# Busara Institutional Scientific and Ethical Review Committee (Busara ISERC)

## Service Delivery Charter

**Our vision**
To be a leading ethical review committee, advancing high-quality, contextually grounded, and participant-centered research that creates meaningful impact.

**Our Mission**
To provide rigorous, efficient, and context-sensitive ethical review of research involving human participants, safeguard their rights and welfare, and promote continuous improvement in ethical research practices through accountability, community engagement, and scientific expertise.

### Core Competencies

**Behavioral science expertise:** A lack of behavioral science expertise can lead to miscalibrated attention, with too much scrutiny on some protocols that are genuinely low risk and not enough scrutiny on protocols that present higher levels of risk. Both the secretariat and committee at Busara ISERC is staffed with members who have a good understanding of behavioral science.

**Community input:** To ensure knowledge and expertise on context is left to the experts - communities themselves - the Busara ISERC has seats reserved on the committee for members of the communities where Busara works most frequently, such as Kibera and Kawangware.

**Accountability:** Busara ISERC is committed to accountability at two levels; shielding the ethics review process from outside influence and establishing proper feedback mechanisms and acting on all learnings they provide

**Efficiency:** Busara ISERC is committed to streamlined and user- friendly processes

## INTRODUCTION

The Busara Scientific and Ethics Review Committee (Busara ISERC) is an independent ethics oversight body constituted pursuant to the Science, Technology and Innovation Act (No. 28 of 2013), NACOSTI Guidelines for Ethics Review Committees, and applicable international ethical frameworks including the Declaration of Helsinki and the Belmont Report. BESRC is mandated to review and approve all research involving human participants conducted in Kenya, to protect the rights, dignity, and welfare of research participants, and to promote the conduct of ethically sound scientific research. This Charter sets out the standards of service that researchers, participants, and the public may expect from the Busara ISERC.

## SERVICES OFFERED

| S/No. | SERVICE / GOOD | REQUIREMENTS TO OBTAIN SERVICE | COST | TIMELINE |
|---|---|---|---|---|
| 1 | **Ethics Review: (New Applications)** | • Completed Busara ISERC Application Form<br>• Full research protocol<br>• Informed consent form(s) in English & local languages<br>• Curricula vitae (CVs) for all members of the research team<br>• Valid ethics training certificates for all members of the research team<br>• Data collection instruments<br>• Proof of regulatory approvals<br>• Any other relevant documents | **Non-clinical trial studies**: USD 1000<br><br>**PhD** (International Universities): USD 1000<br><br>**PhD** (Kenyan Universities): USD 80<br><br>**Master's**: USD 50 | • **Full Committee:** 21 working days<br>• **Expedited:** 7 working days<br>• **Exempt:** 5 working days |
| 2 | **Protocol Amendments** | • Amendment request form<br>• Revised study protocol with tracked-changes<br>• Revised study tools with tracked-changes (if applicable)<br>• NACOSTI Permit | No Charges | 7 working days |

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| 3 | **Continuing / Annual Review of Approved Studies** | • Annual progress report form<br>• Summary of adverse events (if any)<br>• Revised study documents (if applicable) | **Non-clinical trial studies**: USD 250<br><br>**PhD** (International Universities): USD 250<br><br>**PhD** (Kenyan Universities): USD 50<br><br>**Master's**: USD 50 | 15 working days |
| 4 | **Adverse Event / Protocol Deviation Reporting** | • Completed adverse event / deviation report form<br>• Supporting study documentation | No Charges | Serious AEs: acknowledged within 24 hrs;<br>full review within 10 working days |
| 5 | **Issuance of Ethics Approval Certificate** | • Completion of all conditions attached to approval<br>• Confirmation of NACOSTI registration | No Charges | 3 working days after completion of all conditions attached to approval |
| 6 | **Research Ethics Training & Capacity Building** | • Written request / booking form<br>• Number of participants and preferred dates | As per schedule | By appointment;<br>min. 5 working days' notice |
| 7 | **Response to Written Correspondence / Email** | • Email to Busara ISERC Secretariat | No Charges | Within 24 hrs |
| 8 | **Complaints, Grievances & Appeal Handling** | • Verbal or written complaint / appeal to the Busara ISERC Secretariat | No Charges | Acknowledgement: within 24 hrs<br>Resolution: 30 working days |
| 9 | **Access to Busara ISERC Records (Approved researchers / auditors)** | • Formal written request<br>• Statement of legitimate interest / authorisation | No Charges | 10 working days |

**WORKING HOURS**
Monday to Friday
**8:00 am – 5:00 pm** (Except Public Holidays)

**SUBMISSION DEADLINE**
Applications must be received at least **4 weeks** before research commencement.


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