# 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. Provide evidence of payment of US150 processing fee.*

|  |
| --- |
| 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[ ] or No[ ]  |
| 02 | Covering letter of introduction from Investigator | Yes[ ] or No[ ]  |
| 03 | The study protocol which should include the following:- |  |
| Study Title | Yes[ ] or No[ ]  |
| List of Investigators and institution(s) involved | Yes[ ] or No[ ]  |
| Executive Summary | Yes[ ] or No[ ]  |
| Background/Introduction | Yes[ ] or No[ ]  |
| Rational/justification | Yes[ ] or No[ ]  |
| Objectives of the study: Main objective and Specific Objectives | Yes[ ] or No[ ]  |
| Methods: |  |
|  | Type of study - place of study | Yes[ ] or No[ ]  |
| Study population | Yes[ ] or No[ ]  |
| Study period Sample size | Yes[ ] or No[ ]  |
| Data collection procedures | Yes[ ] or No[ ]  |
| Data management/analysis | Yes[ ] or No[ ]  |
| Presentation of results | Yes[ ] or No[ ]  |
| Dissemination of results | Yes[ ] or No[ ]  |
| Ethical considerations: including consenting procedures, participant compensation, participant confidentiality etc. | Yes[ ] or No[ ]  |
| Possible constraints | Yes[ ] or No[ ]  |
| Requirements | Yes[ ] or No[ ]  |
| Training provided for study staff | Yes[ ] or No[ ]  |
| Budget and Justification of budget | Yes[ ] or No[ ]  |
| References | Yes[ ] or No[ ]  |
| 04 | Consent forms: include consent forms in both English & Chichewa for adult 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. | Yes[ ] or No[ ]  |
| 05 | Data collection tools (proformas): those that will involve obtaining information from research participants should be translated into Chichewa | Yes[ ] or No[ ]  |
| 06 | Material transfer agreement forms/documents | Yes[ ] or No[ ]  |
| 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[ ] or No[ ]  |
| 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[ ] or No[ ]  |
| 09 | Letter of support from COM Head of the Principal Department hosting the research | Yes[ ] or No[ ]  |
| 10 | Letter(s) of support from Heads of all other Depts. and institutions in which any research work will be done. | Yes[ ] or No[ ]  |
| 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[ ] or No[ ]  |
| 12 | Brief CV of each investigator | Yes[ ] or No[ ]  |

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

Signed: Name (print):

Date: