

FORM 2A: CHECKLIST FOR ETHICAL CLEARANCE APPLICATION SUBMISSION

Required Documents: Five (5) hard copies of all documents	Attached with application?
KNCHREC Application Form	<input type="checkbox"/>
Cover letter with Institution logo signed by PI	<input type="checkbox"/>
Commitment letter from affiliated institution and/or local government officials	<input type="checkbox"/>
Full study proposal (s) /or Amendment (s) with all relevant sections: Summary, Background and Rationale, research questions/hypothesis/es Objectives, Methodology, Ethical considerations, Budget and Budget justification, References and Appendices, etc.	<input type="checkbox"/>
Informed Consent Forms/Assent Forms in English and Kiswahili with institution logo Local PI and KNCHREC contacts	<input type="checkbox"/>
IRB approval certificate from overseas institution (s) where applicable	<input type="checkbox"/>
Data collection tools in English and Kiswahili	<input type="checkbox"/>
Elaborated recruitment procedure	<input type="checkbox"/>
Written information to be provided to participants in English & Kiswahili	<input type="checkbox"/>
Curriculum Vitae (CVs) and composition of the research team	<input type="checkbox"/>
Evidence of application and registration fees payment (Bank slip)	<input type="checkbox"/>
For Clinical Trials: Additional documents must be submitted with application	
Investigator's Brochure and Case Report Forms	<input type="checkbox"/>
Certificate of Insurance or the commitment letter that shows the intention that trial participants will be insured	<input type="checkbox"/>
List of DSMB members (with at least one Tanzanian)	<input type="checkbox"/>
NB: For Amendment proposals: attach copy of Initial Ethical Clearance Certificate	

FORM 2B: CHECK LIST ETHICAL CLEARANCE FOR USING ROUTINE CLINICAL REPORTS

Required Documents: Five (3) hard copies of all documents	Attached with application?
KNCHREC Application Form	<input type="checkbox"/>
Cover letter with Institution logo signed by PI or CO-PI	<input type="checkbox"/>
Commitment letter from affiliated institution and/or local government officials	<input type="checkbox"/>
Study proposal (s) /or Amendment (s) with relevant sections: Summary, Rationale, Objectives, Methodology, References and Appendices, etc.	<input type="checkbox"/>
Curriculum Vitae (CVs) and composition of the research team	<input type="checkbox"/>
Evidence of application receipt (Bank slip)	<input type="checkbox"/>