



MALAWI GOVERNMENT

**THE NATIONAL HEALTH SCIENCES  
RESEARCH COMMITTEE GENERAL  
GUIDELINES ON HEALTH RESEARCH**

***“Valuing Collective Responsibility in Promoting  
Excellence in Scientific and Ethical Conduct of  
Health Related Research in Malawi”***

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**THE NATIONAL HEALTH SCIENCES  
RESEARCH COMMITTEE GENERAL  
GUIDELINES ON HEALTH RESEARCH**

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## **Acronyms And Abbreviations**

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CHAM	Christian Health Association of Malawi
CHSU	Community Health Sciences Unit
CIOMS	Council for International Organizations of Medical Sciences
COMREC	College of Medicine Research and Ethics Committee
MOH	Malawi Ministry of Health
NHSRC	National Health Science Research Committee
NRCM	National Research Council of Malawi
RU	Ministry of Health Research Unit
WHO	World Health Organization

## **1.0 Introduction**

In 1988, the Ministry of Health (MOH) established the Research Unit (RU) whose mandate is to promote and co-ordinate health research in Malawi. At that time, all health related 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 facilitate the speedy approval of research proposals, NRCM decentralized its functions of review and clearance of research proposals to sectoral institutions. Thus, 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 and their collaborators, Government authorized the establishment of the College of Medicine Research and Ethics Committee (COMREC) as a sister committee to NHSRC. Currently, the COMREC reviews and clears research proposals from faculty members and students of the College of Medicine, Kamuzu College of Nursing and institutions and researchers affiliated to these training institutions. COMREC like the NHSRC is also charged with the responsibility to monitor and evaluate research projects it approves. Both of these committees derive their authority from the National Research Council of Malawi.

These Guidelines have been developed basing on a number of resource materials including the Republic of Malawi Constitution; National Science and Technology Policy; National Procedures and Guidelines for the Conduct of Research in Malawi; Policy Measures for the Improvement of Health Research Co-ordination in Malawi; Council for International Organizations of Medical Sciences (CIOMS); WHO Operational Guidelines for Ethics Committees That Review Biomedical Research; UNESCO Declaration on Bioethics and Human Rights, and other many relevant international ethical guidelines and regulations .

## **2.0 Purpose of the Guidelines**

Committed to the fundamental ethical recognition that human subjects are partners and participants in health research; and recognizing the committee's philosophy that human subject

research is a privilege, not a right, this set of Guidelines shall serve the purpose of accelerating the attainment of research of the highest quality, a precursor for improved health service delivery in Malawi, through ensuring the protection of human subjects. The guidelines will not only ensure that review of proposals is standardized but will also promote the co-ordination of activities of the NHSRC. Furthermore, the guidelines provide researchers with information regarding recommended steps for conducting health research in Malawi including submission of research proposals, data collection and analysis, monitoring and evaluation of research studies approved by NHSRC and dissemination of research findings.

### **3.0 Functions, Organization and Administration of the NHSRC**

#### **3.1 Functions of the NHSRC**

The NHSRC, being subject to the rules and regulations that shall be set by Government from time to time, shall have the following functions;

- i. Advise Government including the Ministry of Health on all scientific and ethical aspects of research pertaining to the health sciences.
- ii. Foster the rights and welfare of human subjects
- iii. Review for clearance all research proposals with a health science content from prospective researchers whatever their discipline. However, research involving members of the College of Medicine and Kamuzu College of Nursing and their collaborators shall be reviewed and authorized by College of Medicine Research and Ethics Committee (COMREC) and shall be referred to the NHSRC only if national interests are at stake<sup>1</sup>. Each Committee shall keep each other informed by means of cross representation.

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<sup>1</sup> This requirement is in line with Government Policy Measures for the Improvement of Health Research Co-ordination in Malawi, dated 25<sup>th</sup> October 2005.

- iv. Offer guidance in relation to each research proposal, on the balance between the use of laboratories and expertise outside the country, and the import of techniques and equipment (including personnel) into the country.
- v. Review and clear for publication all materials originated from studies approved by NHSRC
- vi. Encourage and make recommendations to Government on contacts among research scientists of varying capabilities and/or attachments to advanced research centers, within and outside Malawi, for the purpose of upgrading the available research manpower and skills.
- vii. Enhance capacity building and promote health research especially among local professionals
- viii. Ensure proper collection, acquisition, dissemination, use, storage and management of research information
- ix. Perform any function related to the protection of health research participants

## **3.2 Membership**

### **3.2.1 Membership requirements**

Members of the National Health Sciences Research Committee are either individuals or representatives of organizations with an interest in the protection of human subjects participating in health research. The committee shall have members with varying backgrounds including social sciences to promote complete and adequate review of research proposals.

To reduce incidence of conflict of interest, Research Project Directors shall not be members of the NHSRC. Membership shall include at least one lay public.

In addition to possessing the professional competence necessary to review specific research activities, NHSRC shall be able to ascertain the acceptability of proposed research in terms of institutional commitments, regulations, applicable law and



standards of professional conduct and practice, and as such the NHSRC membership shall be required to include persons knowledgeable in these areas.

