse, or immediate family member) has a financial interest that could be affected by the outcome of a research protocol under review.
- when a Busara ISERC member or the spouse or dependent of a member receives monetary benefits including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests), and intellectual property rights (e.g., patents, copyrights, product or service being evaluated).

3.5 Declaring a Conflict of Interest

- Upon receiving the committee agenda, committee members should review it and notify the Secretariat if they are aware of any potential conflicts of interest (COIs) related to the studies listed.

- Members should not participate in discussing, or decision making on research proposals' applications reviewed at any level (exempt, expedited, or full-board) when they have conflicts of interest except to provide information requested by the Busara ISERC.

- If a member has a COI for review outside a meeting (e.g., the expedited review, amendments,...etc), he or she should notify the Secretariat and return the documents.

- If a member has a COI for a study for which he or she has been assigned as a primary reviewer, he or she will inform the secretariat so that the review is reassigned to other members.

- If a member has a COI for review of research study at a meeting, he or she will inform the Chairperson and leave the meeting room while discussion of the study takes place. He/she may stay in the meeting room only to answer questions about the research. This is applicable also for meetings at which discussion on serious adverse events,

deviations/violations, amendments/ continuing review reports related to studies are discussed.

- A member who declares COI and leaves the meeting does not count towards the quorum for the vote. The member's absence under these circumstances will be deemed a recusal, not an abstention or an absence.
- If a member finds that he/she has a COI during the conduct of an approved research project he/she shall report the conflict at the next committee meeting.
- At the start of each committee meeting, the Chair shall ask members to declare in writing any potential COIs for the full review items on the agenda.
- If the Chairperson has a COI for a particular project, it will be declared and handled like any other member's conflict is handled. An acting Chairperson will be appointed for discussion on such a project.
- When determination regarding existence of COI is uncertain, more information is gathered from relevant sources and determination is done by the member with the help of the Chairperson or Secretary (as applicable)
- The Chairperson has the final authority to determine whether a COI has been managed appropriately for research participant protection. The Busara ISERC shall not approve a research study proposal where a COI is not managed according to this SOP
- The declaration and management of COI will be recorded in the proceedings of the Busara ISERC meetings.

SOP 4: Review and Management of Submitted Protocols

4.1 Purpose

This SOP describes how the secretariat manages submitted protocols. The scope of this SOP includes:

4.2 Scope

1. Research Protocols submitted for Initial Review
2. Research Protocols resubmitted with corrections
3. Approved Research Protocols submitted for Continuing Review

a. Study completion
b. Protocol violations/deviations
c. Initial/follow-up/final SAE reports
d. Protocol deviations and Protocol violations

4.3 Responsibility

It is the responsibility of the Principal Investigator (s) to submit Research Protocols according to Busara ISERC's guidelines and it is the responsibility of the Busara ISERC secretariat to receive and record submitted protocols and documents.

4.4 Submission Procedure

- All research proposals requiring ethics review shall be submitted to the Busara ISERC Secretariat via the online system RHinnO
- The PI submits all the relevant documents as per the Busara ISERC checklist for submission of new proposals

4.4.1 Protocol Lifecycle

The Busara ISERC shall manage all research protocols through a defined lifecycle to ensure consistency, transparency, and compliance.

The protocol lifecycle shall include the following stages:

- **Submission:** Investigator submits the complete application to the Secretariat;
- **Screening:** Administrative review for completeness and eligibility;
- **Review:** Ethical and scientific evaluation by the Busara ISERC;
- **Decision:** Communication of approval, modification, deferral, or rejection;
- **Monitoring:** Ongoing oversight of approved studies, including continuing review and reporting;
- **Closure:** Formal completion of the study upon submission of final reports and required documentation.

4.5 Management of Protocols

4.5.1 Administrative screening

Within 24 hours of submission (on weekdays), the secretariat acknowledges receipt of an application and conducts an administrative review using the Busara ISERC checklist.

4.5.2 Handling incomplete submissions

- If an application package is incomplete, the applicant is notified and required to provide the missing document(s)/information with five (5) calendar days
- If the missing document(s)/information is not received within the 5-day period, the secretariat issues reminders
- If the submission remains incomplete after 21 days from initial submission, it will be archived. The applicant is at liberty to submit a new application at any time

4.5.3 Acceptance notification

Within 24 weekday hours of receiving a complete submission, the secretariat informs the Principal Investigator that the protocol has been accepted for review.

4.5.4 Pre-screening and Categorization

The Busara ISERC administrator conducts a pre-screening to categorize proposals into one of the following review levels based on the risk involved:

- Exempt Review
- Expedited Review
- Full Review

4.5.5 Reviewer Assignment

The Busara ISERC Secretariat assigns the submitted protocol to a designated review panel or reviewer based on their expertise in the subject area of the study and the type of review required.

4.5.6 Reviewer Confirmation

The secretariat confirms the availability of the assigned reviewer(s) via email, SMS, or phone call.

4.5.7 Distribution of study materials to Reviewers

The secretariat sends the proposal and all accompanying documentation to the reviewer(s) via email, through the portal, or by hard copy. Feedback is expected within 14 calendar days.

4.5.8 Reviewer Reminders and Extension

The secretariat sends reminders to the reviewer(s) if feedback is not received within the 14-day period. If a reviewer needs additional time, a 3-calendar-day extension may be granted.

4.5.9 Review Criteria

- The review panel conducts an in-depth evaluation of the protocol, considering relevant ethical guidelines, institutional policies, and regulatory requirements.

