PREFACE

Health research is an important tool for strategic planning and policy development. It assists in generating new knowledge and technologies that help to deal with unresolved health problems. It also assists in identifying priority health problems and ways for combating them.

These procedures and guidelines (P&Gs) are the first of its kind for health research in Malawi. They have been developed based on international guidelines including the Declaration of Helsinki, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects and the WHO Operational Guidelines for Ethics Committees that Review Biomedical Research. Their development also involved consultations with various stakeholders. The P&Gs are meant to address a wide spectrum of research areas in the biomedical sciences such as clinical, pharmaceutical, surgical procedures, medical records, biological samples, social, epidemiological and health systems research.

The purpose of these P&Gs is to safeguard people participating in health research, and to maintain high standards of research in Malawi. They are also meant to provide a guiding framework for research proposal development. The P&Gs cover topics such as recommended outline of research protocol and the steps for submission of application materials for scientific and ethical review. It is hoped that dissemination of these guidelines will not only result in increased number of professionals conducting research, but will also enhance scientific and ethical standards of health research in the country.

Clearly, it is not possible to address all research procedures in this kind of summarized document. Potential researchers are therefore encouraged to obtain additional information from the National Health Sciences Research Secretariat at the Ministry of Health and Population or from the College of Medicine Research Secretariat at the addresses shown in section 3.3 inside the document. It is intended that these guidelines will be updated regularly. To ensure improved procedures and guidelines in future editions, I would like to invite comments or suggestions from all stakeholders.

Let me take this opportunity to acknowledge with gratitude the financial support from the European Union through the currently expired Health Sector Reform and Decentralization Project. Printing of these Procedures and Guidelines was made possible with financial support from DFID through the Sexual Reproductive Health Project (SRHP). I would also like to urge local health professionals to dedicate some of their time to carry out essential health research necessary for sound policy and improved health management.

Dr R.B. Pendame
Secretary for Health

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ACRONYMS

COMRC	College of Medicine Research Committee
MOHP	Ministry of Health and Population
NHSRC	National Health Sciences Research Committee
NRCM	National Research Council of Malawi
P&Gs	Procedures and Guidelines
RU	Research Unit

1.0 INTRODUCTION

In 1988, the Ministry of Health (MOH) established the Research Unit (RU). This unit was given the mandate to promote and co-ordinate health research in Malawi. At that time, all research proposals were reviewed and cleared by the National Health Sciences Research Committee (NHSRC) whose secretariat was located at the National Research Council of Malawi (NRCM). In order to improve efficiency, the NRCM decentralized the functions for review and clearance of research proposals; the NHSRC secretariat was transferred to the RU of the MOH in 1993.

To provide timely review and clearance of proposals from faculty members and students of the College of Medicine, the MOHP later authorized the formation of the College of Medicine Research Committee (COMRC) as a sub-committee of the NHSRC. Currently, the COMRC reviews and clears research proposals from faculty members and students of the College of Medicine and Kamuzu College of Nursing. Like the parent committee, the COMRC is also charged with the responsibility to monitor and evaluate research projects it approves.

Considering the increasing number of research activities in the country and the efforts by the MOH to accelerate health research especially among local professionals, there is need to develop and disseminate procedures and guidelines (P&Gs) for the conduct of health related research in Malawi. These P&Gs are intended to promote adherence to acceptable ethical and professional conduct in health research in the country.

The P&Gs have been developed based on a number of resource materials including the Republic of Malawi Constitution, the National Science and Technology Policy and the WHO Operational Guidelines for Ethics Committees that Review Bio-Medical Research.

These P&Gs will provide researchers with information regarding recommended steps for conducting health research in Malawi including submission of research proposals, data collection and analysis and dissemination of research findings.

Monitoring and evaluation of research projects is part of the research process. These P&Gs also describes briefly the recommended steps for monitoring research activities.

It is expected that dissemination of these P&Gs will lead to increased awareness regarding requirements for application and conduct of health-related research and that this will result in smooth implementation of the Essential National Health Research in Malawi.

2.0 OBJECTIVES

2.1 GENERAL OBJECTIVE

The objective of these P&Gs is to improve the health and well being of Malawians. The P&Gs have been developed to accelerate quality health research, a precursor for improved health service delivery in Malawi.

2.2 SPECIFIC OBJECTIVES

The P&Gs are intended to help the NHSRC, COMRC and all stakeholders to guide researchers/health workers in:

i) Appraisal of proposals for scientific, professional and ethical merits
ii) Ensuring that technical and ethical review of proposals is standardized
iii) ensuring proper collection, acquisition, dissemination, storage and management of research information
iv) enhancing capacity building and promote health research especially among local professionals
v) promoting coordination of activities of the NHSRC and the COMRC.

3.0 PROCEDURES AND REQUIREMENTS

The NHSRC has the responsibility of reviewing and approving all research proposals from prospective researchers whatever their discipline. Research proposals from faculty members and students of the College of Medicine and Kamuzu College of Nursing shall be reviewed

and approved by the COMRC on behalf of the NHSRC with the exception of all research proposals of national interest. The two committees shall keep each other informed by means of active cross representation.

The Principal Investigator shall submit the application materials for review of the ethics and scientific merit of the proposed research.

3.1 APPLICATION REQUIREMENTS AND PROTOCOL FORMAT

All submissions of the research proposals should be double-spaced with font size of 12. The outline of the proposal should be as follows:

3.1.1 **A title page** with a specific heading on the front page. This page should have the following information:

- title of the research projects;
- names, titles, disciplines and institutional mailing addresses of all investigators;
- the total amount of funding sought for the study (in Malawi Kwacha and / or US$) and;
- duration of the project (in months), with tentative beginning and ending dates specified.

3.1.2 **A summary** (1 page) that presents the problem statement, research questions, objectives, methodology, findings recommendations and conclusions.

3.1.3 **A table of contents –** listing the major sections and the corresponding page numbers

3.1.4 **A description** part that includes the following sections:

(i) **Introduction** (1 page). This should include background information, rationale for the research and literature review.

(ii) **Objectives** (1/2 – 1 page). A clear statement of the overall aim of the research should be stated. A list of specific objectives and hypotheses for the study should also be provided.

(iii) **Methodology** (3-5 pages). Describe details of the relevant methods to be used. Considering the diversity of study designs including qualitative and quantitative studies, it is important that the methods be clearly articulated. The description should include study site(s), study subjects, sample size determination, recruitment

(iv) plan and procedures for informed consent. Also indicate the amount of time each of the investigators will spend on the research study.

(a) Research facilities (1-2 pages). Describe the facilities and service available at your institution including computer equipment,

software and programming support that will be used for the project. Describe any collaborative arrangements you have made with other institutions or researchers, and provide supporting documentation.

(b) clear justification for the intention to include research **individuals who cannot consent**, and full account of the arrangements for obtaining consent and / or authorization for the participation of such individuals.

(c) Data (2-4 pages). The methods for data collection should be explained and data collection instruments at the annex appropriately referred to. Procedures for data management and methods for assuring good quality of the data during data collection, entry and data analysis must be clearly stated.

(d) Protection of Human Subjects. The process that will be followed to guarantee protection, confidentiality, rights, and welfare of subjects should be fully described.

(e) Dissemination of the Research Findings (1 page). All data originating from research study conducted in Malawi are the property

of the Malawi Government irrespective of the source of funds for carrying out the study. Researchers are expected to prepare at least one article for each research project for submission to a local peer review journal. All papers to be published both within and outside the country shall be reviewed by the NHSRC. All researchers are, therefore, expected to indicate plans for dissemination of research findings especially within Malawi.

3.1.5 A **Gantt chart** or other forms of time line for the study should be included.

3.1.6 **An Itemized Budget** should be included, showing all costs in Malawi Kwacha and / or US$ for each budget item. Key budget items should be fully explained and justified. Any salary supports should be decent. Information should also be provided regarding any other pending requests or current financial support (agency, amount, status) for this or related projects. The budget to be submitted should be the one approved by the sponsor(s). Any salary and/or allowance for research assistants, enumerators and study subjects should be paid as indicated in the original budget approved by the sponsor(s).

3.1.8 **A Curriculum Vitae** should be submitted for each investigator, giving educational and employment histories, publications (if available) and a brief synopsis of previous relevant work.

3.1.9 **Reference** provide a full citation for each of your bibliographic works in the description of your project.

3.2 **DATES FOR REVIEW MEETINGS AND DEADLINE**

The NHSRC meets every three months during the months of **March**, **June**, **September** and **December**. The COMRC meets once **every month**. Both committees require that proposals be submitted at least two weeks before the dates of their respective review meetings.

3.3 **SUBMISSION OF RESEARCH PROPOSALS**

3.3.1 At least 15 copies of the research proposal should be submitted to the NHSRC at the following address:

The Secretary for Health
Ministry of Health
Research Unit
P.O. Box 30377
Lilongwe 3
MALAWI
Attention: Chief Research Officer

Tel: 265 – 789400
Fax: 265 - 789527
E-mail: doccentre@malawi.net

Research proposals to the COMRC should be addressed to:

The Chairman
College of Medicine Research Secretariat
Private Bag 360
Chichiri
Blantyre 3
MALAWI

Tel.: (265) 671 911

3.3.2 The same addresses should be used for obtaining additional information and for questions.

3.3.3 The NHSRC Secretariat shall acknowledge in writing receipt of the application materials.

3.3.4 Applicants shall be informed of the decision taken by the NHSRC and the COMRC within 14 days after the review meeting.

3.3.5 In cases where the NHSRC request an applicant to submit supplementary information on the research proposal, such information shall be expected to be submitted to the NHSRC Secretariat within a period of one month after the notification.

3.4 RESEARCH FEES

3.4.1 All applicants shall pay to the NHSRC and COMRC a fee of 10% of the total budget indicated in the proposal. As the fees might be revised anytime, it is recommended that the secretariat for the respective committees be consulted for confirmation of the current fees. This fee shall be paid as follows:

3.4.2 The first payment shall be a non-refundable amount of US$150 for non-Malawian researchers, and MK500 for Malawian researchers upon submission of their research proposals. The NHSRC will not review the proposal if the first payment is not made at the time of submission of the proposal.

3.4.3 The second payment shall be made for all research projects that have been approved by the NHSRC prior to commencement of the research study. This payment will be delivered together with a signed Contractual Agreement Form (Ref. Annex 10.2). The amount of the second payment shall be the balance from the 10% after the first payment. Only studies approved by the NHSRC or the COMRC and those whose researchers have paid the stipulated fee shall be allowed to proceed.

3.4.4 Where applicable, the researcher and the Person in Charge of the public institution where the study will be conducted shall make agreement to allow the researcher contribute a fee to off set overhead costs.

3.5 RESEARCH CAPACITY BUILDING

Non-Malawian researchers are expected, as much as possible, to collaborate with local (Malawian) researchers to support efforts in capacity building. All research projects with non-Malawian Principal Investigator(s) should have Malawian Co-Principal Investigator(s) and the local counterpart should be involved from proposal development through to implementation. Research projects with no involvement of local personnel will rarely be approved.

3.6 RE-USE OF RESEARCH MATERIALS

Where a researcher intends to use research material collected for a different study, a new research proposal shall be required for review by the committee. In such cases the researcher shall be expected to specify how informed consent shall be obtained from owners of the materials.

3.7 AMENDMENTS TO THE APPROVED PROTOCOL

Where it becomes necessary to make amendments to an approved proposal, the modified proposal should be submitted to the NHSRC for review and approval before implementation of the changes. Additional fees may be needed depending on the extent of the modification and the urgency for obtaining the approval.

4.0 ESSENTIAL ELEMENTS FOR REVIEW OF PROTOCOLS

Review meetings of the NHSRC shall proceed only when the required quorum (at least 50% of the regular members present) has been formed.

The primary task of a NHSRC and the COMRC lies in the review of research proposals and their supporting documents. Special attention is given to ethical and technical suitability of the research proposal. Procedures for obtaining informed consent, documentation and feasibility of the protocol shall be examined. The committees shall also examine the relevance of literature review. Each of the proposals shall be considered within the context of the existing laws and regulations for conducting research involving human subjects. The following elements of the proposal will be carefully examined during the review:

4.1 SCIENTIFIC DESIGN

4.1.1 appropriateness of the study design in relation to the objectives of the study, statistical methodology including sample size determination, and the potential for reaching sound conclusions with the proposed sample size;

4.1.2 justification of predictable risks and inconveniences weighed against the anticipated benefits for the research subjects and the local communities;

4.1.3 justification for use of control arms, where applicable;

4.1.4 criteria for suspending or terminating the research. This is applicable to certain studies (e.g. some clinical research) where suspension or premature termination may be necessary to safeguard the well-being of the study subjects;

4.1.5 adequacy of the provisions made for monitoring and auditing the research study;

4.1.6 adequacy of the site, including supporting staff, available facilities and, where applicable, emergency procedures especially for the study subjects;

4.1.7 the manner in which results of the research will be reported and published.

4.2 RECRUITMENT OF RESEARCH SUBJECTS

4.2.1 the characteristics of the population from which the research subjects will be drawn including gender, age, literacy, culture, economic status and ethnicity;

4.2.2 the means by which initial contact and recruitment is to be conducted;

4.2.3 the means by which full information is to be conveyed to potential research subjects or their representatives;

4.2.4 inclusion criteria for research subjects;

4.2.5 exclusion criteria for research subjects;

4.3 CARE AND PROTECTION OF RESEARCH SUBJECTS

4.3.1 suitability of the investigator(s) for the proposed protocol;

4.3.2 any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action;

4.3.3 medical care to be provided to research subjects during and after the course of the research;

4.3.4 steps to be taken if research participants voluntarily withdraw during the course of the research. This may be applicable to certain studies (e.g. some clinical research) where premature withdrawal may be risky to the study subjects;

4.3.5 description of plans to make the study product(s) available to the research subjects after the research;

4.3.6 a description of the compensation and / or incentives for the time, transport and other costs/ inconveniences incurred by the study subjects while participating in the study;

4.3.7 the rewards or compensation in the event of injury, disability or death of a research subject attributable to participation in the research study;

4.3.8 the insurance and indemnity arrangements.

4.4 ETHICAL CONSIDERATION

4.4.1 a description of the person(s) who will have access to personal data of the research participants, including medical records and biological samples;

4.4.2 measures put in place to ensure confidentiality and security of personal information concerning the research subjects;

4.4.3 a full description of the process for obtaining informed consent;

4.4.4 the adequacy, completeness and clarity of written and oral information to be given to the research subjects or their legally acceptable representative(s) / caretakers;

4.4.5. where applicable, assurances that research subjects will receive information that becomes available during the course of the research, especially that suggesting increased risk or improved well-being as a result of their participation in the study;

4.4.6 where applicable, the provision made for receiving and responding to queries and complaints from research subjects or their representatives during the course of the research project;

4.5 COMMUNITY CONSIDERATION

4.5.1 the impact and relevance of the research on the local communities from which the research subjects are drawn;

4.5.2 the steps taken to consult with the local communities during the course of designing and implementation of the research study;

4.5.3 the extent to which the research contributes to capacity building such as enhancement of local healthcare, the conduct of health research and the ability to respond to public health needs;

4.5.4 where applicable, a description of how the local community will benefit from the research product(s);

4.5.5 the manner in which the results of the research will be made available to the research subjects and the local community;

5.0 EXPEDITED REVIEW

5.1 Considering that scheduled meetings for the NHSRC are only four times in a year, arrangements can be made to expedited review of research proposals. Examples where special arrangements may be considered include a) research proposals from Malawian students and b) review of modified research protocols. Procedures for submission of proposal materials to the NHRC are as outlined above.

5.2 The NHSRC may convene unscheduled review meetings if the secretariat receives many (more than ten) research proposals or if a researcher make special request for speedy review. In the latter case, the researcher will be expected to pay for all the expenses of the meeting besides the 10% fees.

6.0 CONDUCT OF RESEARCH

6.1 to maximize the benefits of research activities, researchers should stick to the approved procedures outlined in the protocol when conducting their study. Approval should be sought where changes in an approved protocol are necessary;

6.2 the NHSRC and the COMRC shall exercise their powers on behalf of the NRCM to promote ethical standards in Malawi. These committees also have the responsibility to investigate violation of code of conduct and to summon any researcher for further discussion on charges of breech of conduct;

6.3 the NHSRC and the COMRC shall expect progress reports for all approved research proposals for the purpose of monitoring and evaluation;

6.4 final reports of research projects should be submitted to the NHSRC or the COMRC Secretariat within three months of completion of the study, including an abstract;

6.5 In addition to the final reports, interim reports will be required outlining:

name / topic of the research project; objectives of the study; summary of what has been accomplished so far; revised plan for the next phase (s); operational problems if any and suggested solutions.

6.6 the Principal Investigator(s) shall be responsible for submitting progress reports. The number of reports to be submitted will depend on the life span for each of the projects and will be as follows:

- short projects of six (6) months or less may submit only the end of project (final) report;
- projects lasting between six and twelve months should have one interim and a final project report;
- research projects lasting more than 12 months shall submit interim reports to the NHSRC and the COMRC once every six (6) months until the end of the project when a final report will be expected.

6.7 The NHSRC Secretariat may arrange “field” visits to any of the research study sites any time during implementation. The visits shall be conducted by members of the NHSRC Secretariat, members of the NHSRC or any other competent persons appointed by the NHSRC. The visiting team shall have the mandate to ask for any relevant information and should be allowed access to data and / or specimen banks.

6.8 The field report shall be prepared and discussed at the next meeting of the NHSRC or the COMRC. Copies of the report will be sent to the Principal Investigator(s) of the visited projects.

7.0 BIOLOGICAL SPECIMEN

7.1 Biological specimens shall be collected only by a qualified individual. There should be proper handling of specimens to avoid wastage and recollection of the specimens;

7.2 Researchers should refrain from collecting biological specimens that are not required to address their study objectives.

7.3 Collection of specimens should be done only after the study subject or their representatives / caretakers have given informed consent.

7.4 Collection of excess specimens from study subjects should be avoided.

7.5 Tests on biological specimens should only be as described in the approved protocol.

7.6 Specimens collected for a particular purpose should not be used for other purposes except where:

a. re-collection of specimens is unethical.
b. recollection of specimens is impossible
c. there is a clear national / individual benefit from re-using the specimens
d. there is need to confirm results due to technological problems
e. there is a way of obtaining informed consent from the subjects from whom specimens were collected.

7.7 As much as possible analysis of specimens should be done within Malawi by local technicians / professional. In exceptional circumstances researchers may be allowed to export specimens especially where:

a. there is no technology available to conduct the desired tests
b. such technology can not be imported
c. further tests are necessary to confirm the results, and
d. quality control and validation are desired.

7.7.1 It is recommended that a local (Malawian) technician or professional should accompany the specimens and participate in carrying out the tests where specimens are being exported, this is in line with capacity building.

7.8 In any case, the Principal Investigator should submit an application to the NHSRC or the COMRC for permission to export biological specimens. In the application, the researchers should explain why it is necessary to expert the specimens, how the specimen will be used, how long they will be kept and the name of the local technician / professional to carry out or participate in the testing.

8.0 VIOLATION OF PROTOCOL AND INADEQUATE ETHICAL CONDUCT

8.1 The NHSRC and the COMRC, respectively, shall thoroughly investigate all reported violations of protocol or ethical conduct.

8.2 Where there is sufficient proof of violation, one or all of the following actions shall be taken:

a) the researcher may be asked to stop the study,
b) the researcher may be asked to compensate study subjects where ethical violation took place,
c) the researcher may be taken to court.

9.0 FINAL REPORT

9.1 At the end of the project, the Principal Investigator shall prepare and submitted to the NHSRC or the COMRC final report of the project including an abstract.

10.0 ANNEX

CHECKLIST OF DOCUMENTS TO BE INCLUDED WHEN SUBMITTING AN APPLICATION

All applications for review of research proposals should include the following documents:

1. protocol of the proposed research formatted as recommended in these P&Gs;

2. data collection instruments in both English and Chichewa (or other appropriate local language);

3. Informed Consent in English and Chichewa (or other appropriate local language);

4. Detailed budget as approved by sponsor of the research;

5. Curriculum Vitae (CV) for all the investigators;

6. Letter of approval from the foreign university ethics committee (for all students studying at foreign universities);

7. Application fee;

8. Approval certificate from the Pharmacy, Medicines and Poisons Board where the research involves products such as new pharmaceutical products.