Busara Institutional Scientific and Ethical Review Committee (Busara ISERC)

IERC Submission Checklist

Study Title: *[Insert Study Title]*

BSERC Protocol Number: *[Insert Protocol Number]*

Principal Investigator: *[Insert Name]*

Institution: *[Insert Your Institution's Name]*

Date of submission: *[Insert Date]*

1. General Submission Requirements

Item	Completed? (Yes/No/NA)	Comments
Fully completed IERC application form.		
Signed and dated application by the PI.		
Payment of ethics review fee		

2. Study Protocol

Item	Completed? (Yes/No/NA)	Comments

Detailed research protocol.		
Study objectives and rationale clearly stated.		
Methodology, including study design and population, detailed.		
Data collection tools and procedures are described.		
Study timeline and milestones provided.		

3. Informed Consent Documents

Item	**Completed? (Yes/No/NA)**	**Comments**
Informed consent form (ICF) in English.		
ICF translated into local language(s).		
Simplified ICF for vulnerable populations (e.g., minors, non-literate participants).		
Assent form for minors.		
Consent process described in the protocol.		

4. Supporting Documents

Item	**Completed? (Yes/No/NA)**	**Comments**
Questionnaire(s), interview guide(s), or other data collection tools.		

Recruitment materials (e.g., posters, flyers)		
CV of the PI and key personnel.		
Proof of training in research ethics (e.g., CITI certification)		
Letters of support or collaboration		
Data safety and monitoring plan.		
Copies of relevant permits (e.g., institutional approval, national research permits).		

5. Risk and Safety Management

Item	Completed? (Yes/No/NA)	Comments
Description of potential risks to participants		
Mitigation measures for identified risks.		
Safety monitoring procedures outlined.		
Plan for reporting adverse events to IERC.		

6. Data Management and Confidentiality

Item	Completed? (Yes/No/NA)	Comments
Data management plan included.		
Measures to protect participant confidentiality.		

Anonymization and de-identification procedures.		
Data sharing and storage plan.		

7. Declaration and Approvals

Item	Completed? (Yes/No/NA)	Comments
Declaration of any conflict of interest.		
Approval from collaborating institutions.		
Insurance for participants.		

8. Additional Requirements

Item	Completed? (Yes/No/NA)	Comments
Community engagement plan.		
Justification for use of vulnerable populations.		
Plans for return of results to participants or communities.		
Post-study care or compensation described.		

9. Submission Confirmation

Item	Completed? (Yes/No/NA)	Comments
All required documents are compiled in a single submission package.		

Submission conforms to IERC deadlines and format requirements.		
Electronic and/or hard copy submission completed.		