

## CHECKLIST ETHICAL CLEARANCE APPLICATION SUBMISSION

### 1. NEW PROPOSAL AND AMENDMENT

<b>Required Documents: Five (5) hard copies of all documents</b>	<b>Attached with application?</b>
1. National Health Research Ethics Committee (NatHREC) Application Form	<input type="checkbox"/>
2. Cover letter with Institution logo signed by PI or CO-PI	<input type="checkbox"/>
3. Commitment letter from affiliated institution and/or local government officials	<input type="checkbox"/>
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 and Appendices, etc.	<input type="checkbox"/>
5. Informed Consent Forms/Assent Forms in English and Kiswahili with institution logo Local PI and NatHREC contacts	<input type="checkbox"/>
6. IRB approval certificate from affiliating institution (s) where applicable	<input type="checkbox"/>
7. Data collection tools in English and Kiswahili	<input type="checkbox"/>
8. Elaborated recruitment procedure	<input type="checkbox"/>
9. Written information to be provided to participants in English & Kiswahili	<input type="checkbox"/>
10. Curriculum Vitae (CVs) and composition of the research team	<input type="checkbox"/>
11. Evidence of application and registration fees payment (Bank slip)	<input type="checkbox"/>
12. Filled in Data Transfer Agreement (DTA) and/or Material Transfer Agreement (MTA) (where applicable)	<input type="checkbox"/>
<b>For Clinical Trials: Additional documents must be submitted with application</b>	
1. Investigator's Brochure and Case Report Forms	<input type="checkbox"/>
2. Proof of Insurance Coverage arrangement	<input type="checkbox"/>
3. List of DSMB members (with at least one Tanzanian)	<input type="checkbox"/>
<b>NB: For Amendment proposals: attach copy of Initial Ethical Clearance Certificate</b>	

## 2. RENEWAL OR EXTENSION

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

## 3. PROGRESS REPORT

<b>Required Documents: Two (2) hard copies of all documents</b>	<b>Attached with application?</b>
1. Cover letter with Institution logo signed by PI or CO-PI	<input type="checkbox"/>
2. Progress report of study including status of: <ul style="list-style-type: none"><li>➤ Activities that have been conducted</li><li>➤ Activities that remain to be conducted</li></ul>	<input type="checkbox"/>
3. Copy of previous ethical clearance certificate	<input type="checkbox"/>