

**UNIVERSITY OF MALAWI - COLLEGE OF MEDICINE RESEARCH and
ETHICS COMMITTEE (COMREC) CHECKLIST TO ACCOMPANY
NEW RESEARCH PROPOSALS SUBMITTED TO THE COMMITTEE**

*When you submit a research proposal for the Committee to approve, first read the document entitled **COMREC Elements Of Review** attached to this check list. Make sure that your proposal is in the format outlined in the document.*

Before sending or giving the proposal to the Committee, complete the following check-list by ticking each item you have included. Do not submit the proposal unless you can tick all the boxes, or provide a reason for the absence of any item. Attach the completed check-list to the front of your submission.

TITLE OF PROPOSAL:
Name of Principal Investigator:
Name of Sponsor and amount of sponsorship:

Submit all documents in one pdf file of not more than 5MB by email to comrec@medcol.mw (if the file size is more than 5MB, then please zip the file and submit it as a compressed zipped file).

The **single** pdf file should include the following information in the following order:

01	Completed copy of this checklist as stated above	Yes <input type="checkbox"/> or No <input type="checkbox"/>
02	Covering letter of introduction from Investigator	Yes <input type="checkbox"/> or No <input type="checkbox"/>
03	The study protocol which should include the following:-	
	Study Title	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	List of Investigators and institution(s) involved	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Executive Summary	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Background/Introduction	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Rational/justification	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Objectives of the study: Main objective and Specific Objectives	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Methods:	
	Type of study - place of study	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Study population	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Study period Sample size	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Data collection procedures	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Data management/analysis	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Presentation of results	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Dissemination of results	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Ethical considerations: including consenting procedures, participant compensation, participant confidentiality etc.	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Possible constraints	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Requirements	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Training provided for study staff	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	Budget and Justification of budget	Yes <input type="checkbox"/> or No <input type="checkbox"/>
	References	Yes <input type="checkbox"/> or No <input type="checkbox"/>
04	Consent forms: include consent forms in both English & Chichewa for adult	Yes <input type="checkbox"/> or No <input type="checkbox"/>

	participants aged 18 and above, parental consent forms for all minors and assent forms (in addition to the parental consent forms) for all minors between the ages of 7 and 17 years. Any participant payments e.g. compensation, reimbursement etc should be stated by amount in the consent forms.	
05	Data collection tools (proformas): those that will involve obtaining information from research participants should be translated into Chichewa	Yes <input type="checkbox"/> or No <input type="checkbox"/>
06	Material transfer agreement forms/documents	Yes <input type="checkbox"/> or No <input type="checkbox"/>
07	Have you applied for a waiver of 10% COM overhead fee from the Office of Postgraduate Dean of Studies and Research? If yes, please attach a waiver letter.	Yes <input type="checkbox"/> or No <input type="checkbox"/>
08	Have you submitted this proposal to another Ethics Committee? If yes, please specify whether approval has been given, and if approval has been awarded, please submit a copy of the approval letter with this submission	Yes <input type="checkbox"/> or No <input type="checkbox"/>
09	Letter of support from COM Head of the Principal Department hosting the research	Yes <input type="checkbox"/> or No <input type="checkbox"/>
10	Letter(s) of support from Heads of all other Depts. and institutions in which any research work will be done.	Yes <input type="checkbox"/> or No <input type="checkbox"/>
11	Evidence of current active registration with the Medical Council of Malawi for Principal Investigator and other investigators who are involved in clinical research	Yes <input type="checkbox"/> or No <input type="checkbox"/>
12	Brief CV of each investigator	Yes <input type="checkbox"/> or No <input type="checkbox"/>

If any item is not ticked, explain why this is not included with the submission.

Signed:

Name (print):

Date: