ST. FRANCIS UNIVERSITY COLLEGE
OF HEALTH AND ALLIED SCIENCES (SFUCHAS)

A Constituent College of St. Augustine University of Tanzania

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SFUCHAS – INSTITUTIONAL REVIEW BOARD (IRB) APPLICATION FORM

(Prepared in accordance with NIMR–Tanzania Ethical Review Guidelines)

1. Project Title

Provide a clear, concise, and scientifically sound title reflecting study design, population, and location.

2. Date of Submission

Day/Month/Year: _____

3. Principal Investigator

i. Full Name:

……
……

ii. Institutional Affiliation

……
……

iii. Department

……
……

iv. Postal Address

v. ……
……

vi. Email

……
……

vii. Phone Number

……
……

viii. Academic/Professional Qualifications

……
……

ix. Experience relevant to the study topic

……
……

x. Proof of Human Research Ethics Training attached? Yes / No

……
……

5. Co-Investigator(s) (if applicable)

(Add additional pages if necessary)

Name:

- Institution:
- Email:
- Phone No.:
- Fax No.:
- Role in the Study:

6. Type of Submission (Tick One)

☐ New Protocol
☐ Feedback/Response to IRB comments
☐ Amendment
☐ Extension
☐ Progress/Final Report

7. Collaborating Institution(s) (if applicable)

Name of Institution

……

- Contact Person

  ……

- Email

  ……
  ……

- Phone No.
- ……
  ……
- Nature of Collaboration (technical/financial/data sharing/etc.)

  ……
  ……

Attach: Collaboration agreement/MoU/ DTA (if applicable).

8. Proposed Study Start Date

Month/Year: _____

9. Proposed Study End Date

Month/Year: _____

10. Has this protocol been approved by another Ethics Committee (EC)?

☐ Yes
☐ No

If Yes:

i. Name of EC: _____
ii. Date of Approval: _____
iii. Attach Approval Letter

11. Has this protocol been previously disapproved by another IRB?

☐ Yes
☐ No

If yes, provide reasons and attach documentation:

12. Research Site(s)

- Region:
- District:
- Health Facility/Community/Institution:
- Justification for site selection:

Attach site permission letters.

13. Expected Start Date (Month/Year)……..

14. Duration of Study Period (Months)……..

15. Sponsor/Funding Agency

- Name of Sponsor:
- Grant Number (if applicable):
- Funding Amount (if required):
- Is the sponsor involved in study design or publication decisions? Yes / No

Attach funding approval letter (if applicable).

16. Proposed Study Population (Tick all that apply)

☐ Males/Females
☐ Adolescents (12–17 years)
☐ Children (<12 years)
☐ Pregnant Women
☐ Elderly (≥60 years)
☐ Infants
☐ Other (Specify): _____

Inclusion Criteria:

Exclusion Criteria:

Sample Size and Justification:

(Provide statistical justification and assumptions used in calculation.)

17. Type of Study (Tick all that apply)

☐ Survey
☐ Case-Control
☐ Secondary Data Analysis
☐ Clinical Trial
☐ Community-Based Trial
☐ Longitudinal Study
☐ Other (Specify): _____

Study Design Description:

(Describe methodology, recruitment process, data collection tools, and analysis plan.)

…….

……..

18. Scientific Background and Rationale

- Problem Statement

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  .
  ……..

- Literature Review Summary

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  .
  ……..

- Knowledge Gap

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  .
  ……..

- Study Objectives (General and Specific)

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  .
  ……..

- Research Questions/Hypotheses

  ……
  .
  ……..

19. Ethical Considerations

19.1 Informed Consent (Tick applicable)

☐ Written
☐ Oral
☐ English
☐ Local Language (Specify): _____
☐ Assent (for minors)

Attach:

- Participant Information Sheet
- Consent/Assent Forms

19.2 Risk Assessment

☐ Greater than Minimal Risk
☐ Minimal Risk
☐ No Risk

If Minimal or Greater than Minimal Risk:

i. Describe potential risks (physical, psychological, social, economic):
ii. Risk mitigation strategies:
iii. Adverse event monitoring plan:
iv. Referral mechanism (if harm occurs):

19.3 Benefits

i. Direct benefits to participants:
ii. Indirect/community benefits:

19.4Confidentiality

i. Coding system for participants

……

ii. Data storage location

……
…

iii. Who has access to data

……

iv. Data retention period

……

v. Data disposal plan:

……

19.5 Compensation

i. Will participants receive compensation? Yes / No
ii. Describe type and amount:

iii. Justification (ensure no undue inducement):

20. Availability of Emergency Equipment

Is equipment available at this site to treat life-threatening adverse events?

☐ Yes
☐ No

If No, describe contingency plan (referral facility, ambulance access, emergency contacts):

21. Data Management and Analysis Plan

i. Data collection procedures
ii. Tools validity and reliability
iii. Data entry and cleaning procedures
iv. Statistical analysis methods
v. Software to be used
vi. Handling missing data
vii. Bias minimization strategies

22. Feasibility and Resources

i. Staffing and roles
ii. Equipment availability
iii. Timeline (attach Gantt chart)
iv. Potential challenges and mitigation strategies

23. Study Topic Classification

a. Malaria
b. HIV/AIDS
c. Tuberculosis
d. Reproductive Health
e. Other (Specify): _____

If Other, specify clearly: _____

24. Payment/Invoice

Is receipt of IRB payment attached?

☐ Yes
☐ No

26. Ethics Training

Did the PI undertake a short course in protecting human research participants?

☐ Yes (Attach Certificate)
☐ No

27. Attachments Checklist

☐ Full Research Protocol
☐ Investigator CVs
☐ Ethical Clearance from other EC (if applicable)
☐ Site Permission Letters
☐ Consent/Assent Forms
☐ Data Collection Tools
☐ Budget
☐ Gantt Chart
☐ Payment Receipt
☐ Ethics Training Certificate
☐ Collaboration Agreement (if applicable)

Declaration by Principal Investigator

I certify that the information provided in this application is accurate and complete. I agree to conduct this study in accordance with:

i. SFUCHAS IRB regulations
ii. National Institute for Medical Research ethical guidelines
iii. National and international principles for protection of human research participants

Name: _____
Signature: _____
Date: _____