The standards described above represent minimum requirements which Government of Malawi typically exceeds. In many instances, the NHSRC will, therefore, strive to uphold highest standards in order to adequately meet the requirements of research review.

### **3.2.2 Membership of the NHSRC**

The Committee shall have the following membership:

National Research Council of Malawi	1
Ministry of Health Headquarters	2
College of Medicine Research and Ethics Committee	2
Community Health Sciences Unit (CHSU)	1
National AIDS Commission	1
Center for Social Research	1
Queen Elizabeth Central Hospital	1
Zomba Central Hospital	1
Lilongwe Central Hospital	1
Christian Health Association of Malawi (CHAM)	1
Lay/Community member	1
Mzuzu University	1
Mzuzu Central Hospital	1
Nurses and Midwives Council of Malawi	1
Ministry of Justice (Lawyer)	1

### **3.2.3 Appointment of members**

The National Health Sciences Research Committee comprises members nominated by organizations listed in 3.2.2. Their appointment to serve on NHSRC shall officially and procedurally be done by the Chairman<sup>2</sup> of the National Research Council of

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<sup>2</sup> The Chairman of the National Research Council of Malawi is the Chief Secretary for Public Service. As this is one of the technical standing committees of the Council, members are appointed by the Council's Chairman but nominated by their organizations.

Malawi. Both the NRCM and MOH shall play an active role in recommending the appointment of members.

Once constituted, the committee shall have powers to recommend the co-option of certain individuals with special expertise as identified by the committee to serve as honorary members of the committee.

Members shall serve for three years and will be liable for re-appointment if the organizations they represent re-appoint them.

### **3.2.4 Appointment of the Chairperson and Vice Chairperson**

The Chairperson and the Vice-Chairperson of the National Health Sciences Research Committee are elected by members from among themselves. The chair and vice chair should be individuals with credibility and standing to command respect in the research community and on the committee, and who are committed to the protection of human subjects in research. Their term shall last for three fiscal years. However, they are eligible for re-election for further terms if the committee is satisfied with their performance.

### **3.2.5 Alternate members**

At times it may not be possible for a member to attend the National Health Sciences Research Committee meeting in person. In such a case prior arrangement should be made with the chairperson for an alternate person to attend the meeting.

### **3.2.6 Non-voting Members**

The secretariat shall be a non-voting member. Their presence at meetings of NHSRC would largely be secretarial in nature and to aid NHSRC in conducting its business. These members will not vote on decisions. Non-voting members are not included in determining or establishing a quorum. The NHSRC shall reflect the presence of non-voting member(s).

### **3.2.7 Membership confidentiality agreement**

Members serving on the National Health Sciences Research Committee are expected to keep all business of the committee confidential. Therefore, upon appointment to NHSRC, members will sign a confidentiality agreement that shall be made available by the secretariat. Any external reviewers appointed by the chairperson to review a specific study and visitors present during the deliberations of the NHSRC meetings shall also be required to sign a confidentiality agreement. The agreement form appears in **Appendix A**.

### **3.2.8 Orientation and training of members**

Once *new*<sup>3</sup> members have been appointed, they may attend the first one or two meetings as observer in order to learn about the workings of NHSRC before being assigned reviewer responsibility. Such members will undergo NHSRC orientation sessions covering Guidelines and Standard Operating Procedures of the committee and any practical matters with secretariat and chair.

Continuing education for all members in matters of health research ethics and related disciplines in human research protections will be essential. As such, opportunities shall be sought for members' continuing education. Short courses, workshops and exchange visits shall be some of the means for achieving member continuing education. The chairman shall lead in fostering local and international networks, links and partnerships for purposes of continuing education and development of NHSRC.

### **3.2.9 Termination/disqualification of membership**

Appointment to NHSRC may be terminated before the expiration of the three-year term if the Chairman of the NRCM upon recommendation from the Chairperson of NHSRC with knowledge of MOH generally determines that the member fails to perform his or her duties as a member.

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<sup>3</sup> A new member is the one who has been appointed and was not on the committee in the previous term.

Specifically, NHSRC membership shall be terminated/disqualified due to the following reasons:

- i. Unsound mind
- ii. Grave breach of conduct like corruption, confidentiality, conflict of interest, and failure to attend more than three consecutive times without proper reasons.

When a member leaves Malawi on a long leave of absence rendering him or her unable to serve on the committee, he or she shall write the chairman of the committee expressing voluntary termination of his/her appointment. In the event that there is no voluntary termination but long leave of absence is observed, the chairman shall recommend the termination of the member's appointment.

### **3.2.10 Member resignation**

Members of the NHSRC shall be allowed to resign from the committee. The resignation shall be made in writing to the Chairperson of the committee through the head of the institution. Resignation from the organization that nominated a member to the committee may not necessarily translate into resignation from the committee. In the event that an individual ceases to be a member of staff for the organization which nominated him/her to the NHSRC, the committee shall make a decision on whether that member should serve up to the end of his/her term or not.

### **3.2.11 External Reviewers**

The NHSRC, at the discretion of the chair but with prior information to members, may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on NHSRC.

Such individuals will not be members and will not be included in determining or establishing a quorum at the NHSRC meetings if they are present. Such individuals are referred to as external reviewers.

### **3.2.12 Conflict of interest**

In the event that the NHSRC is discussing a proposal in which a member has specific interest, it is mandatory that a member concerned should declare the nature of interest. In such a case the concerned member will get out of the meeting room before deliberations on that particular research proposal. He/she will be made to sign a Conflict of Interest Declaration Form provided by the Secretariat. Secretariat is expected to document such an action in the minutes.

At the maximum, the member with a conflicting interest may only provide relevant information if so requested by the committee.

Conflicts of interest could include but not limited to : a member of NHSRC who serves as an investigator on research under consideration by NHSRC; a member who holds a significant financial interest in a sponsor or product under study; a member whose spouse or close relative has the research under review by NHSRC; a member who has any other special form of relationship with the investigator or sponsor of the research under consideration if such a relationship is likely to influence decision of the committee.

### **3.2.13 Liability coverage for members**

NHSRC members function as agents of Government of Malawi. As such their actions are covered by Government of Malawi relevant statutes provided that they perform within the course and scope of their NHSRC responsibilities. This means that members of the National Health Sciences Research Committee will not be held personally liable in the course of performing their duty.

### **3.2.14 Compensation for members**

Membership is based on principle of voluntarily rendering state service to the nation. As such members shall not be provided monetary compensation for their service. However, members shall be entitled to accommodation coverage, subsistence allowance and sitting-in-allowance at the equivalent of the

existing Government rate. For all donor funding, NHSRC shall foster the letter and spirit of agreement reached by Government of Malawi and donors on payment of allowances and accommodation coverage applicable to local meetings.

In addition, secretariat shall arrange for refreshments and/or food as a token of limited compensation.

### **3.3 Administrative support**

The Research Unit of the Ministry of Health serves as a secretariat for the committee. The unit is responsible for preparing materials and logistics for the meetings of the committee and other follow-ups.

## **4.0 Meetings of the NHSRC**

### **4.1 Scheduling of meetings**

As read with 4.4 below, NHSRC meets every two months. The National Health Sciences Research Committee is responsible for scheduling of meetings. The secretariat ensures that the general public is aware of the scheduled meetings well in advance through print and other electronic media.

### **4.2 Materials for the meeting**

Complete research proposals submitted for review and all other materials pertaining to the meetings of the committee are processed by the Secretariat of the committee i.e. the Research Unit of the Ministry of Health. Research proposals shall be distributed to members of the committee two weeks before the scheduled meetings to allow members time to adequately review the submitted proposals.

Complete proposals shall include protocol, consent forms, data collection tools eg questionnaires translated in local language, CVs and any other information as indicated under 5.1.2.

### **4.3 Quorum**

Half of the committee membership constitutes a quorum of any meeting. In the event that no quorum is reached, a meeting is rescheduled within the following two weeks. If no ordinary quorum is reached at that meeting, then half of the ordinary quorum forms a quorum for that meeting, otherwise meeting shall be rescheduled.

### **4.4 Conduct of the meetings**

In line with 4.1 above, the committee meets for business every two months (i.e. at least six times per fiscal year). Extraordinary meetings may, however, be convened at the discretion of the Chairperson or at the request of at least half the membership.

### **4.5 Decisions at meetings**

Decisions at the meetings of NHSRC are reached by a consensus. If there is no consensus, a decision is made by simple majority of members present through an open ballot. In the event of a tie, the chair casts a vote.

## **5.0 NHSRC Research Reviews, Procedures, Criteria and Actions**

The National Health Sciences Research Committee shall review research proposals, which fulfill requirements set by the committee. Proposals not fulfilling the requirements shall be sent back to the researchers to rework on them and submit them when they are ready.

### **5.1 Applications for NHSRC review**

#### **5.1.1 Application for new studies and requirements**

All applications must fulfill the following requirements:

Foreign researchers must be affiliated to a local institution evidence of which must be a supporting letter from such an affiliating institution. In addition, they will have a local collaborator.

A Complete submission of a new study for the NHSRC review shall include:

- 20 hard copies of the protocol written/adapted in a format specified by the NHSRC, which is provided by the Secretariat;
- informed consent/assent documents in English and any other appropriate local language;
- data collection instruments in English and any local language of an area in which the study is going to be conducted;
- copies of CVs of the Principal Investigator and Co-investigator(s) or collaborator(s);
- documentation of approvals from any foreign based research ethics committee/institutional review board for a study originating from outside Malawi;
- approval certificate from the Pharmacy, Medicines and Poisons Board where the research involves pharmaceutical products

*All applications shall be submitted to the secretariat, at the latest, two weeks before the committee meets.*

*All submissions shall be sent to the following address: The Chairman, National Health Sciences Research Committee, C/O Ministry of Health Research Unit, P.O. Box 30377, Capital City, Lilongwe 3, Malawi.*

All incomplete submissions shall not be reviewed.

### **5.1.2 NHSRC proposal format**

The NHSRC requires protocol to be written and submitted in the following format:

All submissions of the research proposals should be double-spaced with font size of no less than 12 and the pages clearly numbered. Outline of the proposal should be as follows:



**A title page** with a specific heading on the front page. This page should have the following information: Title of the research proposal; name(s) of the investigator(s) and collaborator(s); and institutional mailing addresses of all investigators; duration of the project (in months) with tentative beginning and ending dates specified.

**A summary** (1 page) that presents the research problems, objectives, methods, benefits and risks of the study; and an indication of how study results will be disseminated.

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

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

**Objectives** (1/2-1 page). A clear statement of the overall aim of the research should be stated. A list of specific objectives should be clearly stated. Where applicable, study objectives should be qualified by their hypotheses.

**Methodology** (1-3 pages). Describe details of the study design and methods to be used. Considering the diversity of study designs (that are qualitative and quantitative in nature), it is important that the methods be clearly articulated. The description should include study site(s)/locations, study subjects, sample size determination, recruitment plan and procedures for informed consent. Data collection instruments should be attached in the annex and be appropriately referred to.

**Research facilities** (1 page). 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.

**Data management and analysis** (1/2-1 page). The methods for data management and analysis must be clearly defined. Methods for assuring good quality of the data during data collection, entry and data analysis must be clearly stated.

**Protection of Human Subjects (Ethics)** (1/2 page). The process that will be followed to guarantee protection, confidentiality, rights, and welfare of subjects should be fully described.

**Dissemination of the Research Findings** (1 page). As a policy of government, 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. As such researchers shall indicate that they will submit copies of their study reports to NHSRC for review in preparation for their submission for publishing either within or outside the country. In addition, all researchers are expected to indicate plans for dissemination of research findings especially within Malawi.

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

**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 support should be reasonable and justified. 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).

**Curriculum Vitae** giving educational and employment histories, publications (if available) and a brief synopsis of previous relevant work.

**Reference** that should provide a full citation for each of the referred materials

### **5.1.3 Processing at the Secretariat**

The secretariat will conduct an initial screening of all applications for completeness and make a preliminary determination according to the criteria in 5.1.1 and recommend to the chair the type of review to be conducted.

The ultimate determination as to the type of review will be made by the Chairperson or the Vice Chairperson in absence of the Chairperson

Once a complete package of information has been received and a determination made that the study does not qualify for exemption, the submission should be assigned NHSRC study number. This number remains with the study in the NHSRC records for ease of referencing.

#### **5.1.4 Amendments/modifications**

Amendments or modifications are changes to the originally approved study. Any proposed change to a previously approved study must be submitted as an amendment to that study and will be reviewed by the convened NHSRC irrespective of the magnitude of any associated risks that have come with the amendments.

#### **5.1.5 Continuing Review**

All approved studies that will run for more than one year are subject to continuing review by the NHSRC. Such on-going approved studies shall be reviewed by NHSRC once per year. The application for continuing review shall be made on special form that is provided by the secretariat on request. The application for continuing review will include a progress report in which the Principal Investigator shall describe the number of subjects enrolled, any problems that occurred during the prior approval period and as generally specified on the continuing review form.

If a Principal Investigator fails to submit the materials for continuing review within one month following the expiration date, then the study will be classified as having been lapsed and inactive. If a study has lapsed, the NHSRC will send an order to immediately cease all study related operations except those that are necessary for the welfare of the human subjects

If Principal Investigator desires to continue a study that has lapsed for two months, then the PI must submit a new application for review by NHSRC, and must wait for NHSRC approval before resuming research under the protocol.

Otherwise, the study shall be considered having been terminated and the PI shall be asked to indicate procedures of how study subjects shall be monitored.

## **5.2 Determination of Type of Review**

In line with 5.1.3, the secretariat in consultation with the chairperson or the vice will screen the entire application and determine the type of review that will be required.

### **5.2.1 NHSRC Types/Levels of Review**

#### **5.2.1.1 Convened full NHSRC**

Generally, any new study will be reviewed by a fully convened NHSRC meeting. The following studies will be reviewed by a full NHSRC:

- All high risk studies
- Studies involving vulnerable populations (including pregnant women, prisoners, mentally incompetent patients etc)
- Any clinical interventional study that randomly assigns human subjects to alternative experimental or placebo groups
- Studies involving sensitive information connected to personal identifiers
- Studies previously reviewed but require major issues to be addressed

The NHSRC may call for an open session during which an investigator is called upon to clarify certain issues regarding his/her protocol. The investigator will move out of the meeting room immediately after being heard. Thus, decision, on that protocol will be made in a closed session (ie after the investigator has walked out of the room).

#### **5.2.1.2 Expedited Review**

Research studies that have previously been reviewed by a fully convened committee and require the PI to address minor issues may be approved through the expedited process but those requiring major issues to be addressed would be referred for full committee meeting as in 5.2.1.1.

Studies by students may also be considered for expedited review.

Expedited review can be considered for continuing review of research previously approved by the scheduled NHSRC where the research is permanently closed to the enrolment of new subjects, and all subjects have completed all research related interventions and the research remains active only for long-term follow up; where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis and report writing.

At least 3 members will be appointed by the chairperson to undertake the expedited review.

The chairperson shall keep members informed of research proposals that have been approved by expedited review by providing members with title, investigator and brief summary of each of expedited protocol at the next scheduled meeting.

### **5.2.1.3 Exemption from review**

Certain types of human subjects research may be exempted from review. Exemption may be considered for research involving the collection or study of existing data, documents, records, programme evaluation, pathological specimens or diagnostic specimens, if the sources are publicly available or if the information is recorded by the investigator in such a manner that subjects can not be identified directly or through identifiers linked to the subjects.

The chairperson will review the application for exemption and determine whether to guarantee the exemption by himself or herself or by a convened NHSRC meeting.

The chairperson will notify members of the committee of any exemption granted at his or her discretion, detailing out the nature of exemption that had been applied for by the investigator.

An investigator will not initiate research involving human subjects that the investigator believes is exempt until the investigator has received formal written communication from the Chairperson granting the exemption.

Changes to exempted studies must be reviewed by the convened NHSRC just as amendments to studies receiving expedited review.

### **5.3 Review of Studies of National Interest**

Health research is generally of national interest. However, there are some studies that deserve particular attention because of their sensitive, political and safety implications.

Studies covering the following areas are regarded as examples of “National Interest Studies” All *vaccine trials; stem cell research; cloning research; all genetic studies; drug trials where patent issues are involved and where safety issues remain fully unknown; and national health surveys.*

All “studies of national interest” regardless of the origin of the protocol should be referred to the NHSRC which may form a standing committee for that specific project composed of members to be drawn on the basis of their expertise rather than which committee they come from.

This ad hoc committee will review and monitor the project through to its conclusion. The project may be carried out in any geographical location as the committee sees fit.

This ad hoc committee shall include a representative each from NHSRC, MOH, NRCM and COMREC.

## **5.4 NHSRC Actions Following Study Review**

**5.4.1 Approval of research:** In the case of an approval with no changes, the chairperson shall inform the investigator in writing within 7 days

**5.4.2 Stipulated minor changes:** The NHSRC shall determine that a study may be approved with stipulated minor changes/clarifications. Such studies shall also qualify for expedited review if such minor changes/clarifications are addressed. Minor changes/clarifications are those that do not involve potential for increased risk or decreased benefit to the human subjects

**5.4.3 Deferral:** If the NHSRC determines that substantive changes/clarifications must be made before approval may be granted, the study shall be deferred for a full committee meeting

**5.4.4 Not approved:** If a proposal requires major changes not likely to be feasible without a complete redo of the proposal by the investigator, the study will not be approved and reasons will be communicated to the investigator.

## **5.5 NHSRC mechanism of review**

For each proposal, there shall be three lead reviewers assigned by the chairperson as primary, secondary and third reviewer. Assigned reviewers shall be according to their field of expertise.

## **5.6 Completion of the study**

The investigator shall submit a written notice of completion of the study accompanied by at least 3 copies of the final technical report.

## **5.7 Suspension and/ or Termination of Study**

The chairperson or the convened NHSRC may suspend a study at any time if it is determined that the study requires further review or evaluation. This determination may be made in the event of adverse event, non-compliance or other danger to human subjects.

The study will be reviewed at the next convened meeting to determine if it requires changes. The NHSRC shall notify the Principal Investigator and the sponsor of the research in writing specifying reasons for suspension or termination with a copy to the National Research Council of Malawi. The NRCM shall be informed of all the suspended or terminated studies with detailed reasons for such a decision.

In the event of documented serious adverse events and any unanticipated problems as documented by the researcher, the NHSRC shall terminate the study and order the investigator to follow up study subjects.

In the case of any officially reported and un officially reported non-compliance, protocol violation or deviation by the researcher, the NHSRC shall suspend the study to ensure safety of the study subjects and carry out an investigation.

Upon investigation of the problem prompting the suspension of the study, the convened NHSRC shall terminate the study if convinced beyond any reasonable doubt that there was non-compliance, deviation or violation of the protocol.

Once the approval period for a given study has expired prior to the renewal of approval by NHSRC, it is considered a lapsed study and all research related procedures must halt, except where doing so would jeopardize the welfare of the human subjects. If the investigator fails to submit the materials for continuing review within one month following the expiration date, then the lapsed study will be classified as inactive. If the investigator submits the materials for continuing review within one month following the expiration date, NHSRC will conduct continuing review and reactivate the protocol. This reactivation establishes a new approval period.

If the investigator desires to continue a study that has lapsed for more than one month, then the investigator must submit a new application for re-review by NHSRC, and must wait for NHSRC approval before resuming research under the protocol.



## **5.8 Reporting of Adverse events**

Adverse event or adverse experience is an undesirable and unintended, though not necessarily unanticipated injury or physical or emotional consequence to a human subject. Serious adverse events are those which are fatal or life threatening; result in significant or persistent disability; require or prolong hospitalization; result in a congenital anomaly/birth defect, or in the opinion of the investigators represent other significant hazards or potentially serious harm to research subjects or others.

Unexpected and unanticipated refers to adverse events or other problems in the research where the nature and/or severity are not consistent with the information already provided to the Ethics review committee.

The NHSRC requires that the investigator should submit a written report for any occurrence of an adverse event.

The report shall provide the following details: Title of protocol; NHSRC assigned reference number; name of investigator; local affiliating institution for studies originating from outside Malawi; subject identifier; date and site/place of event; description of event (i.e. nature of injury, or other adverse occurrence, assessment of severity and assessment of relationship of the event to the study); action taken by the researcher; and signature of the principal investigator.

## **6.0 Elements of Protocol Review**

The following shall constitute the basic elements which NHSRC shall adhere to in reviewing a protocol:

### **6.1 Scientific Section**

Members will comment on the following elements: Appropriateness of the study design, methods/tools to be used; adequacy of the design to answer the study questions/objectives; achievability of objectives within a given period; clarity and relevance of study objectives.

- ***Study population***

Members to comment on the relevance of study setting, population and participants recruitment process. The characteristics of the population from which the research participant will be drawn will be required to be clearly defined. Such characteristics may include but not limited to gender, age, literacy, economic status, ethnicity, etc.

- ***Recruitment of Research Participants***

Members will examine the suitability of the inclusion and exclusion criteria. They will also examine the adequacy of the means by which initial contact and recruitment is to be conducted, and means by which full information is to be conveyed to potential research participants or their representatives.

- ***Sample size calculation and selection of sample***

Members will examine the appropriateness regarding sample size, statistical power, sampling methods used.

- ***Data Analysis method***

Members will examine the suitability of method used for data analysis

- ***Factual accuracy of the protocol***

Members will comment on facts in relation to current knowledge on the subject;

Use of quotes and appropriateness of references; and proposal format and presentation

## **6.2 Ethical Section**

- ***Risks and benefits involved***

Members will examine the adequacy of the identification of all the risks involved in the study. Members will also examine the following: Criteria for prematurely withdrawing research participants; criteria for suspending or termination of the research as a whole; adequacy of the site including the

supporting staff, available facilities, and emergency procedures; management plans for all predictable and known risks.

Members will look for a detailed description of direct and indirect benefits to participants

- ***Consent Process***

Members will also comment on informed consent process to identify if all the risks have been explained in the consent form and measures put in place to address them. Members will also pay attention to identify investigator's further explanation for any other risk that may occur as a result of participation in the study.

- ***Privacy, confidentiality, direct benefits, indirect benefits***

Members will look for explanation of measures put in place to ensure privacy and confidentiality including a description of the persons who will have access to personal data of the research participants as well as medical records and biological samples.

- ***General Care and Protection of participants***

Members will comment on possible adverse events and protection of participants. Specifically members will comment on the following elements; the suitability of the investigator(s) qualifications and experience for the proposed study; any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action; the medical care to be provided to research participants during and after the course of the research; the adequacy of medical supervision and psycho-social support for the research participants; steps to be taken if research participants voluntary withdraw during the course of the research; the criteria for extended access to the emergency use of, and/or the compassionate use of study products; a description of any financial costs to research participants; the rewards and compensations for research participants (including money, services, and/or gifts); the provisions for compensation/treatment in the case of the

injury/disability/death of a research participant attributable to participation in the research; post-trial or post- research benefits to the study participants?

- ***Samples collection, storage, testing and/or shipping***

Clear explanation and justification for the collection and exporting of biological samples will have to be made. Procedures for specimen storage will have to be clearly defined.

### **6.3 Administrative Section**

- ***Budget to conduct study***

Members will comment on the adequacy of budget and justification for each to carry out the proposed study.

- ***Suitability of the personnel including the qualifications of the investigation team***

Members will, by examining the CVs, comment on the suitability of the qualification of the investigators in relation to the study they want to undertake. They will also comment on the adequacy of the number of study personnel including the appropriateness of their qualification.

### **7.0 Informed Consent for Participants**

Any individual invited to participate in a research study must be given an adequate description of the study that is clear and complete enough for the individual to judge whether she or he wants to participate. The informed consent process should be designed to provide potential participants with readily understandable information in amount and timing appropriate to achieve the participant's understanding.

Consent must be obtained from each subject who is legally, mentally and physically able to provide it unless waived by NHSRC. Consent for those who are not legally, mentally and physically able should be sought from parents or legal guardians or any of their legally authorized representatives.

Consent must be in writing unless NHSRC finds that written documentation of informed consent may be waived. Consent forms and other informational documents (like information sheets) should be written in simple language so as to be easily understood by potential participants and any persons without technical background in the field.

NHSRC shall allow an oral/verbal consent in the case of potential participants who do not read or do not understand the language of the written consent form. However, the script or information sheet to be read to the potential participants must be approved by the NHSRC and be signed for by their parents or legal guardians or any of the legally authorized representatives.

No informed consent, whether written or oral, will include any exculpatory language through which the subject or the subject's authorized representative is made to lose/ waive or appear to lose/waive any of the subject's legal rights, or releases or appears to release the investigator or sponsor from liability for negligence or any negative harmful consequences originating from participating in the research.

The standard expectation is that all subjects will in person sign a consent document/form containing adequate elements of an informed consent. Those who cannot sign, due to illiteracy, will provide a thumbprint under a witness who shall also sign for witnessing. For those who can not legally, mentally and physically give consent, their parents/legal guardians or authorized legal representatives will be required to sign or thumb-print for them.

Assent to participate in a study must be obtained from minors who are capable of providing assent. In determining whether children are capable of assenting, NHSRC shall take into account the ages, maturity and psychological state of the children involved. However, minors must assent in tandem with parental permission.

In certain cases, NHSRC may regard assent by minors to represent an informed consent Typical case is when such minors are emancipated. These emancipated minors may include those

that society may regard them as mature minors; that are legally married; or university students under a defined Malawian adult age of 18 years.

### **7.1 Basic Elements of an Informed Consent**

At the minimum the following are the elements that any consent form is expected to contain unless NHSRC approves exceptions. This information must be provided to the subjects when seeking informed consent.

- Statement that the study involves research.
- Explanation of the purposes of the research.
- Expected duration of the subject's participation in the research.
- Description of the procedures to be followed.
- Identification of any procedures that are experimental.
- Description of any reasonably foreseeable risks or discomfort to the subject.
- Description of any benefits to the subject or to others that may reasonably be expected from the research.
- Disclosure of appropriate alternate procedures or courses of treatment, if any that might be advantageous to the subject.
- A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be kept and maintained.
- An explanation of who to contact for answers to pertinent questions about the research and research subject's rights, and who to contact in the event of a research related injury to the subject, if relevant. Typically, questions concerning a research project should be

referred to the PI for that project, whereas questions concerning the rights of human subjects should be referred to the NHSRC Chairperson.

- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subjects is otherwise entitled.
- For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

In addition to the above elements, for some studies one or more of the following elements may be appropriate and required by NHSRC:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or foetus if the subject is or may become pregnant) that are currently unforeseeable.
- Anticipated circumstances under which the subject's participation may be terminated by the investigator with knowledge of the subject and NHSRC.
- Any additional costs to the subject that may result from participation in the research.
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue or discontinue participation will be provided to the subject.

## **7.2 Translation of Informed Consent**

Attention should be paid to both oral interpretation and written translation in the informed consent process. Oral interpretation for verbal consent should be performed by a qualified individual who is not a family member of the prospective subject. The

individual performing the interpretation should be available for on-going communication between subjects and investigators.

Written translation of informed consent documents should be performed by a qualified individual. In this regard, the investigator should demonstrate due diligence in obtaining an adequate translation of the informed consent documents from an individual whose qualifications would appear adequate to a reasonable person.

Back translations to English must be done as a method for validating the accuracy of the translation. All back translations documents will be reviewed by NHSRC.

### **7.3 Verifying Subject consent**

Unless waived by NHSRC, participants shall only sign and date the NHSRC approved consent form prior to participation in the study. The NHSRC approved consent form should bear the NHSRC stamp of approval which investigators must obtain from NHSRC secretariat before starting the process of obtaining consent.

One copy of the signed and dated consent form shall be retained in the investigator's file and another copy shall be provided to the person giving consent.

### **7.4 Exceptions and Waiver of Consent**

The NHSRC may waive the requirement for the investigator to obtain a signed informed consent in cases where circumstances warrant such a waiver. The following conditions may be considered for a waiver:

- The research presents no more than a minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context.
- The research could not practically be carried out without the consent waiver and Obtaining informed consent is not practicable



- The consent document is the only link between the subject and the research and the principal risk of harm would come from a breach of confidentiality
- Waiver is consistent with individual's rights

In lieu of a signed consent form, the NHSRC may require the investigator to provide subjects with a written statement regarding the research in the form of an information or fact sheet. This statement should contain, at a minimum:

- A statement verifying that the project involves research
- A description of the level of involvement and amount of time expected from subjects
- A description of the study
- A description of the risks and benefits to the subjects
- A statement describing the subject's rights
- A description of the compensation to be provided to subjects
- Contact information for both the investigator and Chairperson of the NHSRC

## **8.0 Fees**

As standard practice and requirement of NHSRC, a non-refundable amount of US\$150 for non-Malawian researchers, and MK500 for Malawian researchers shall be paid upon submission of their research proposals. The NHSRC will not review any proposal if this fee is not paid at the time of submission of the proposal.

If after review, the proposal is approved, the investigator shall pay to the Ministry of Health a fee of 10% of the total budget indicated in the proposal for institutional capacity strengthening

and operations of the NHSRC. As policy on fees might be revised anytime, it is recommended that the secretariat be consulted for confirmation of the current fees. Payment of the 10% fee 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. Only studies approved by the NHSRC and those whose researchers have paid the stipulated fee shall be allowed to proceed.

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.

## **9.0 Special Forms of Research and Vulnerable Populations**

The following may be special forms of health research for which the NHSRC requires procedures and guidelines as stipulated below.

### **9.1 Pilot Studies**

Pilot studies in health research may represent complex research even though they may be conducted as preludes to more expansive studies. Therefore, pilot studies must be reviewed by the NHSRC in the same manner and requirement as described for all other general forms of studies as pointed out in this set of Guidelines.

