



UNIVERSITY OF MALAWI

COLLEGE OF MEDICINE

COLLEGE OF MEDICINE RESEARCH AND ETHICS COMMITTEE

3.0 RESEARCH PROPOSAL FORMAT

N.B. The College of Medicine Research and Ethics Committee is aware of the fact that different funding agencies may have different guidelines/format requirements. Where this is the case, the Principal Investigator should prepare the proposal in the required format, provided that the format used gives all or most of the details as contained in the College Research and Ethics Committee Guidelines. The Principal Investigator must provide supportive evidence for the format used to the Secretariat. Otherwise the proposed guidelines and format should be followed.

The following is the recommended format for research proposals in which members of staff of the College of Medicine, University of Malawi, are involved.

[a] **Title**

This should be specific and precise. It should not be more than 2 to 3 lines long, and should indicate what one intends to do/find out.

e.g. "Validation of an algorithm on the management of urethral discharge in Malawi".

[b] **Investigators**

- Full names, qualifications, academic titles of all the investigators, including trainees (Assistant lecturers or postgraduate students) and their institutional/departmental affiliation(s).

The principal/main investigator (responsible for the work) should be the first one. If there are co-investigators these should be indicated as appropriate with their qualifications, academic titles and institutional affiliations.

- A brief up to date C.V. of each of the investigators and co-investigators should be provided. (if it has not been submitted within the past one year).

N.B Most journals have restrictions on the number of authors for a paper to be published. This may be an important consideration when preparing a research proposal.

[c] **Institution[s] under whose umbrella the research project will be conducted:**

- e.g. [i] The World Health Organisation.
[ii] The College of Medicine - University of Malawi.
or

- [i] The Welcome Trust Centre.
- [ii] The College of Medicine, University of Malawi, etc

[d] **Executive Summary**

- This should include:-
 - The type of research study
 - The problem [to be studied]
 - The objectives
 - Methodology
 - Expected findings and their dissemination.

All in summary. This should not exceed one and half pages.

[e] **Background information and introduction:**

- This should include:-
 - A review of the relevant literature. It should be most current. (Majority being in the past five to ten years at most).
 - Locally available information - either published or not. It may include clinical or laboratory observations (e.g. increasing number of adult males presenting with head injuries at the QECH during national holidays).

[f] **Rationale/justification for the research project:**

- There should be a statement explaining why the researcher[s] feel the research project is important and therefore should be carried out, (i.e. the potential significance to health care delivery, or otherwise). It should not be more than a paragraph or two.

[g] **Objectives of the study**

[i] **Broad**

The main issues that are being looked at/for, (e.g. to survey the socio-demographic and reproductive profiles of patients with acute gonococcal urethritis at the QECH).

[ii] **Specific**

The specific issues that are being looked at/for. These must be measurable, either qualitatively or quantitatively and form a guide to the research methodology, data analysis and presentation of results.

- Examples:-

1. To survey the age distribution of patients presenting with acute gonococcal urethritis at the QECH.
2. To survey the sexual behaviour of such patients,

[h] **Methodology**

This should be very detailed as it is your guide on how the study will be done as well as the data analysis. It should provide relevant information on:-

i] **The type of research study, e.g**

- case - control
- prospective, descriptive
- randomised clinical trial
- double - blind clinical trial,
- cross sectional

This should reflect exactly what the researchers intend to do.

ii] **Study Place**

- Where the study is going to be conducted (e.g. ten secondary schools in Mangochi District or The Queen Elizabeth Central Hospital, Chiradzulu District Hospital and South Lunzu Health Centre).

All the areas in/at which the survey/study will be carried out must be indicated.

iii] **Study Population**

- Who are to be included in the study or from which group[s] of people is the study group going to draw, e.g.
 - Patients presenting with multiple pregnancy at the QECH, in Blantyre, Malawi.

iv] **Study Period**

- The entire period of the study including preparation of the proposal, submission and approval, training (where necessary), pretesting (of the questionnaire), data collection, data analysis, report preparation, and dissemination of the findings.
- If the study is in phases, each must be specified and the time for each given.

v] **Sample Size**

- Details on the sample size and how it has been arrived at/worked out.
- It's justification.
- The selection/inclusion/exclusion criteria (e.g. - every 10th client
 - randomised (and how random)
 - every patient who consents.
- The need for and type of consent must be specified, and how it will be obtained, e.g. - written consent , verbal consent

vi] **Data Collection:**

- Details on:-
 - What information is going to be looked for/collected.
 - How that is going to be done (e.g. laboratory test, with provision of appropriate details).
 - Requirements for that, (e.g. reagents, culture media, blood samples and their relevant tests etc). It should include - who is going to do each of the aspects of data collection (e.g. who will draw blood, perform the tests, do the physical examination, interview the study group, etc).

vii] **Data Management and Analysis**

- Details should be provided on how the collected data is going to be managed, (e.g. coding)
- Details on data analysis
 - the computer package to be used in data entry and analysis e.g.
 - SPSS
 - EPI - INFO 6.0, etc
- The type of statistical tests to be used
 - e.g. - regression analysis
 - student 't' test of significance,

viii] **Results Presentation**

- A brief explanation of the format of the results as they will be presented, e.g.
 - Pie charts
 - Histograms
 - Line graphs,
 - Tables

ix] **Dissemination of the Results**

- Indicate the person or institution to whom the report is going to be submitted and why.
- How does/do the investigator[s] propose to disseminate their research findings, such as;
 - attendance at local, regional or international conferences/seminars, workshops.

- holding of a dissemination seminar/workshop.

- publications in peer-reviewed journals etc.

N.B. A copy of the final report and any published paper(s) or abstracts of papers read at conferences out of the research findings should be submitted to each of the following:-

- **The College of Medicine Research and Ethics Committee (COMREC)**
- **College of Medicine Library**
- **The Health Sciences Research Committee (through the COMREC Secretariat)**
- **The University Research and Publication Committee (URPC) (through the COMREC Secretariat)**

i] **Ethical Considerations**

- What ethical issues need to be addressed.
- How are they going to be addressed.
- This should include protection of human subjects [clients rights] [Declaration of Helsinki - 1964]. (Annex 1)
- If animals will be used there is need to consider the International Guiding Principles for Biomedical Research Involving Animals [WHO, 1985]. (Annex 2)

- If using human tissues or other biological materials, refer to [Guidelines for the Opportunistic Procurement and Use of Human Tissue and other Biological Materials in Research, WHO 1991]. (Annex 3)

j] **Possible Constraints:**

- Any envisaged problems in undertaking the study.
- How these will be addressed, by whom and when.

k] **Requirements:**

Details should be provided on what the research project will require.

- e.g.
- personnel - and their individual roles
 - training (of whom, why, when, where, by who)
 - paper - for the questionnaires, reports, etc.
 - transport - what form and for what.
 - reagents - which/how much of each and for what.
 - drugs - which, how much of each, for what, their source(s).
 - space - how that will be obtained, where, when.

l] **Budgetary Estimates**

- Each line item should be quantified in monetary terms.

- The investigator should indicate the amount to be asked for and what the institution(s) under which the research project will be conducted, will contribute.

For example:-

	Institutional Contribution	Being asked for
(i) Personnel		
- Principal	X	Y
Investigator's salary		

- Each item should be quantified if possible. If it is not possible (e.g. premises or space), it should just be mentioned as an institutional contribution. However small the institutional contribution is, it should be indicated.
- Sub-totals for each group should be indicated and then the grand total.
- A 10% [of the total] administrative contribution to the College of Medicine, should be included

If there are two or more donor agencies supporting the study, each organization's contribution should be shown and possibly what it is meant to support; e.g. The WHO - supply of all the reagents total cost = US dollars 20,000.00; IDRC = salary of the Principal Investigator; COM = space, etc).

m] **Justification of the Budget**

The investigators must indicate how they arrived at the amount of money being asked for, and how it is going to be disbursed.

e.g. 2 principal investigators - for overall supervision of the project, data analysis, report production and dissemination. 10% of their time for 24 months at US dollars 300.00 = $2 \times 300 \times 24 =$ US dollars 14,400.00.

n] **References**

- The cited literature, it should be as current as possible and include locally available information.

These should be in the internationally accepted format (e.g. E. Afr. Med. J. 1995; Vol. 71. 55-60).

4.0 SUBMISSION AND REVIEW OF THE PROPOSAL:

- i] The Principal investigator shall prepare (4) copies of the proposal together with \$100 processing fee or its equivalent.
- ii] The copies shall reach the Secretary - COMREC 30 days before the date of the meeting.
- iii] A letter from the respective head[s] of department(s) indicating that the research has the blessing of the department(s) shall be sent to the Secretariat together with the proposal. Research affiliations like Wellcome Trust, John Hopkins Project etc need a supporting letter from Head of Department.
- iv] Every thing should go through the head of department including resubmissions.
- v] A copy of a brief CV of each of the investigators shall be sent to the Secretariat [1 copy of each]. (Except those which have been submitted within the same academic year).

- vi] Within two weeks receipt of the proposal will be acknowledged in writing.
- vii] Following the review the results together with comments from the Research Committee will be sent to the Principal investigator within two week. This response will include - how to proceed e.g. resubmission or response for specific issues.
- viii] Resubmission shall also be at least two weeks before the following meeting.
- ix] Research affiliations need a supporting letter from the head of department.
