NATIONAL COMMITTEE ON RESEARCH IN THE SOCIAL SCIENCES AND HUMANITIES (NCRSH)

GENERAL ADMINISTRATIVE GUIDELINES

July, 2011

THE NATIONAL COMMITTEE ON RESEARCH IN THE SOCIAL SCIENCES AND HUMANITIES GENERAL ADMINISTRATIVE GUIDELINES

1.0 Introduction

The National Commission for Science and Technology (NCST) was established under section 5 of the Science and Technology Act No.16 of 2003. The mandate of NCST is to advise Government and other stakeholders on all science and technology matters in order to achieve a science and technology-led development. Its mission is to promote, support, co-ordinate and regulate the development and application of science, technology and innovation so as to create wealth in order to improve the quality of life. For the purpose of performing functions under this Act and to execute its mandate and mission, the Commission established committees under section 11(1) of the Act. One of these committees is the National Committee on Research in the Social Sciences and Humanities (NCRSH). NCRSH is principally a national research ethics committee in the social sciences and humanities. The mandate of NCRSH is to promote, support, co-ordinate and regulate research and development in the fields of social sciences and humanities. Its specific terms of reference are;

(i) To review, vet and clear research proposals in line with the existing legislation and national guidelines in the social sciences and humanities originating from researchers and institutions where there are no relevant functional institutional research and ethics review committees that are recognized by the National Commission for Science and Technology.
(ii) Foster the rights, welfare, privacy and confidentiality of research participants in the social sciences and humanities research
(iii) Promote and strengthen social sciences and humanities research capacity building programmes in Malawi
(iv) Advise the National Commission for Science and Technology on best practices for promoting and coordinating research in the social sciences and humanities.
(v) Receive and investigate complaints related to violation of ethics in social sciences and humanities research and recommend to the National Commission for appropriate action.
(vi) To interface with other functional committees of NCST on matters of research in the social sciences and humanities.
(vii) To inspect, monitor and evaluate all the approved research studies in the social sciences and humanities.
(viii) To support or organise purposefully targeted research dissemination fora in the social sciences and humanities in liaison with stakeholders
(ix) Perform other functions as may be directed by the Commission that are geared towards promoting research in the social sciences and humanities

Within the purview of the committee's legal mandate, the committee's guidelines shall serve the purpose of aiding the secretariat, its members and researchers/investigators on

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

general procedures and accelerating the attainment of the social sciences and humanities research of the highest ethical and scientific quality while adhering to the existing national laws and universally acceptable norms, standards and declarations in research. These administrative guidelines are to be used in tandem with the committee's specific standard operating procedures and the Framework of Guidelines for Conduct of Research in the Social Sciences and Humanities in Malawi.

2.0 Membership and Secretariat

2.1 Membership requirements

Members of the National Committee on Research Ethics in the Social Sciences and Humanities are representatives of organizations with an interest in the promotion of social sciences and humanities research and protection of human subjects participating in such research. The committee shall have members with varying backgrounds who shall possess adequate knowledge to perform tasks of the committee including reviews of research proposals.

To reduce incidence of primary conflict of interest, research project directors and directors of research organisations shall not be members of NCRSH. Consideration of inclusion in the membership of NCRSH of a lay public and at least an individual in one's own capacity shall be promoted.

In addition to possessing the professional competence necessary to review specific research protocols, NCRSH shall have members who shall be able to ascertain the acceptability of proposed research in terms of national policy commitments, regulations, applicable laws and standards of professional conduct and practice besides being capable of performing other tasks related to other TORs of NCRSH. As such, NCRSH membership shall be required to include persons knowledgeable in these areas. Principally, membership of NCRSH shall include persons who are or are not members of the commission. The specific membership of NCRSH is presented below;

2.2 Membership of NCRSH

The Committee shall have the following membership:

1 Representative from the Centre for Social Research
I Representative from National Statistical Office
1 Representative from Sociology Department at Chancellor College
1 Representative from the National Archives of Malawi
1 Representative from Centre for Education Research and Training
1 Representative from Bunda College at Lilongwe University of Agriculture and Natural Resources (LUANAR)-Faculty of Development Studies)
1 Representative from The Catholic University of Malawi
1 Representative from Faculty of Education at Mzuzu University

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

1 Representative from Malawi Human Rights Commission
1 Commissioner representing the Board of Commissioners of NCST
1 Individual Appointed in his/her own right basing on Special/Relevant Expertise and Experience

2.3 Appointment of members and tenure of office

2.3.1 The National Committee on Research in the Social Sciences and Humanities comprises members nominated by organizations listed in 2.2 except a member identified in his/her own individual capacity.

2.3.2 Members of NCRSH **shall exclude directors, trustees or owners of research affiliates, institutions or organizations.** This stipulation is towards managing first level conflict of interest on a research ethics committee.

2.3.3 Appointment to serve on NCRSH shall officially and procedurally be done through the Office of the Director General. Once constituted, the committee shall have powers to co-opt certain individuals with special expertise as identified by the committee to serve as honorary members of the committee with voting rights.

2.3.4 The constituted committee may also develop a standing list of experts whose expertise may not be available on the committee. However, experts on the standing list shall not be members of the committee but to provide expert opinion on a research protocol whose expertise is not available on the committee.

2.3.5 Similarly, under some exceptional circumstances, the committee, at the approval of its chair and with prior knowledge of the members, may invite individuals with competence in special fields to meetings of NCRSH in order to assist in the review of protocols that require special expertise not available on the committee. Just like those on the standing list of experts, these individuals shall not be members and will not form part of the quorum at any of the NCRSH meetings if they are present. Such individuals shall be referred to as external reviewers.

2.3.6 Members shall serve on the duly constituted committee for **three years** from the date of appointment. After three years, the committee shall be dissolved for fresh nomination and appointment of members. However, any person who had served in the preceding term would be liable for consideration of re-appointment, if re-nominated.

2.4 Appointment of the Chairperson and Vice Chairperson

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

The chairperson and vice chairperson of the Committee are elected by members from among themselves. The chair and vice chair shall be individuals with credibility and standing to command respect in the research community and on the committee, and who are likely to be committed to not only the protection of human subjects in research but also with likely dedication to perform other tasks associated with the committee's TORs. **Their term shall last for three years occurring within the tenure of a duly constituted committee.**

In case of a vacancy of the office of the chair or vice, elections shall be done to fill the vacancy in the remaining period before the committee dissolves. Replacement of any member shall follow the same procedure for nomination and appointment but to serve for the remaining period before the committee dissolves.

2.5 Secretariat

The secretariat shall be a non-voting member. The principal role of the secretariat shall largely be to provide technical, regulatory and administrative back up services. Secretariat will not vote on decisions and shall not form part of the quorum. The secretariat responsible for the affairs of NCRSH is the Division of Health, Social Sciences and Humanities within the Department of Research and Technology Transfer of NCST.

2.6 Membership confidentiality agreement and oath of secrecy

Members serving on the National Committee on Research Ethics in the Social Sciences and Humanities are expected to keep all business of the committee confidential. Therefore, upon appointment to NCRSH and at first ordinary meeting, members will sign a confidentiality agreement that shall be made available by the secretariat. Any external reviewers appointed by the chairperson through the secretariat to review a specific study and visitors present during the deliberations of the NCRSH meetings shall also be required to sign a confidentiality agreement. The agreement form shall be in accordance with NCRSH SOP on Confidentiality. Where the S&T Act requires (section 16), members shall take or sign an oath of secrecy.

2.7 Continuing education, training and orientation of members

Once a committee is constituted for a given term of office, secretariat shall organize an induction for members in order to learn about the workings of NCRSH before being assigned reviewer responsibility. Thus, members shall undergo NCRSH orientation sessions covering Guidelines and Standard Operating Procedures of the committee and any practical matters. Essentially, all members shall undergo induction/orientation back to back with the first meeting of a duly constituted committee.

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

Continuing education for all members in matters of research ethics and related disciplines in human research protections will be essential. As such, opportunities shall be sought for members' continuing education. Short courses, periodical training workshops and/or exchange visits shall be some of the means for achieving member continuing education. The chairman and secretariat shall lead in fostering local and international networks, links and partnerships for purposes of continuing education. Members' continuing education, training and orientation is fully described in the standard operating procedure for continuing education and training.

2.8 Termination/disqualification of membership

Appointment to NCRSH may be terminated before the expiration of the three year term if the Commission determines that that a member fails to perform his or her duties as a NCRSH member. Specifically, NCRSH 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 meetings of NCRSH for three consecutive times without proper reasons.
iii. Violation of committee's procedures and guidelines, regulatory standards, requirements and applicable law.

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 Office of the NCST Director General expressing voluntary termination of his/her membership for the attention of the NCRSH secretariat and Chairperson. In the event that there is no voluntary termination but long leave of absence is observed, the chairman of NCRSH shall recommend the termination of the member's appointment, and replacement shall be sought.

2.9 Member resignation

Members of the NCRSH shall be allowed to resign from the committee. The resignation shall be made in writing to the NCST Director General with copy to the chairperson of the committee and the head of the institution/department that a member was a representative of (in case of institutional representation membership). In the event that an individual ceases to be a member of staff for the organization which nominated him/her to serve NCRSH, that member shall automatically cease to serve on the committee.

2.10 Conflict of interest

In the event that the NCRSH is discussing a protocol/proposal in which a member has specific conflict of interest (either positive or negative interest), it is mandatory that a member concerned should declare the nature of the conflict of interest. In such a case,

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

the concerned member shall recuse from review and/or deliberation on the protocol and 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. A disclosure of interest shall be recorded in the minutes of the meeting at which it is made [Section 13 (1) (2) of the S&T Act].

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 NCRSH who serves as an investigator/collaborator on research under consideration by NCRSH;
- 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 NCRSH;
- 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.

The committee reserves the right to determine or ascertain any other forms or instances of conflict of interest.

2.11 Protection of members/Liability coverage for members

NCRSH members function as public agents. Their actions are covered by the Science and Technology Act No.16 of 2003. No action, suit or other proceedings shall be brought or instituted personally against a member of the committee in respect of any act done in good faith in the course of carrying out the provisions of this Act (Section 14).

2.12 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 a rate that shall be determined by the Commission from time to time. For all donor funding, NCRSH shall foster the letter and spirit of agreement entered into by NCST and the donor on payment of allowances, accommodation coverage and other legible costs as shall be applicable.

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

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

3.0 Meetings of the NCRSH

3.1 Scheduling of meetings

As read with 3.4 below, NCRSH shall meet every three months. NCRSH secretariat is responsible for scheduling of meetings. The secretariat shall ensure that the general public is aware of the scheduled meetings well in advance through print and other electronic media. Depending on the intensity and volume of proposals, **NCRSH reserves the right to alter the intervals for ordinary meetings.**

Extra-ordinary meetings may, however, be convened at the discretion of the Chairperson or at the request of at least half the membership or at the advice of the secretariat.

3.2 Materials for the meeting

Complete research proposals submitted for review and all other materials pertaining to the meeting of the committee are processed by the Secretariat of the committee. Research proposals shall be distributed to members of the committee at least two weeks before a scheduled meeting to allow members time to adequately review the submitted proposals.

Complete proposals shall include protocol, consent forms, data collection tools e.g. questionnaires translated in an appropriate local language if such require translation, CVs and any other information as specified in the NCRSH checklist for protocol submission.

3.3 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 for the next ordinary meeting.

3.4 Decisions at meetings

Decisions at the meetings of NCRSH are reached by a consensus. If there is no consensus, a decision is made by simple majority of members present through either a secret or open ballot. In the event of a tie, decision shall be made as per applicable standard operating procedure of the committee.

4.0 NCRSH Research Reviews, Procedures, Criteria and Actions

The National Committee on Research Ethics in the Social Sciences and Humanities shall review research proposals which fulfill requirements set by the committee. Proposals not

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

fulfilling the requirements shall be sent back to the researchers to be reworked on and shall be submitted when they are ready.

4.1 Applications for NCRSH review

4.1.1 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. It is not a must for a foreign student researcher to have a local collaborator but at least a local affiliation.

A Complete submission package of a new study for NCRSH review shall satisfy all the applicable elements of the NCRSH checklist and any applicable standard operating procedure.

Applications shall be submitted to the secretariat any time.

All submissions shall be sent to the following address: Secretariat, National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Lilongwe 3, Malawi; E-mail address: ncrsh@ncst.mw

All incomplete submissions shall not be reviewed.

4.1.2 NCRSH proposal format

The NCRSH requires protocol to be written and submitted in the format as specified in its checklist and as fully described under section 9.2 of the Framework of Guidelines for Conduct of Research in the Social Sciences and Humanities Malawi. Refer to the checklist and Framework available at the secretariat.

4.1.3 Processing at the Secretariat

The secretariat will conduct an initial screening of all applications for completeness and make a preliminary determination according to the elements of the checklist and standard operating procedure for managing protocol submissions.

The ultimate determination as to the type of review shall be made in accordance with the standard operating procedure (SOP) for managing protocol submissions and other applicable SOPs.

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 NCRSH

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

study number. This number remains with the study in the NCRSH regulatory records and file for ease of referencing.

4.1.4 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 in accordance with the SOP for managing applications for amendments. Amendments applications shall be on a Request for Amendment Form.

4.1.5 Continuing Review

All approved studies that will run for more than one year are subject to continuing review by NCRSH. Such on-going approved studies shall be reviewed by NCRSH once per year. The application for continuing review shall be made on a special continuing review form that is available at the secretariat. 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 NCRSH 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 (PI) desires to continue a study that has lapsed for two months, then the PI must submit a new application for review by NCRSH, and must wait for NCRSH 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.

4.2 Determination of Type of Review

In line with 4.1.3, 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.

4.2.1 NCRSH Types/Levels of Review

4.2.1.1 Convened full NCRSH

Generally, any new study will be reviewed by a fully convened NCRSH meeting. Notwithstanding elements of SOPs for full committee meeting and expedited reviews, the following studies will be reviewed by a full NCRSH;

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

- All high risk studies,
- Studies involving vulnerable populations (including pregnant women, prisoners, mentally incompetent patients etc)
- Studies involving sensitive information connected to personal identifiers
- Studies previously reviewed but require major issues to be addressed

The NCRSH may, under exceptional circumstances, 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 (i.e. after the investigator has walked out of the room).

4.2.1.2 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.

Studies by students may also be considered for expedited review.

Expedited review is considered and allowable under NCRSH standard operating procedure for expedited review. The following circumstance may be warrant expedited review;

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

At least three members shall be appointed by the chairperson to undertake the expedited review.

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

4.2.1.3 Exemption from review

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

There are no stipulations for exemption from ethics review of social sciences and humanities research. Applications for exemptions shall be screened and reviewed on case by case basis.

An application shall be received and screened in accordance with NCRSH standard operating procedure for managing protocol submissions**.** An application fee shall be paid for all applications as per standard operating procedure on fee requirement.

.

Secretariat shall submit a report of all exemptions granted through expedited review procedure at a fully convened committee meeting, detailing the nature of the exemption that had been applied for and granted. In the case of determination of an exemption by the committee, the applicant shall be exempted from paying a stipulated ten per cent compliance and capacity building fee which is the proportion of the actual budget as indicated in a research protocol/proposal.

An investigator will not initiate the implementation of research that the investigator believes is exempt until the investigator has received formal written communication from the committee granting the exemption.

Changes/amendments to exempted studies must be screened and reviewed by the committee before their implementation.

4.4 NCRSH Actions Following Study Review

4.4.1 Approval of research: In the case of an approval with no changes, the committee shall inform the investigator in writing within seven (7) days.

4.4.2 Stipulated minor changes: The NCRSH 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.

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

4.4.4 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.

4.5 NCRSH mechanism of review

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

For each proposal, there shall be three lead reviewers assigned by the secretariat on the basis of members' expertise as primary, secondary and third reviewer. Thus, assigned reviewership shall be in accordance with members' field of expertise.

4.6 Completion of the study

The investigator shall submit a written notice of completion of the study. After completion of the study, the investigator shall submit one hard copy and a soft copy of the final technical report.

4.7 Suspension and/ or Termination of Study

NCRSH 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 NCRSH shall notify the Principal Investigator and the sponsor of the research in writing specifying reasons for suspension or termination with a copy to the Director General of the National Commission for Science and Technology (NCST). The NCST 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 NCRSH shall terminate the study and order the investigator to follow up study subjects or the communities.

In the case of any officially reported and un officially reported non-compliance, protocol violation or deviation by the researcher, the NCRSH 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 NCRSH 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 NCRSH, 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, NCRSH will conduct continuing review and reactivate the protocol. This reactivation establishes a new approval period.