### **9.2 Research involving vulnerable populations**

The term “vulnerable populations” refers to potential research participants that are relatively or absolutely incapable of protecting their own interests. As such researchers must justify the proposed involvement of these populations in research and must provide additional safeguards for their safety and welfare. Some groups are traditionally considered vulnerable research participants. These include minors, pregnant women, prisoners, refugees, sex workers and persons with mental disabilities. Other vulnerable groups include persons with limited education or illiterate persons; women in some settings (for example, some

women who culturally must ask their husbands before consenting to participate in a research study); and persons with few economic resources who may have limited access to health services and may see their participation in a research study as the only opportunity to obtain needed health care. Primarily, research involving vulnerable populations may be justified on the following account:

- The research is directly related to the specific conditions of the class involved; and
- Subjects may personally benefit from the research

As part of ensuring safeguards, NHSRC requires that research involving vulnerable subjects should take into consideration the following elements:

- The methods of recruitment, selection and the inclusion/exclusion criteria should be considered by the NHSRC, as should informed consent, the confidentiality of data, and the willingness of the subjects to volunteer.
- Group characteristics such as economic, social, physical and environmental conditions should be considered to ensure that the research includes appropriate safeguards for the protection of vulnerable subjects
- Applicable local laws that bear on the decision-making abilities of potentially vulnerable subjects
- Research studies involving potentially vulnerable subject groups should have adequate procedures in place for assessing and ensuring subjects' capacity, understanding and informed consent or assent.
- Safeguards could include NHSRC monitoring of the consent process where possible.

In reviewing such research and in addition to these elements, NHSRC shall be sensitive to the vulnerability of subjects resulting from:

- Unique socio-economic factors; for example, an offer of financial compensation for participation in research may be interpreted as exploitative when directed toward impoverished subjects.
- Cultural factors; these may affect the ability of some subjects to give informed consent. For example, if a chief/local leader has urged participation in research, prospective subjects may not feel free to opt out of the study.

### **10.0 Accessing, collection, Storage and Use of Biological Specimen**

Researchers, in need of accessing, collecting, storing and using biological specimen shall be required to fulfill the following requirements:

Only a qualified individual shall collect biological specimens; there should be proper handling of specimens to avoid wastage and spillage of the specimens; researchers should not collect biological specimens that are not required to address their study objectives; collection of specimens should be done only after the study subject or their representatives/caretakers have given informed consent; collection of excess specimens from study subjects should be avoided; tests on biological specimens should only be as described in the approved proposal; specimens collected for a particular purpose should not be used for other purposes; analysis of specimens should be done within Malawi by local technicians/professional. In exceptional circumstances researchers may be allowed to export specimens especially where:

- There is no technology available in Malawi to conduct the desired tests and such technology cannot be imported
- Further tests are necessary to confirm the results, and
- Quality control and validation are desired.

In either of the above cases, the Principal Investigator should submit an application to the NHSRC for permission to export biological specimens. In the application, the researchers should

explain why it is necessary to export 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. Under this circumstance, the NHSRC shall require a signing of a contractual agreement that will specify terms and conditions.

### **11.0 NHSRC Inspection, Monitoring and Evaluation**

NHSRC will conduct monitoring by establishing a monitoring sub-committee, which will be responsible for monitoring ongoing studies. In addition, this sub-committee will undertake investigations responsibilities. The monitoring process will take the following mechanism:

- Submission of progress report within three months of approval of the study, then annual report for medium to long-term studies as defined in the national procedures for conduct of research in Malawi.
- Monitoring visits to the study sites at least twice a year shall be made by the sub-committee and/or other members of the committee (depending on the volume of ongoing studies). In conducting field visits, members shall use the NHSRC Monitoring and Evaluation Form, which shall be provided by the Secretariat.
- The Monitoring team/sub-committee shall use the following monitoring procedure: meeting with Principal Investigator or Co-investigator and study staff; meeting, if applicable study coordinator; if applicable, visit recruitment site, ward, clinic and meet with some study staff and participants; checking patient study forms and consent forms; if available manual of operation or written study procedures; verification of type of specimens collected, tests done and if applicable specimens shipped outside
- The NHSRC reserves the right to appoint any competent individual outside the membership of the committee to undertake monitoring and evaluation of the NHSRC approved studies.

**Appendix: Confidentiality Agreement/Statement**

**[NOTE : The following agreement shall be signed once by all NHSRC members upon appointment and kept on file. *Visitors attending NHSRC meetings shall be required to sign before the meeting starts*].**

I acknowledge that confidential, proprietary and/or other sensitive information may be discussed or distributed at meetings of the National Health Sciences Research Committee of the Government of Malawi. Except to the extent that disclosure may be required by law, I affirm that I will hold in strictest confidence all information that I receive during the course and scope of my service to the NHSRC and/or attendance at NHSRC meetings.

Full Name in Block Capital :

\_\_\_\_\_

Signature:

\_\_\_\_\_

Date : \_\_\_\_\_

Tick the box below if you are member or visitor.

<b>Characteristic</b>	<b>Tick</b>
Member	
Visitor	