

TROPICAL DISEASES**RESEARCH CENTRE**

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NDOLA, ZAMBIA

TDRC RESEARCH ETHICS COMMITTEE
IRB REGISTRATION NUMBER : 0002911
FWA NUMBER : 0003729

This form should be completed and submitted by the Applicant (PI) when responding to comments raised by TDRC REC during initial review. The form is aimed at ensuring speedy processing of re-submissions by ensuring that reviews of responses to comments are more focused. Re-submissions will not be accepted if not accompanied by the following: (1) completed and signed re-submission form (2) table describing responses. Any documents revised in response to TDRC REC should be submitted and all changes/revisions should be clearly **highlighted**. Any new changes being proposed by PI before initial approval, should be indicated using template-2 provided below. Such changes should also be clearly highlighted using color highlighter or track-change function. For any post-approval change/modifications, please use the Amendment Form as appropriate.

Principal Investigator:	
Study Title	
TDRC REC REF Number:	

YES	NO	DOCUMENTS SUBMITTED AS PART OF RE-SUBMISSION
		A document containing a table with 4 columns indicating how PI has addressed the comments (See the 4 column Template-1 below for guidance). For comments that are not addressed, in third column, researchers should justify.
		Revised proposal with tracked changes. Highlight all revised sections using track-change function or colour highlighter.
		New/revised consent/assent forms
		New/revised interview/instruments/questionnaires/recruitment materials
		Revised translated consent/assent forms
		Other supporting document (specify):
		Other supporting document (specify):
		Other supporting document (specify):
		Document containing a table indicating any other additional changes being proposed to protocol and supporting documents. For any such changes, the PI should prepare a 3 column table as per below template:
		Soft copies of revised documents

TEMPLATE 1: Please use the following template in responding to ALL comments raised by TDRC REC .

No.	Comment	Has comment been addressed (Yes/No)	Details on how comment has been addressed
1.	English consent form needs to be translated into local languages	Y	Consent form has been translated into Bemba and Tonga.(Page 40)

Template 2: If additional changes are being proposed to protocol and other supporting documents before initial approval, the PI needs to prepare a two-column table on separate sheet(s) of paper using following template:

No.	Description of change to original protocol	Justification for the change
1.	Sampling	Random sampling has now been proposed as a way of minimizing bias brought about by purposive sampling. See Page 85 of protocol (highlighted).

Failure to adhere to the above guidance will result in delays in the processing of re-submissions including returning of unprocessed documents to the Applicants.

Applicant's (PI) Signature:	Date:
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This section to be completed by TDRCREC Secretariat	
Date of re-submission:	Signature: