FORM 04: APPLICATION FORM

ZANZIBAR HEALTH RESEARCH INSTITUTE

APPLICATION FORM FOR ETHICS APPROVAL

HEALTH RESEARCH COORDINATING COMMITTEE

Secretariat
Zanzibar Health Research Ethics Committee
Zanzibar Health Research Institute
Binguni
P.O. Box 236
Zanzibar, Tanzania
Mobile: +255776264880
Email: info@zahri.go.tz
Website: 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

PREVALENCE AND DETERMINANTS OF PSYCHIATRIC READMISSION AMONG PSYCHIATRIC PATIENTS AT KIDONGO CHEKUNDU PSYCHIATRIC HOSPITAL UNGUJA ZANZIBAR

2. Investigators

2.1 Principal investigator 01

Name	ABDALLAH KASSIM ABDALLAH		
Qualifications	MSc.PUBLIC HEALTH		
Designation	STUDENT		
Official address	KIANGA,ZANZIBAR		
Telephone	0656427735	E-mail address	nurseabidal@gmail.com
Signature			

Principal investigator 02

Name			
Qualifications			
Designation			
Official address			
Telephone		E-mail address	
Signature			

2.2 Co-investigator 01/ Supervisor

Name	DR.CANDIDA MOSHIRO		
Qualifications	Phd		
Designation	LECTURE		
Official address	MUHAS,SCHOOL OF PUBLIC HEALTH AND SOCIAL SCIENCE		
Telephone	0784950071	E-mail address	cmoshiro@gmail.com
Signature			

Co-investigator 02/Supervisor

Name	DR. THERESIA AMBROSE		
Qualifications	MSc		
Designation	LECTURE		
Official address	MUHAS,SCHOOL OF PUBLIC HEALTH AND SOCIAL SCIENCE		
Telephone		E-mail address	tambroce@yahoo.com
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:

Master of Public Health of Muhimbili University of Health and Allied Sciences

4.2.2 Degree awarding University:				
4.2.3 Registration status	Registered	✔	Pending	☐
	Date of Registration:	Registration Number:		
	01/10/2022	HD/MUH/T.667/2022		

5. Proposed dates of commencement and completion the study

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

Date of commencement: 13/06/2024

Date of completion : 13/08/2024

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	MUHAS IRB
Reference number	DA.282/298/01.C/2283
Decision*	APPROVED
Date	31/05/2024

*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

11.1List 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)

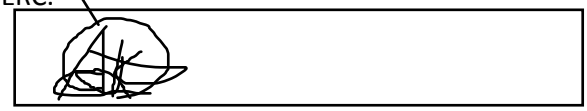
NO CONFLICT OF INTEREST TO REPORT

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

10/06/2024

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:				
Application Number			**Date received (DD/MM/YYYY)**	

Received by:

Names of the Reviewers	
Reviewer1	
Reviewer2	
Reviewer3	