

MINISTRY OF HEALTH

RESEARCH UNIT

SUMMARY OF PROCEDURES AND GUIDELINES FOR THE CONDUCT OF HEALTH RESEARCH IN MALAWI

1. Introduction

Considering the increasing number of research activities in the country and the efforts by the Ministry of Health to accelerate health research especially among local professionals, there is need to develop and disseminate procedures and guidelines for the conduct of health related research in Malawi.

All researchers wishing to conduct health related research in Malawi must submit their research proposals and related materials for scientific and ethical review to the National Health Sciences Research Committee or its subsidiary, The College of Medicine Research and Ethics Committee (COMREC).

COMREC reviews proposals from the faculty and students of the College of Medicine and Kamuzu College of Nursing. Proposals from all other researchers and institutions, including those from COM and KCN with national interest, are reviewed by the NHSRC.

2. General objective

An overall objective of the procedures and guidelines is to accelerate implementation of quality health research in Malawi with the ultimate goal of improving the health and well being of Malawians.

3. Specific objectives

- Develop/appraise proposals
- Standardize review of proposals
- Ensure proper management of research information
- Promote health research among local professionals
- Promote coordination between NHSRC and COMREC

4. Procedure and requirements

Scientists wishing to carry out research in Malawi should ensure that the proposed studies:

- Conform to generally accepted ethical principles
- Are based on adequate knowledge of the relevant scientific information
- Are consistent with acceptable research practice

5. Research protocol

A detailed research protocol may have the following sections:

(1) Cover Page.

This contains title of project, name, address and qualifications of researchers

(2) Abstract

It is a summary of the proposed research project. This covers type of study, research topic, objectives, methodology and plans for dissemination of findings.

(3) **Background and justification**

It provides clear justification of the problem or research question. This should demonstrate the relevance and importance of the problem.

(4) Literature review

This should provide an update review of literature related to research.

(5) **Hypothesis**

The research hypothesis under investigation should be clearly stated. This is not mandatory in research.

(6) *Objectives*

The objectives should be relevant to the research problem.

(7) *Methodology*

This includes study site, study subjects, type of research, sample size and sample determination, inclusion and exclusion criteria, ethical considerations, limitations or constraints, data collection, data management and analysis.

(8) **Dissemination of findings**

State how the findings will be disseminated and how the results will be reported.

(9) **Personnel**

This should describe the research team and their responsibilities.

(10) Work-plan/Gantt chart

This should inform the timing of research activities and duration of the research project.

(11) **Budget**

This is the cost of activities related to the research project.

(12) **Bibliography**

This stipulates the literature used in research. It covers author of the literature, source of publication, publisher and date.

(13) Appendices

Other relevant information such as curriculum vitae questionnaire and consent form should be attached to the research proposal as appendices.

*For Additional information contact the Research Unit in the Ministry of Health

6. Submission of research protocols and relevant materials

Protocols of research studies must be submitted to the:

The Chairperson

National Health Sciences Research Committee

Ministry of Health

P.O. Box 30377

Lilongwe 3

MALAWI

Tel: +265 1 789 400/414

Fax: +235 1 789 527/536

Email: doccentre@malawi.net

7. Date of review meeting and deadline

- ⇒ NHSRC meets **once** every two months while COMREC meets every month.
- Submission of application materials to both committees should be done at least 3 weeks before the date of the review meeting.

8. Fees

- Application fee is \$150 or its equivalent. A 10% Contribution fee (of the total budget indicated in the proposal) for institutional support and strengthening is paid upon approval of the study.
- There are special rates for Malawian students. For information, contact the Research Unit

9. Essential elements for review

The following elements will be carefully examined during review:

- Scientific design
- Recruitment of research subjects
- Care and protection of research subjects
- Ethical consideration
- Community consideration

10. Expedited review

Arrangements can be made to expedite review in cases such as:

- Research proposals from Malawi students
- Review of modified research protocols

11. Conduct of Research

Researchers should stick to the procedures outlined in the approved protocol when conducting their studies. The NHSRC has the responsibility to investigate any violation of code of ethics and bring violator to justice.

12. Biological specimen

Collection and handling of specimens should follow the internationally acceptable ethical guidelines.