- Reviewers may request modifications, clarifications, or additional information from the PI to address any concerns or deficiencies identified during the review process.
- Each review shall evaluate:
    - Scientific merit and methodology
    - Benefit-Risk Assessment: Justification of benefits relative to risks
    - Participant Selection: Voluntary, fair selection, with the option to opt out without penalties
    - Payment and Compensation: No inducement; only reimbursement for costs incurred
    - Social and scientific value of the research, including potential contribution to policy, practice, or knowledge
    - Clarity and adequacy of the dissemination plan, including feedback to participants and stakeholders
    - Data management and governance plan, including data storage, access controls, sharing, and retention
    - Consideration of local context, including cultural appropriateness, power dynamics, and community engagement
    - Investigator Qualifications: Adequacy of investigators and study sites.
    - Conflict of Interest Disclosure: Clear disclosure of any conflicts.
    - Informed Consent Review: Thorough evaluation of the consent process.

4.5.10 Sharing Consolidated Comments

Within 48 weekday hours of receiving the reviews, the secretariat consolidates the comments from all reviewers and forwards them to the PI.

4.5.11 Finalizing for Meeting Scheduling

Once the reviewer(s) are satisfied with the PI's response, the proposal is consolidated and prepared for discussion in a meeting.

4.5.12 Scheduling Review Meeting

The proposal is added to the next available meeting agenda and scheduled within 4 weeks of confirmation, subject to any existing backlog.

4.5.13 Notification of Presentation Date

If applicable, the PI is informed by email about the presentation date and time

4.5.14 Decision

Based on the review findings, the committee shall make one of the following decisions:

a) Approval: The protocol is approved for implementation with or without conditions.

b) Conditional Approval: Approval is granted contingent upon specified modifications or clarifications being addressed.

c) Deferred: Further review or information is required before making a decision.

d) Not approved: The protocol does not meet ethical or regulatory standards and is not approved.

4.5.15 Communication of Decision

- The final decision on the proposal is communicated in writing and sent to the PI via email within 48 weekday hours after the meeting.
- Proposals that are “not approved” must be revised and resubmitted for clearance by the committee during their sitting.
- In the case of conditional approval or deferral, the PI will be provided with specific instructions on addressing the conditions or concerns raised.
- No research activities involving human participants may begin under conditional approval. Full approval is required to initiate the study.

4.5.15 Approval Duration and Continuing Review

Approval is granted for one year. Investigators wishing to continue research beyond the one-year period must submit a continuing review request.

4.5.16 Amendments

Any changes or amendments to an approved study must be approved by Busara ISERC before implementation, except in circumstances where a delay may jeopardize participant safety.

4.5.17 Monitoring and reporting

- Busara ISERC reserves the right to monitor the research study at any point during its duration.
- The PI is required to submit progress reports annually.
- A final report must be submitted upon project completion. A project is considered complete when:
    - All research activities (e.g., data collection, analysis, intervention phases) outlined in the approved protocol have concluded.
    - All study-specific objectives and endpoints have been met or formally revised/closed by the committee.
    - Final deliverables (e.g., datasets, publications, regulatory submissions) are finalized, and no further work requiring committee oversight remains.

4.5.18 Reporting Adverse Events and Protocol Deviations/Violations

- Any serious adverse events must be reported to Busara ISERC within 72 hours.
- All protocol deviations, violations, and amendments must be reported promptly.

4.6 Review Categories

Protocols will be categorized for review as follows:

4.6.1 Expedited review

Expedited review is a process for reviewing certain projects or documents faster and more streamlined than standard review processes. Research involving human subjects may undergo an expedited review by the committee chairperson and/or designated experienced reviewers

- **Eligible protocols:** Expedited review is available for research involving no more than minimal risk, such as minor modifications to previously approved research, continuing review of research with no greater than minimal risk, research involving data collected for non-research purposes, surveys, interviews, or focus groups on non-sensitive topics with adults, and data analysis projects
- **Reviewer requirements:** Expedited review shall be conducted by the Chairperson and/or at least one (1) other designated member within 7 days after Busara ISERC has received all required submission documents from the researcher.
- **Process:** Administrative review determines eligibility, with final ratification at the next committee meeting.

Notes:

- *Any reviewer may refer a protocol to full Committee review if they determine it warrants such consideration.*
- *Reviewers conducting expedited reviews cannot disapprove applications. Disapproval can only occur at a full Busara ISERC meeting.*
- *Conditional approval will be granted pending submission of the NACOSTI permit within 14-21 days. Full approval is contingent upon timely submission.*

4.6.2 Full review

- **Eligible proposals:** required for **humanities and social sciences** research involving more than minimal risk, including: Interventional studies involving human participants, Research involving vulnerable populations, Research involving deception or incomplete disclosure, Research involving sensitive topics, Research with significant risks to participants' privacy or confidentiality and Any research the Secretariat and Chairperson determines warrants full review.
- **Reviewer Requirements:** A minimum of three reviewers is required.

Note: *Conditional approval will be granted pending submission of the NACOSTI permit within 21 days. Full approval is contingent upon timely submission.*

4.6.3 Exempt review

Certain categories of research may be exempt from full ethics review, but must still be registered with the Busara ISERC Secretariat.

- **Eligible protocols:** Studies deemed to present “less than minimal risk” such as research conducted in established educational settings involving normal educational practices, Secondary analysis of fully anonymised, publicly available datasets, and Routine programme evaluations and quality improvement studies are not intended for external publication.
- **Reviewer requirements:**The determination of exemption status shall be made by the Chairperson in consultation with the Secretariat, and shall not be self-determined by the researcher. The decision on exempt review status shall be communicated to the researcher within 5 days of submission to the Busara ISERC.