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

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 NCRSH, and must wait for NCRSH approval before resuming research under the protocol.

4.8 Reporting of Adverse events

Adverse event or adverse experience is an undesirable and unintended, though not necessarily un anticipated 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 NCRSH.

The NCRSH 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; NCRSH 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.

5.0 Elements of Protocol Review

The elements of the research protocol review shall be those detailed in the NCSRH standard operating procedure for reviewing protocols. These elements are generally legal regulatory and policy in nature on the one hand and ethical and scientific in form on the other hand.

6.0 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 NCRSH. Consent for those who are not legally, mentally

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

and physically able should be sought from parents or legal guardians or any of their legally authorized representatives.

Consent must be in writing unless NCRSH 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.

NCRSH 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 NCRSH 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 can not sign, due to illiteracy, will provide a thumb-print 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, NCRSH 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, NCRSH 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. The conditions and elements contained in the Framework Guidelines for Conduct of Research in the Social Sciences and Humanities in Malawi shall be adhered to as minimum standards.

6.1 Basic Elements of an Informed Consent

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

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

- 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 or otherwise.
- 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 NCRSH secretariat.**
- 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 (insurance) compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

The elements of a consent form/information sheet are fully described in the Framework of Guidelines for Conduct of Research in the Social Sciences and Humanities in Malawi.

6.2 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 NCRSH.

6.3 Verifying Subject consent

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

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

6.4 Exceptions and Waiver of Consent

The NCRSH may waive the requirement for the investigator to obtain a signed informed consent in cases where circumstances warrant such a waiver. These circumstances may be those as described in the Framework of Guidelines for Conduct of Research in the Social Sciences and Humanities in Malawi.

In lieu of a signed consent form, the NCRSH 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
- Contact information for both the investigator and NCRSH secretariat

7.0 Fees

As a regulatory requirement of NCRSH, a non-refundable amount of US$150 shall be paid as an application/processing fee for each protocol submitted for ethical review. If after review, the protocol is determined to be towards approval, the investigator shall pay to the National Commission for Science and Technology a fee of 10% of the total budget as indicated in the proposal/protocol for ethical/regulatory compliance and capacity building. Ethical approval and regulatory permit shall only be issued after payment of all the required fees except where there has been a waiver for ethical review granted by NCRSH and where such a waiver shall be an exemption from review. Under no circumstance shall an application fee waived. Noncompliance with payment of any lawfully stipulated fee(s) is an offence under the S&T Act. Such offences shall attract legal and/or administrative penalties lawfully imposed under the S&T Act from.

8.0 Special Forms of Research and Vulnerable Populations

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

The following may be special forms of social sciences and humanities research for which the NCRSH requires procedures and guidelines as stipulated below.

8.1 Pilot Studies

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

8.2 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 socio-economic support or 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 or the class of persons to which the subjects belong may benefit from the research

As part of ensuring safeguards, NCRSH 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 NCRSH, 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 national laws, regulatory requirements and policies that bear on the decision-making abilities of potentially vulnerable persons

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw

- 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 NCRSH inspection of the consent process where possible.

In reviewing such research and in addition to these elements, NCRSH shall be sensitive to the vulnerability of participants 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.

9.0 NCRSH Inspection for Compliance

NCRSH will conduct inspections to monitor investigator' compliance with the approved protocol. In addition, this sub-committee will undertake investigations responsibilities.

The inspection process will take the following mechanism:

- Submission of reports as follows;
  - progress report within three months of approval of the study;
  - final report; and
  - annual report for medium to long term studies.

- Periodical inspection 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 on- going studies). In conducting inspection visits, members shall use the NCRSH inspection form.
- The inspection team/sub-committee shall use the following inspection procedure: meeting principal investigator or co-investigator and study staff; meeting, if applicable with study co-ordinator; if applicable, visit recruitment sites/units, and meet some study participants; checking participants study files and consent forms etc.

- The NCRSH reserves the right to appoint any competent individual on its standing list of experts (outside the membership of the committee) to undertake inspection of some specific studies.

Address : National Committee on Research in the Social Sciences and Humanities, National Commission for Science and Technology, P/Bag B303, Capital City, Lilongwe 3, Malawi E-mail address: ncrsh@ncst.mw