Continuing Review/Amendment Application Form

1. Do not leave unanswered questions; incomplete forms will not be accepted
2. All responses must be typed; handwritten forms will not be accepted
3. All applications must be submitted through the Busara ISERC's web-based submission portal (https://busara.rhinno.net/login).
4. Documents must be submitted in PDF format

1. Information

1.1. **Study details**

Study Title:	
Name of Funder:	
Study Site	
Total Budget:	
Anticipated End Date:	

1.2. **Principal Investigator**

Name:	
Institutional affiliation:	
Primary email address:	
Phone Number:	
Date of Submission:	

1.3. **Co-investigators**

Full Name	Institution	Email & Mobile No.	Role in the study	Qualifications

NB: All correspondence shall be addressed to the Principal Investigator. Research Coordinators may have delegated signatory authority only when listed as Co-investigators.

2. Type of Application(tick appropriately):

- Renewal
- Amendment

3. Requirements

3.1. **For Amendments:**

a) Please provide a summary and justification of the amendments requested

b) Summary of document changes

Document Name	Summary of Changes

c) Does this amendment require re-consenting participants?

- No
- Yes (please provide reason(s).....

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d) Complete the application form in English and submit the following documents
   i) Complete Amendment Application form
   ii) Approval Certificate before the amendment
   iii) NACOSTI permit
   iv) Updated Complete Study Protocol
   v) Updated Study tools e.g., questionnaires, guides - both English and translated
   vi) Updated Adult Informed Consent Form - both English and Translated
   vii) Updated Informed Assent Form where applicable- both English and Translated
   viii) Curriculum Vitae and Ethics Certificate of any new members joining the study team
   ix) Any other supporting documents

3.2. For Renewals:

a) Please provide the following information:
   i) Number of Participants enrolled to date
   ii) Study milestones completed
   iii) Adverse events summary (if any)
   iv) Anticipated completion date

b) Complete the application form in English and submit the following documents
   i) Complete Continuing Review Application form
   ii) Current version of the study protocol
   iii) Current version of the study tools
   iv) Current version of the Adult Informed Consent
   v) Current version of the Assent Form if applicable
   vi) Complete progress report form
   vii) Complete Adverse Events form where applicable
   viii) Complete Protocol Violation/Deviation form where applicable
   ix) Corrective and Preventive action plan where applicable
   x) Any relevant monitoring or audit reports

4. For Amendment only:

Document	Previous Version/Date	New Version/Date	Summary of Changes

5. Does this amendment require re-consenting participants?
    - No
    - Yes (please provide reason(s)……
      ……
      ……

6. For Renewals only:
    a. Number of Participants enrolled to date: ……

    b. Study milestones completed: ……

       ……

       ……

    c. Adverse events summary (if any)……

       ……

       ……

    d. Anticipated completion date: ……

7. State all reasons for Amendment and/or Renewal.

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8. Declaration:

   I……., the Principal Investigator of this study, declare that:

    a. All information provided is correct

    b. The research will be conducted per the National Guidelines on Ethical Conduct in Human Research

c. I will immediately report to the Busara IERC anything that might warrant a review of the ethical approval of the proposal

d. I will inform the Busara IERC if the research project is discontinued before the expected date of completion

e. Any change to this protocol and/or procedure shall be notified to the IERC and effected only after approval by the IERC.

f. I will adhere to the conditions of approval stipulated by the Busara IERC and will cooperate with the IERC monitoring requirements

g. There is no conflict of interest in this study/project

h. Other members of the research team are bound by this declaration.

PI Signature:..... Date.....

Collaborators Signature:..... Date.....

Collaborators Signature:..... Date.....

FOR OFFICIAL USE ONLY

Note: To be completed by the BSERC secretariat

I have checked the proposal, and I confirm that the application is complete.

Checklist for Completeness – [Indicate Yes or No for each]

Copy of application and all supporting documents.

a. The application contains original inked authorization signatures.
    - Yes
    - No
b. Application/proposal signed by all investigators on the study/project.
    - Yes
    - No

c. Any other comment
   (describe):.....
   .....
   .....
   .....
   .....

d. Received by:

   Name of recipient::.....

   Signature of recipient:.....

   Date:.....