

**FORM 04: APPLICATION FORM**

**ZANZIBAR HEALTH RESEARCH INSTITUTE**



**HEALTH RESEARCH COORDINATING COMMITTEE**

Secretariat  
Zanzibar Health Research Ethics Committee  
Zanzibar Health Research Institute  
Binguni  
P.O. Box 236  
Zanzibar, Tanzania  
Mobile: +255776264880  
Email: [zahrec@zahri.go.tz](mailto:zahrec@zahri.go.tz)  
Website: [www.zahri.go.tz](http://www.zahri.go.tz)

# APPLICATION FORM

**Application for:**

Ethics Review	Renewal (extension)	Termination
Resubmission	Expedited	Specify if any other

**Study type:**

Intervention

Nonintervention

Non-degree project

Degree project:

Degree project	Undergraduate	Master	PhD
----------------	---------------	--------	-----

Other specifies:

**Part I**

**Title of the Project**

## 2. Investigators

### 2.1 Principal investigator 01

Name			
Qualifications			
Designation			
Official address			
Telephone		E-mail address	
Signature			

### Principal investigator 02

Name			
Qualifications			
Designation			
Official address			
Telephone		E-mail address	
Signature			

### 2.2 Co-investigator 01/ Supervisor

Name			
Qualifications			
Designation			
Official address			
Telephone		E-mail address	
Signature			

### Co-investigator 02/Supervisor

Name			
Qualifications			
Designation			
Official address			
Telephone		E-mail address	
Signature			

### Co-investigator 03/Supervisor

Name			
Qualifications			
Designation			
Official address			
Telephone		E-mail address	
Signature			

**Co-investigator 04/Supervisor**

Name			
Qualifications			
Designation			
Official address			
Telephone		E-mail address	
Signature			

(If there are any more investigators please add their details in an additional sheet)

**3. Select all that applies to this study**

- a) Does this research involve collection or use of individual level data? YES NO
- b) Does this research involve collection or use of community level data that are on sensitive topics? YES NO
- c) Are all data to be used in the research in the public domain? YES NO
- d) Are participants in this study considered as a vulnerable group? YES NO
- e) Is the risk involved to the participants minimal? YES NO
- f) Does the research involve use of biological material? YES NO

**4. Nature of the research project****4.1 Specify the type of study**

4.1.1 Observational/non interventional study:

Investigator initiated

Industry sponsored

4.1.2 Clinical trial:

Investigator initiated

Industry sponsored

4.1.3 Other intervention studies

4.1.4 Research database

4.1.5 Other, specify: .....

**4.2 Is this for an academic degree?**

Yes

No

4.2.1 If for an academic degree, specify:

--

4.2.2 Degree awarding University:

4.2.3 Registration status	Registered		Pending	
	Date of Registration:	Registration Number:		

**5. Proposed dates of commencement and completion the study**

*[From initial recruitment of participants until completion of the project]*

Date of commencement:

Date of completion :

**6. Has ethical approval for this study been requested earlier from this Ethics Review**

**Committee? YES NO**

If yes,

Reference number	
Decision*	
Date	

\*Attach documentary evidence

**7. Has ethical approval for this study been requested from any of the Ethics Review**

**Committee? YES NO**

If yes,

Name of ERC	
Reference number	
Decision*	
Date	

\*Attach documentary evidence

**8. Has this project been subjected to scientific review?**

**YES NO**

If yes,

Name and address of the committee	
Decision*	
Date	

\*Attach documentary evidence

**9. Estimated budget of your project\***

Over 100,000

USD 100,000

USD 100,000-10,000

USD 10000- 1000

Less 1000

**\* Include budget in the proposal**

**10. Funding status**

10.1Status

Planning to apply

Decision pending

Funding secured

Self-funded

10.1.1 If funded:

Name and address of funding agency	
Amount	

10.2 Do the study subjects have to incur any expenses by being participants in the study?

YES

NO

Yes (Specify)

--

## 11. Collaborative research

11.1 List the collaborating institutes and their role

	Institution	Recruitment	Lab facility	Logistics	Intellectual	Any other
1.						
2.						
3.						

### \*Attach documentary evidence

11.2 Has this study been submitted to an ERC/similar body in the country/countries of foreign collaborator/s? YES NO

If yes,

a)

Name and address of the committee	
Decision*	
Date	

b)

Name and address of the committee	
Decision*	
Date	

c)

Name and address of the committee	
Decision*	
Date	

### \*Attach documentary evidence

If no, give reason/s

--



11.3 What is the relevance of this study to Zanzibar?

11.4 Are biological samples to be transferred abroad?

YES

NO

If YES

- a) Attach the material transfer agreement
- b) Describe the fate of the biological sample at the conclusion of the study

## 12. Intervention study

12.1 What phase clinical trial/intervention study is being conducted?

Phase I

Phase II

Phase III

Phase IV

Others (Specify)

12.2 If it is the clinical trial, is it registered with a clinical trial registry (CTR)?

YES

NO

12.2.1 In which CTR is this registered?

Name of the registry:

12.3 Is it a multi-center trial? YES

NO

If yes, list the centers.

Country	Center	Effective date of joining the trial

12.4 Has ethical approval been obtained to conduct the study in centers given in 12.3 from Relevant bodies? \* YES NO

Center	Name of the ERC	Date of approval

**\*If yes, attach documentary evidence**

**\*If no, give justification**

12.5 What is the procedure for dealing with adverse events?

12.6 What is the procedure for reporting adverse events?

**\*Attach documentary evidence**

12.7 What is/are the criteria for termination of the trial?

12.8 Are the participants paid? YES NO  
If yes, amount of money per participant per visit?

12.9 Are the investigators paid? YES NO  
If yes, by whom and the amount?

12.10 Details of insurance coverage for participants

**\*Attach documentary evidence**

12.11 If Patient recruitment is not taking place in foreign collaborating institution explain why?

### 13. Conflicts of Interest

13.1 Declare any conflicts of interest that you may have in conducting this project (commercial/financial/intellectual/Other)

13.2 Does any member of the research team have any affiliation with the providers of funding/support or financial interest in the outcome of research? YES NO

If YES Explain.

#### 14. Declaration of Applicant

1. As the Principal Investigator/Co PI of this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant national and international policies and regulations that govern research involving human participants.
2. I understand that if there is any deviation from the project as originally approved I must submit an amendment to the ERC for approval prior to its implementation.
3. I have submitted all significant previous decisions by this or any of their ERC and/or regulatory authorities relevant for the proposed study.
4. 4. I declare that I am not seeking approval for a study that has already commenced or has already been completed.
5. 5. I will submit progress reports/reports of adverse events and side effects/final report as requested by the ERC.

Signature of the Principal  
Investigator/ Co PI

Date

#### 15. Consent from all investigators

We, the undersigned hereby confirm that we have consented to be co-investigators of the project

Titled:

--

Name	Institutional Affiliation	Signature

***For office use only:***

<b>Application Number</b>			<b>Date received</b> <b>(DD/MM/YYYY)</b>	
---------------------------	--	--	---	--

**Received by:**

--

<b>Names of the Reviewers</b>	
<b>Reviewer1</b>	
<b>Reviewer2</b>	
<b>Reviewer3</b>	