Note:

- *Any reviewer may refer a protocol to full Committee review if they determine it warrants such consideration.*
- *Conditional approval will be granted pending submission of the NACOSTI permit within 21 days. Full approval is contingent upon timely submission.*

4.6.4 Continuing Review

- **Eligible Proposals:** All approved research protocols shall be subject to continuing review by the Busara ISERC at intervals appropriate to the degree of risk, but not less than once per year.
- **Reviewer requirements:** At least 2 reviewers (one reviewer involved in the initial review and a member of the committee involved in monitoring and evaluation of the study) with guidance from the chair and the secretariat

4.6.5 Review of Amendments

An amendment is any change to a Busara ISERC approved research project. This includes changes to participant recruitment, research personnel, funding sources, study sites, study design or procedures, participant privacy and confidentiality protections, data management processes, research instruments, informed consent or assent materials and procedures, participant compensation, or conflicts of interest.

Categories

- **Major Amendment:** These are changes that are likely to significantly affect the following aspect of a study:
    - The safety or physical or mental integrity of the subjects of the study;
    - The scientific value of the study.
    - The conduct or management of the study
    - The objectives of the study
    - Sampling and study design
- **Minor Amendment:** These are changes to the protocol or other study documentation, e.g., correcting errors, updating contact points, and minor clarifications, including:
    - Updates of the Investigator's Brochure (IB) (unless there is a change to the risk/benefit assessment for the trial)
    - Changes to the chief investigator's research team

- Changes to the research team at particular trial sites (other than the appointment of a new principal investigator)
- Changes in funding arrangements
- Changes in the documentation used by the research team for recording study data;
- Changes in the logistical arrangements for storing or transporting samples or new requests to ship materials out of the country
- Inclusion of new sites and investigators in studies
- Extension of the study beyond the period specified in the application form.
- Changes to contact details for the sponsor (or the sponsor's representative), chief investigator, or other study staff are minor amendments. Still, they should be notified to the Busara ISERC for information.

- **Reviewer requirements:** At least 2 reviewers (one reviewer involved in the initial review and a member of the committee involved in monitoring and evaluation of the study) with guidance from the chair and the secretariat

4.6.6 Conditional Approvals

a) **Conditional Approval**: Following initial review under any category (Expedited, Full, Exempt, Continuing), the Busara ISERC may issue Conditional approval valid for 21 days. This approval is conditional and requires the PI to submit the NACOSTI permit within the stipulated timeframe.

b) **Full Approval:** Upon receipt of the NACOSTI permit during the Conditional period, the committee will issue full approval, enabling the study to start. If the NACOSTI permit is not submitted within 14–21 days, the Conditional approval lapses. The PI must resubmit the application, including the NACOSTI permit, for review under the applicable category.

c) **Restrictions:** No research activities involving human participants may begin under Conditional approval. Full approval is required to initiate the study.

SOP 5: Application Procedures

5.1 Submission Requirements

5.1.1 Initial review

The following documents are required when submitting a protocol for initial review:

#	Document Required	Notes
1	Completed Busara ISERC Application Form	*Use the current version from the Busara ISERC website*
2	Full Research Protocol	*Use the current template from the Busara ISERC website*
3	Informed Consent Form(s)	*In English and relevant local languages. Use the current template from the Busara ISERC website*
4	Investigator's CV	*Use the current template from the Busara ISERC website*
5	Data Collection Instruments	*Questionnaires, interview guides, etc.*
6	Funding/Sponsorship Agreement	*If applicable*
7	Material Transfer Agreement	*For primarily datasets and related documentation such as survey responses, interview transcripts, audio recordings, codebooks, and questionnaires*
8	Regulatory Approvals	*NACOSTI, KEBS, PPB, etc., where applicable*
9	Evidence of Ethical Training	*Good Clinical Practice (GCP) certificate for clinical trials*
10	Proof of payment	*Any document that serves evidence of payment*

5.1.2 Amendments

The following documents are required when submitting a protocol amendment for review:

#	Document Required	Notes

1	Completed Busara ISERC Amendment Application Form	*Use the current version from the Busara ISERC website*
2	Full Research Protocol	*Submit an updated full research protocol if any changes are made to the approved protocol*
3	Updated Informed Consent Form(s)	*Submit updated Informed Consent Form (s) if any changes are made to the approved Informed Consent Forms*
4	Investigator's CV	*Submit the CV of any new investigator joining the study*
5	Data Collection Instruments	*Submit updated Questionnaires, interview guides, etc. if any changes are made to the approved Data collection instruments*
6	Funding/Sponsorship Agreement	*Submit new agreements If applicable*
7	Material Transfer Agreement	*Submit an updated agreement if applicable*
8	Regulatory Approvals	*NACOSTI, KEBS, PPB, etc.,if the amendments warrant obtaining further regulatory approvals*
9	Evidence of Ethical Training	*Good Clinical Practice (GCP) certificate for clinical trials for any new investigator joining the research team*

5.1.3 Continuing review

The PI shall submit a completed continuing review form accompanied by:

- A progress report summarizing study activities conducted during the approval period including any changes to the approved protocol
- The number of participants enrolled, withdrawn, and completed

- A summary of any adverse events, unanticipated problems, or protocol deviations;
- Any relevant monitoring or audit reports;
- Current versions of study documents (e.g., protocol, consent forms, tools), where applicable;
- A justification for continuation of the study, including any emerging ethical considerations.
- NACOSTI permit

Note: *Download the latest continuing review form and template on the Busara ISERC website*

5.2 Submitting a Protocol

5.2.1 Plan accordingly to allow sufficient time for review

- Investigators should submit protocols for initial review at least 21 days before the next committee meeting
- Investigators must submit a continuing review application at least 60 days prior to the expiry date of the current ethical approval. Failure to submit a continuing review application before the expiry date shall result in automatic suspension of ethical approval, and all research activities must cease immediately, except where continuation is necessary to eliminate immediate hazards to participants.

