NATIONAL INSTITUTE FOR MEDICAL RESEARCH

APPLICATION FORM FOR ETHICS APPROVAL

MEDICAL RESEARCH COORDINATING COMMITTEE

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APPLICATION FORM FOR ETHICS APPROVAL

For use of Ethics Committee only	Application No.	
Name, date and signature of NatREC administrator receiving the application	Name:_____ Signature:_____Date:	

Instructions: All applications for ethics approval should be submitted using this form. The Principal Investigator is required to ensure the information provided is accurate and will sign on this form to indicate that he/she approves the content. Although it is required that the final protocol approved by the sponsor and other relevant documents are submitted for review together with this form, the information provided in this form is expected to be complete and adequate for reviewers to make a decision on the final disposition of the proposal.

First (initial) submission: Revised/Amended submission:

Protocol Version/Revision No..... Protocol Version Date:

Title of Project:	
Name of the Principal Investigator (PI) based in Tanzania	
Names of other investigators (PIs and Co-PIs)	
Qualifications of PI	
Position	
Institution and Department/Unit	
Other co-investigators at the PI institution	
Signature of the PI	
If Research student: Name, signature and approval of Supervisor (include letter from the student institution or university)	Name: _____ Signature: _____
Contact details for correspondence (include the name of contact if different from the PI)	

If this study involves more than one institution, name the overall study PI, institution and contact address	
Name of other institutions involved in the study if this study involves more than one institution	

Is this a randomized controlled trial?	
Does this study involve the taking of blood and/or any other biological samples?	
Does this study involve shipment of biological samples outside Tanzania?	
Does this study going to involve data transfer outside Tanzania?	
Provide details of all ethical clearances sought or obtained from other ethics committees? (This includes institutional ethics approval within Tanzania and in other countries if appropriate). Please attach approval certificates from other ethics committee(s).	

Provide the list of changes from the first (initial)/previous submission in case of revised/amended submission

1.	Provide the scientific background, study design and objectives and hypotheses. Max 400 words

2.	State the intended value of the project or rationale. Why it is important to conduct this study in Tanzania? Provide relevant references as appropriate. Max 300 words
3.	State the total duration of the project, and where it will be undertaken in Tanzania (and also in other countries if appropriate).
4.	Provide evidence (such as commitment/endorsement letter) to show that local government officials in the region(s)/district(s) where the proposed research will be conducted have been informed about this study. IF THIS HAS NOT BEEN DONE, describe how you plan to achieve this BEFORE the study starts.
5.	Specify the number of the study participants, with scientific justification for sample size, age, gender.

6.	Specify recruitment methods, inclusion and exclusion criteria and study end points.
7.	Specify data collection procedures, including interviews and sample collection, involving human participants with brief details of actual methods. Attach copies of questionnaires and other data collection tools in English and Kiswahili. Max 500 words
8.	If applicable, describe procedures to be used to process, store and test biological samples (e.g. blood, genital swabs, urine, etc).

9.	If samples will be taken overseas, are there samples which will be left in Tanzania? Describe procedures to be used in their shipping, storage and when will be destroyed. Indicate which institution or laboratory samples will be analysed. Please note that before samples are shipped outside Tanzania MTA clearance is required.
10	Is the technology required for analysis of samples available in Tanzania? If YES, please describe why are samples being taken outside the country
11	Would local scientist(s) (Tanzanian) be involved in sample analysis? If YES describe her/his involvement, and if NOT please explain what are the strategies for technology transfer
12	Specify data management procedures and methods to be used during data analysis.
13	If data will be taken overseas, please describe why are being taken outside the country Please note that before data are take outside Tanzania, clearance is required by completing a Data Transfer Management Agreement Form
14	Describe the potential risks, discomfort, distress or hazards that research participants may be exposed to (these may be physical, biological and/or psychological). What precautions will be taken to reduce risks and ensure participants' safety?

15	Describe potential benefits for the participants and the population where they come from. Are there direct benefits for the people of Tanzania and/or other countries?
16	Specify how confidentiality of the study participants and data collected will be maintained.
17	State the manner in which consent will be obtained and documented in writing. Provide copies of the informed consent forms and other relevant documents in English and Kiswahili. Describe steps to be taken to minimise coercion/undue influence during the consent process.
18	Describe how you are going to assess comprehension of the information provided during the consent process.
19	Will payments be made to participants? (These should usually not be for more than travelling expenses and/or loss of earnings and must not be coercive or represent an undue inducement to take part). If YES give details and justification.
20	State the experience of the PI and co-investigators in the study in the field concerned, and their role will be on the project.
21	Please describe how project staff (PI and other staff) will be trained on the protection of study participants in research. In case already trained attach certificate.

22	When applicable, state what medical supervision is available to the participants
23	Describe the facilities available to support the successful conduct of the proposed research study, i.e.; office space, equipped laboratories.
24	If this is a clinical/intervention trial of a medicine, device, biologic/vaccine, or any other form of treatment or intervention, please respond to the following questions:
a)	How does the trial comply with Good Clinical Practice (GCP)?
b)	Does this trial involve testing a new drug, vaccine or medical device which is not registered in Tanzania?
	YES ☐ NO ☐
c)	If this trial involves testing a new drug, vaccine or medical device, please attach the investigator brochure? If there is no investigator brochure, please explain the reason.
d)	What will be offered to the control arm?
e)	Please confirm that TFDA approval will be processed before data collection begins.
f)	Is there a Data Monitoring & Safety Committee in place? If NO, please explain reasons

g)	If the intervention to be tested is found to be effective, describe plans to make it available to the participants and other people after the end of the trial.
h)	Have you obtained a certificate insurance cover for study participants locally (a cover from insurance company based in Tanzania)? If YES please attach If NO please describe how this will be obtained
25.	Is the study going to involve vulnerable population? (Vulnerable population include: pregnant women, human foetuses, neonates, children, prisoners, hospitalized patients, mentally ill persons etc) If YES, describe steps which will be taken to ensure protection of human subjects
26.	Please give details of the funder.
27.	Please give details of research sponsor. This is not necessarily the funding body. The sponsor is responsible for the initiation and management of the study. All clinical trials should have an identified sponsor.