



FORM 03: CHECKLIST ETHICAL CLEARANCE APPLICATION SUBMISSION

1. NEW PROPOSAL ANDA MENDMENT

Required Documents:	Attached with
1.Zanzibar Health Research Ethics Committee(ZAHREC) Application Form	
2.Cover letter with Institution logo signed by PI or CO-PI	
3.Commitment letter from affiliated institution and/or local government officials	
4.Full study proposal (s)/or Amendment(s) with all relevant sections: Summary, Background and Rationale, Objectives, Methodology, Ethical considerations, Budget and Budget justification, References	
5.Informed Consent Forms/Assent Form sin English and Kiswahili with institution logo Local PI and ZAHREC contacts	
6.IRB approval certificate from affiliating institution (s) where applicable	
7.Data collection tool sin English and Kiswahili	
8.Elaborated recruitment procedure	
9.Written information to be provided to participants in English & Kiswahili	
10. Curriculum Vitae (CVs) and composition of the research team	
11.Evidence of application and registration fees payment (Bank slip)	
12.Filled in Data Transfer Agreement (DTA) and/or Material Transfer Agreement (MTA) (where applicable)	
For Clinical Trials: Additional documents must be submitted with application	
1.Investigator's Brochure and Case Report Forms	
2.Proof of Insurance Coverage arrangement	
3.List of DSMB members(with at least one Zanzibarian)	
NB: For Amendment proposals: attach copy of Initial Ethical Clearance Certificate	

2. RENEWAL OR EXTENSION

Required Documents: Two(2) hard copies of all documents	Attached with application?
1. Cover letter with Institution logo signed by PI or CO-PI	
2. Progress report of study indicating what is to be covered in the renewal period	
3. Copy of previous ethical clearance certificate	
4. Evidence of payment(Bank slip)	

3. PROGRESS REPORT

Required Documents: Two(2) hard copies of all documents	Attached with application?
1. Cover letter with Institution logo signed by PI or CO-PI	
2. Progress report of study including status of: Activities that have been conducted Activities that remain to be conducted	
3. Copy of previous ethical clearance certificate	