5.2.2 Complete all the ethical training required

- All members of the research team must complete training in human participant protection and ethical frameworks from a recognized programme such as CITI, TTREE,...etc. Keep your certificate of completion, as you will need to upload it with your application.
- This training must be retaken every 3 years

5.2.3 Obtain any necessary regulatory approvals

- Obtain any necessary regulatory approvals where applicable
- Note, NACOSTI permit can only be obtained after the protocol has been approved

5.2.4 Complete all the required forms and templates

- Complete the appropriate forms and templates. You can obtain the latest forms and templates from the Busara ISERC website

5.2.5 Start a new protocol in RHinnO

- All studies must be submitted through Busara's RHinnO portal.
- Log in to the Busara ISERC RHinnO portal. If you are a new user, click "Create new user" to register an account first.
- Click on the "Create new Application" button in the left panel.
- Select the type of application, then click "Create Application"

5.2.6 Complete the RHinnO Protocol Questionnaire

- Fill out all the required information accurately

5.2.7 Upload all the required documents

- You must include a completed Application Form and any supplemental forms and documents related to your study

5.2.8 Submit your application

- Click on the submit button and your protocol will available to the Busara ISERC secretariat for administrative review

5.2.9 Review process

- All submissions are reviewed under a specific review pathway according to risk level. Please refer to the Busara ISERC website for more information on the review pathways
- You can check on the status of your protocol on RHinnO's "My Applications" tab

5.2.10 Approval

- Once your protocol is approved, you will receive the approval certificate via email
- You cannot commence any study activities before obtaining NACOSTI permit which is required after approval from Busara ISERC
- You cannot implement any changes to your approved study without submitting an amendment request and obtaining approval for the changes.

Note: *For more information on how to use the RHinnO system please refer the Researcher guidance document*

5.3 Application Fees

The Busara ISERC may charge a fee to cover administrative costs of protocol reviews . Fee schedules shall be approved by the Appointing Authority, published on the Busara ISERC's website, and reviewed at least every two (2) years. Provisions shall be made for reduced or waived fees for student research, low-resource settings, and community-initiated research.

The "**Basic**" rate applies only to proposals from within Busara Centre that are fully internally funded.

The "**Standard**" rate applies to all other proposals, including those made by staff members of Busara whose projects are partially- or fully funded by an external funder.

Item	Type	Fees
Initial submissions	Non-clinical trial studies	USD 1000
	PhD (International Universities)	USD 1000
	PhD (Kenyan Universities)	USD 80
	Master's	USD 50
Amendments	Non-clinical trial studies	No Charges
	PhD (International Universities)	No Charges
	PhD (Kenyan Universities)	No Charges
	Master's	No Charges
Continuing reviews / annual renewal	Non-clinical trial studies	USD 250
	PhD (International Universities)	USD 250
	PhD (Kenyan Universities)	USD 50
	Master's	USD 50
Penalties for late renewals	All Studies	USD 50

5.4 Review Timelines

The Busara ISERC shall endeavour to adhere to the following indicative timelines from receipt of a complete application:

- Exemption determination: within five (5) working days;
- Expedited review: within seven (7) working days;
- Full Committee review: within thirty (21) working days;
- Review of amendments: within fifteen (15) working days

SOP 6: Monitoring of Approved Protocols

6.1 Post Approval Monitoring and Audit

- The Busara ISERC may, at its discretion, conduct or commission site monitoring visits for approved research studies to ensure compliance with approved protocols and ethical standards
- Site visits may be announced or unannounced. Principal investigators are obligated to cooperate fully with monitoring activities and to grant access to study records, facilities, and personnel. The findings of monitoring visits shall be documented and communicated to the PI in writing.

6.1.1 Audit types

- Routine Audits: Conducted on all studies at scheduled intervals.
- For-Cause Audits: Initiated based on specific concerns, significant protocol deviations, or complaints.

6.1.2 Audit Process

- The Busara ISERC shall notify the PI 30 days before a routine audit or 5 days before for-cause audits.
- The notification shall include an audit checklist and preparatory instructions.

- Busara ISERC monitoring and audit personnel shall review all study documentation, consent forms, and data records and interview study personnel as needed.
- Observational assessments of study activities may be conducted to confirm adherence to protocol.

- Within **10 working days** of the audit's conclusion, Busara ISERC shall provide a written report detailing findings, potential risks, and recommended corrective actions.
- The PI must submit a **Corrective and Preventive Action (CAPA) Plan** within **14 days**, outlining actions to address findings.
- The Busara ISERC may schedule follow-up audits to verify the implementation of corrective actions.

6.2 Protocol Deviations and Violations

6.2.1 Definitions

Protocol Deviation	An unintended or unplanned departure from the approved research protocol that does not significantly affect participant safety, rights, or the integrity of study data. Deviations are usually unplanned and correctable without significant consequences. Examples include missing or incorrect dates on signed informed consent forms, over-enrollment of subjects in minimal risk studies, and missed study visits due to logistical challenges.
Protocol Violation	These are serious breaches of the protocol that can affect participant safety, rights, or the scientific integrity of the study. Violations may involve intentional non-compliance or significant oversights. Examples include: enrolling ineligible participants, failure to obtain informed consent, or administering the intervention, Use of data collection instruments other than those approved by the Busara ISERC, Changes in study procedures without approval by the Busara ISERC, Failure to report a serious adverse event to the Busara ISERC within the required timeframe among others. Such violations require immediate reporting to the Busara ISERC and may necessitate corrective action.

CAPA	Corrective and Preventive Action Plan: a documented plan submitted by the Principal Investigator outlining the immediate corrective actions taken and the preventive measures put in place to avoid future occurrences.

6.2.2 Responsibilities

- The Principal Investigator: Bears primary responsibility for identifying, documenting, and reporting all protocol deviations or violations to the Busara ISERC Secretariat promptly.
- Study Team: Supports the PI in monitoring study procedures and reporting deviations or violations as they are identified.
- Busara ISERC Secretariat: Receives and logs deviation and violation reports, conducts initial administrative screening, and coordinates the review process.
- Busara ISERC Committee: Reviews deviation or violation reports, assesses their impact on participant safety and data integrity, and determines appropriate corrective actions.

6.2.3 Reporting Procedures

- Protocol violations affecting participant safety or data integrity must be reported to the Busara ISERC Secretariat within twenty-four (24) hours of discovery. Initial notification should be made on email, and must be followed by a formal written Protocol Deviation Report within seven (7) working days.
- Violation reports must include at minimum:
    - A clear description of the violation and how it differs from the approved protocol;
    - The date(s) on which the violation occurred;
    - The participant(s) affected, where applicable;
    - An assessment of the potential impact on participant safety and study outcomes.
    - Corrective actions already taken or proposed.
- Protocol deviations must be documented in the study's Protocol Deviations Log and reported to the Busara ISERC at the time of the next scheduled monitoring report or at the end of the study, whichever occurs first. Where the Busara ISERC specifies reporting intervals, deviations may be reported in aggregate at those intervals.

6.2.4 Reviewing Protocol Violations

- Upon receipt of a violation report, the Busara ISERC Secretariat shall conduct an initial review to assess the urgency of the response required. The Secretariat may contact the PI for clarification before the matter proceeds for review.
- Protocol violations will be reviewed by the full committee at its next scheduled meeting, or at an urgent convened meeting for serious cases involving immediate risk to participant safety. The Committee shall:
    - Assess the impact of the violation on participant safety, study integrity, and ethical standards.
    - Determine whether immediate corrective actions are necessary. For example, halting study procedures or re-consenting affected participants;
- The Busara ISERC may, in its discretion and proportionate to the seriousness of the violation, take any of the following actions:
    - Issue a written decision to the PI outlining the Committee's findings and any required actions, including potential re-training of staff or modifications to the study protocol.
    - Issue a formal written warning to the PI;
    - Require temporary suspension of participant enrolment or study procedures pending implementation of corrective actions;
    - Require mandatory re-training of the study team in relevant areas, such as informed consent procedures or good clinical practice;
    - Require re-consenting of affected participants with updated information;
    - Require amendment and resubmission of the study protocol for review and re-approval;
    - Refer the matter to the institution's research integrity or disciplinary processes;
    - Suspend or withdraw ethics approval for the study

6.2.5 Corrective and Preventive Action (CAPA)

- The PI must submit a Corrective and Preventive Action (CAPA) Plan to the Busara ISERC Secretariat for all protocol deviations and for recurring protocol deviations.
- The CAPA Plan must address:
    - The root cause of the violation or recurring deviations

- The immediate corrective actions taken to address the violation and mitigate any harm.
- Specific, measurable actions to prevent recurrence.

- The Busara ISERC shall review the submitted CAPA Plan and determine whether the proposed measures are adequate to mitigate the risk of future deviations before the study may resume, where activities have been suspended.

6.2.6 Record Keeping

- The Busara ISERC may require the PI to submit periodic follow-up reports to confirm that corrective actions have been implemented and are effective. For ongoing studies, any protocol changes resulting from a violation, including changes to consent processes, study procedures, or data management, must be submitted as formal protocol amendments for Busara ISERC review and approval.

- The Busara ISERC Secretariat shall maintain a complete file for each reported violation, including the original violation report, all related correspondence, the CAPA Plan, and records of all decisions and follow-up actions.

- The PI must maintain a Protocol Deviations Log throughout the duration of the study, recording all deviations and the actions taken to resolve them. This log must be made available for inspection during any audit or monitoring visit.

- The Busara ISERC Secretariat shall maintain a study-specific file containing all submitted deviation reports, related correspondence, and CAPA Plans.

6.2.7 Training of Study Staff

The PI is responsible for ensuring that all study staff are trained on the protocol deviation and violation reporting process and on strict adherence to the approved protocol before the commencement of research activities, and whenever significant amendments are made to the protocol.

6.2.8 Communication with Research Participants

Where a protocol deviation or violation directly affects participants. For example, a missed intervention, incorrect dosing, or a safety concern occurs, the PI must inform affected participants

promptly. The communication must include a clear explanation of the deviation or violation and its implications. Where the deviation or violation materially affects a participant's ongoing involvement or care, the PI must obtain updated informed consent from the affected participant before they continue in the study.

6.2.9 Monitoring and Compliance

The Busara ISERC may conduct periodic audits or site monitoring visits to verify that protocol deviations or violations are being identified, documented, and reported in accordance with this SOP. Non-compliance with this SOP may result in sanctions, including the suspension of study activities or the withdrawal of ethics approval.

6.3 Adverse Event Reporting

6.3.1 Definitions

Adverse Event (AE)	Any untoward occurrence in a research participant that does not necessarily have a causal relationship with the study intervention or procedures.
Serious Adverse Event (SAE)	Any untoward medical occurrence that: (a) results in death; (b) is life-threatening; (c) requires hospitalisation or prolongation of existing hospitalisation; (d) results in persistent or significant disability or incapacity; (e) causes a congenital anomaly or birth defect; or (f) constitutes any other important medical event that may jeopardise the participant's safety or require intervention to prevent one of the outcomes listed above.
Unexpected Adverse Event	An adverse event whose nature, severity, or frequency is not consistent with the risk information described in the approved study protocol, investigator's brochure, or other study documentation.
Causality Assessment	An evaluation of the likelihood that a study intervention or procedure caused or contributed to an adverse event, typically classified as: unrelated, unlikely, possible, probable, or definite.

6.3.2 Reporting

Principal investigators shall report to the Busara ISERC Secretariat:

- Any serious adverse event within twenty-four (24) hours of the PI becoming aware of it, followed by a full written report within seventy-two (72) hours;
- Any unanticipated problem involving risks to participants or others within seventy-two (72) hours;
- All adverse events in the annual progress report.

6.3.3 Corrective and Preventive Actions

Following any SAE, the PI must submit a CAPA Plan to the Busara ISERC Secretariat. The CAPA Plan shall outline the immediate corrective actions taken to address the SAE and the preventive measures put in place to avoid future occurrences. The Busara ISERC shall review the CAPA Plan, determine whether the proposed measures are adequate, and may require periodic follow-up reports to confirm effective implementation.

6.3.4 SAE Review Procedures

Upon receipt of an SAE Report and CAPA, the Busara ISERC Secretariat shall conduct an initial review to determine whether immediate protective actions are necessary, for example, suspension of participant enrolment or halting of specific study procedures. The Secretariat and the Chairperson may act unilaterally to issue an interim protective suspension pending full Committee review.

The SAE Report shall be reviewed by the full committee at its next scheduled meeting. For events of critical urgency, particularly those resulting in participant death or posing an immediate risk to other enrolled participants, an emergency meeting shall be convened within 48 - 72 hrs. The committee review shall assess:

- The impact of the SAE on the safety of enrolled and prospective participants;
- Whether modifications to the study protocol, participant monitoring, or data safety management plan are required;
- Whether affected participants need to be re-consented with updated risk information;
- Whether the study should be suspended or terminated.

Following the review of the SAE report, the Busara ISERC may take any of the following actions: acknowledge and continue the approval; require modifications to the protocol or consent process; require suspension of participant enrolment; or suspend or revoke the ethics approval.

6.3.5 Monitoring and Compliance

The Busara ISERC may require the PI to submit follow-up reports at specified intervals to track the resolution of the SAE, confirm the welfare of affected participants, and monitor ongoing risks to the study population. Where a follow-up report reveals that risks remain unacceptably elevated, the Busara ISERC may impose additional restrictions on the study or withdraw ethics approval.

SOP 7: Informed Consent Requirements and Review

The Busara ISERC shall ensure that all research involving human participants incorporates a robust and ethically sound informed consent process, in line with national regulations and international ethical guidelines.

7.1 General Principles

- Informed consent shall be understood as a process, not a single event, through which a participant voluntarily confirms their willingness to participate in a study after being adequately informed.
- Consent must be free, informed, specific, and voluntary, and may be withdrawn at any time without penalty or loss of benefits.
- The Busara ISERC shall review both the consent process and the consent documentation for all applicable research protocols.

7.2 Required Elements of Informed Consent

All informed consent materials (written and/or verbal) shall include, at a minimum:

- The purpose of the research and why the participant is being invited;
- A clear description of the study procedures, including duration and location;
- Identification of the researchers, institutional affiliations, and sponsors;
- Disclosure of funding sources and any potential conflicts of interest;
- A description of potential risks, discomforts, and benefits;
- Information on alternatives to participation (where applicable);
- A statement that participation is voluntary, with the right to refuse or withdraw at any time without consequences;
- Measures to ensure confidentiality and data protection;
- Details of any compensation, reimbursement, or incentives;
- Information on treatment and compensation in case of research-related harm (where applicable);

- Contact details for:
    - The research team, and
    - The Busara ISERC or relevant ethics body for questions or complaints;
- Information on post-study access to interventions or findings, where relevant.

The Busara ISERC shall ensure that consent information is presented in language that is clear, culturally appropriate, and understandable to the target population.

7.3 Busara ISERC Review of the Informed Consent Process

In reviewing protocols, the Busara ISERC shall assess whether:

- The information provided is complete, accurate, and understandable;
- The consent process allows sufficient time for participants to consider participation and ask questions;
- Consent will be obtained by appropriately qualified and trained personnel;
- The process avoids coercion, undue influence, or excessive inducement;
- Appropriate provisions are made for non-literate participants (e.g., impartial witnesses, oral consent procedures);
- Consent is documented appropriately (written, verbal, or waived with justification);
- Ongoing consent is maintained where required (e.g., in longitudinal studies).

7.4 Vulnerable Populations

The Busara ISERC shall ensure that additional safeguards are in place for research involving vulnerable populations, including but not limited to:

- Children and minors;
- Pregnant women;
- Persons with diminished decision-making capacity;
- Economically or socially disadvantaged individuals;
- Prisoners or institutionalized persons;
- Individuals in dependent relationships (e.g., patients, students, employees).

For such populations, the Busara ISERC shall verify that:

- Participation is justified and cannot be carried out with less vulnerable groups;
- Risks are minimized and are reasonable in relation to potential benefits;
- Appropriate consent/assent procedures are in place:
    - Parental/guardian consent for minors;

    - Assent from children capable of providing it;
    - Consent from a legally authorized representative where applicable;
- Additional measures are taken to ensure voluntariness, especially where there may be power dynamics or dependency;
- There is no undue inducement or coercion, particularly in resource-limited settings.

7.5 Community Engagement and Cultural Considerations

- Where research is conducted within specific communities, the Busara ISERC may require community engagement or permission from recognized leaders or structures.
- However, community consent shall not replace individual informed consent.
- The Busara ISERC shall ensure that cultural practices are respected while upholding individual autonomy and rights.

7.6 Waiver or Alteration of Informed Consent

- The Busara ISERC may approve a waiver or alteration of informed consent only where:
    - The research involves minimal risk to participants
    - The waiver will not adversely affect participants' rights and welfare
    - The research could not practicably be carried out without the waiver
    - Retrospective studies, where the participants are de-identified or cannot be contacted
    - Where appropriate, participants are provided with additional information after participation.

- All waivers must be justified in the protocol and explicitly approved by the Busara ISERC.

- The Busara ISERC members and the reviewers will review the request taking into consideration the types of studies for which waiver of consent may be granted.

- Reviewers must ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data.

- In case of telephone interviews, waiver of written informed consent may be requested but verbal consent is mandatory. The following documents need to be submitted for the review for verbal consent:

- A script for verbal consent providing all of the elements of consent in a more informal style. Participants must be provided with information that describes the study and given contact names and numbers.
- The interview questionnaire to confirm that no questions are asked that compromise a person's confidentiality.

SOP 8: Responsibilities of the Principal Investigator

8.1 Pre-Study Responsibilities

Before commencing any research involving human participants, the principal investigator (PI) shall be responsible for:

- Submitting a complete ethics application to the Busara ISERC Secretariat in accordance with the prescribed procedures;
- Ensuring that all research team members are appropriately qualified and have received training in research ethics and the protection of human research participants;
- Not commencing any research activities involving participants before receiving written ethics approval from the Busara ISERC;
- Obtaining all necessary regulatory approvals, including approvals from bodies such as NACOSTI, the Pharmacy and Poisons Board (PPB), the Kenya Bureau of Standards (KEBS), and any other applicable national or county regulatory authorities, where required.

8.2 Ongoing Responsibilities During Approved Research

The principal investigator shall bear primary responsibility for the ethical conduct of the research throughout its duration, and shall:

- Conduct the research strictly in accordance with the approved protocol and any conditions attached to the approval;
- Ensure that the informed consent process is conducted appropriately, that participants' consent is documented, and that participants' right to withdraw is respected at all times;
- Promptly report any adverse events, unanticipated problems involving risk to participants, or serious non-compliance with the approved protocol to the Busara ISERC Secretariat.

- Seek prior approval from the Busara ISERC for any proposed amendments to the approved protocol that may affect the welfare of participants, the scientific validity of the study, or the ethical acceptability of the research;
- Submit annual progress reports to the Busara ISERC as required, or more frequently if specified in the approval.
- Notify the Busara ISERC immediately upon the early termination of the study and provide a written explanation of the reasons therefor;
- Ensure that all study data and records are maintained securely and in accordance with the approved data management plan.
- Cooperate fully with any monitoring, audit, or investigation activities conducted or authorised by the Busara ISERC.

8.3 Post-Study Responsibilities

Upon completion of the research, the principal investigator shall:

- Submit a final study report to the Busara ISERC Secretariat within three (3) months of study completion;
- Ensure that all study records are archived in accordance with Section 4 of these SOPs.
- Ensure that research participants are informed of relevant study outcomes where practicable.
- Disclose any publication of results arising from the research to the Busara ISERC.

SOP 9: Complaints and Dispute Resolution

9.1 Complaints Handling Procedures

The Busara ISERC shall establish and maintain a transparent, accessible, and fair procedure for handling complaints related to research ethics. Complaints may be submitted by research participants, researchers, members of the public, or any other party with a legitimate interest.

Complaints may relate to:

- The conduct of approved research, including alleged violations of the approved protocol or applicable ethical standards;
- The conduct of the Busara ISERC review process, including alleged bias, conflict of interest, or procedural irregularity;
- The conduct of a researcher, including allegations of research misconduct or unethical treatment of participants;
- Harm or adverse events experienced by research participants.

The following process shall govern the handling of complaints:

- All complaints shall be submitted in writing to the Busara ISERC Secretariat. Where a complainant is unable to write, the Secretariat shall assist in recording the complaint.
- The Secretariat shall acknowledge receipt of the complaint within two (2) working days.
- The Chairperson shall appoint an investigation sub-committee of at least three (3) members with no conflict of interest in relation to the complaint;
- The investigation sub-committee shall review all relevant documentation, interview relevant parties, and submit a report with findings and recommendations to the full Committee within thirty (30) working days.
- The full Committee shall consider the sub-committee's report and decide within fifteen (15) working days;
- The Busara ISERC shall communicate its determination and any remedial action to all relevant parties in writing within two (2) working days of the decision.

9.2 Dispute Resolution

Where a disagreement arises between a principal investigator and the Busara ISERC regarding the review or conditions of an ethics approval, the following dispute resolution process shall apply:

- The PI may submit a written request for reconsideration to the Chairperson within fifteen (15) working days of receiving the Busara ISERC decision, setting out the grounds for reconsideration and providing any additional information or argument.

- The Chairperson shall place the request for reconsideration on the agenda of the next meeting of the full Committee.
- The full Committee shall review the request and may, at its discretion, invite the PI to attend and make a presentation, but the PI shall not be present during deliberations or voting;
- The Committee's decision on reconsideration shall be final at the institutional level.
- The committee's decision is final; unresolved cases escalate to NACOSTI.

9.3 Reporting to NACOSTI

The Busara ISERC shall report to NACOSTI in the following circumstances:

- Annual reports on the Busara ISERC's activities, including the number and types of protocols reviewed, and outcomes of review;
- Prompt notification of any serious or ongoing violation of research ethics standards, including cases of research misconduct that cannot be resolved at the institutional level;
- Notification of any suspension or revocation of ethics approval for ongoing research;
- Notification of any serious adverse events or unexpected outcomes in approved research involving risk to participants;
- Any other matters as required by NACOSTI's guidelines and regulations.

All reports to NACOSTI shall be submitted through the Busara ISERC Secretariat and shall be approved by the Chairperson before transmission.

SOP 10: Documentation, Record Keeping, and Archiving

10.1 Documentation Requirements

The Busara ISERC shall maintain comprehensive and accurate documentation of all its activities. The following documents shall be maintained for each research protocol:

- The complete application as submitted, including all supporting documents;
- All correspondence with the principal investigator and other parties;

- The primary reviewer's evaluation report.
- Minutes of the Committee meeting at which the protocol was reviewed;
- The formal written decision was communicated to the principal investigator.
- Records of all amendments, protocol deviations, and adverse events;
- Progress reports submitted by the principal investigator.
- Final study report or notification of study completion;
- Records of any complaints, investigations, or corrective actions related to the study.

10.2 Record Keeping

The Busara ISERC Secretariat shall maintain all records in a secure, organised, and readily retrievable manner. Records shall be maintained in both electronic and hard copy format where applicable. The following principles shall govern record keeping:

- All records shall be stored securely with access restricted to authorised personnel.
- Any Busara staff who is not a member of the Busara ISERC shall not have access to the records, access shall be restricted to authorised personnel only.
- An electronic database of all research protocols, decisions, and correspondence shall be maintained and regularly backed up.
- Records shall be indexed and retrievable by protocol reference number, principal investigator, study title, and review date.
- The integrity and completeness of records shall be regularly audited.

10.3 Archiving

Approved research protocol files shall be retained for a minimum period of ten (10) years after the completion or termination of the study, or such longer period as may be required by applicable law or regulation.

- Records shall be transferred to an archive at the conclusion of the study and shall remain accessible for audit, inspection, and litigation purposes.

- Electronic records shall be stored in a format that ensures long-term readability and integrity.
- The destruction of archived records shall require prior approval by the full Committee, which shall be documented in the meeting minutes. Following such approval, the destruction shall be authorised in writing by the Chairperson and appropriately documented.
- The institution shall ensure the continued accessibility of archived records in the event of institutional restructuring, closure, or relocation of the Busara ISERC.

SOP 11: Linkages with Other ISERC's

11.1 National Linkages

The Busara ISERC shall establish and maintain formal linkages with NACOSTI and other national ethics review bodies as follows:

- The Busara ISERC shall register with NACOSTI and maintain its registration in good standing, including submission of all required reports and compliance with all applicable guidelines.
- The Busara ISERC shall participate in national forums where possible and/or applicable, workshops, and training activities organised by NACOSTI for ethics review committees.
- The Busara ISERC shall collaborate with the Kenya Medical Research Institute (KEMRI) Scientific, Ethics Review Unit (SERU), Mount Kenya University IERC and other national institutional review bodies on matters of shared interest.
- In cases involving multi-centre research in Kenya, the Busara ISERC shall coordinate review activities with other relevant ISERCs to avoid duplication and ensure consistency.

11.2 Multi-Institutional Research

For research involving multiple institutions:

- The lead institution's ISERC shall generally take primary responsibility for review, and the ISERCs of participating institutions will conduct internal reviews
- The Busara ISERC may enter into formal reliance or work-sharing agreements with the ethics review committees of partner institutions

- All reliance agreements shall clearly define the respective responsibilities of each committee and shall be compliant with applicable national regulations.

11.3 International Linkages

For research involving international collaborators or funding:

- The Busara ISERC shall ensure that all internationally funded or internationally collaborative research involving Kenyan participants complies with Kenyan law and the applicable ethical standards, regardless of the requirements of foreign ethics review bodies.
- The Busara ISERC may accept the review documentation of recognised international ethics review committees as supplementary material, but shall conduct its own independent review and issue its own ethics approval.
- The Busara ISERC shall not accept the ethics approval of a foreign committee as a substitute for the Busara ISERC review.
- The Busara ISERC may enter into memoranda of understanding with internationally recognised ethics review bodies for purposes of capacity building, training, and information sharing.

11.4 Communication and Information Sharing

The Busara ISERC shall foster a culture of cooperation, transparency, and continuous improvement in research ethics through:

- Regular communication with other NACOSTI-registered ethics review committees on matters of shared concern;
- Participation in inter-institutional research ethics networks and working groups;
- Sharing of anonymised data, trends, and learnings to advance the field of research ethics at the national level.

SOP 11: SOP Revisions

These Standard Operating Procedures shall be reviewed at least every three (3) years, or earlier if required by changes in applicable law, regulations, or guidelines. Proposed amendments to these SOPs shall be reviewed and recommended by the Busara ISERC and shall be subject to approval

by the Appointing Authority. Approved amendments shall be communicated to all members and stakeholders and shall take effect from the date specified in the amendment notice.

END OF Busara ISERC STANDARD OPERATING PROCEDURES

Document Reference: Busara ISERC-SOP-001 | Version 1.0