NATIONAL REGULATORY CHECKLIST FOR ETHICS AND REGULATORY AFFAIRS FOR RESEARCH ETHICS COMMITTEES (RECs) IN THE HEALTH, SOCIAL SCIENCES AND HUMANITIES

[Sections 18 & 48 of the S&T Act]

National Commission for Science and Technology

December, 2012

Preamble

This regulatory checklist is for direct use by the National Commission for Science and Technology (NCST). It stipulates minimum regulatory elements that NCST requires and administers in the registration, designation, accreditation and inspection of Research Ethics Committees (RECs). The checklist is also a regulatory tool for ensuring that RECs and their members, administrators and managers adhere to the nationally stipulated regulatory requirements and procedures for establishing and running a Research Ethics Committee in the health, social sciences and humanities sectors in Malawi. A REC that does not have these elements shall not be allowed to operate in Malawi.

1.0 Establishment and Organisation of a REC

1.1 Name the institutional policy that establishes a REC:

1.2 Does this REC have clearly defined functions/TORs? A copy of them should be deposited with NCST.

1.3 Does this REC and institution have a letter of approval/endorsement/registration from the National Commission for Science and Technology?

1.4 Does this REC have Guidelines and Standard Operating Procedures (SOPs)? A copy of the NCST approved SOPs and guidelines shall be retained in the registry of NCST and such original copy be verified in the registry of a REC at the institution.

1.5 For already approved and registered RECs with their Guidelines and SOPs, RECs must ensure that there is periodical realignment and revision of the guidelines/SOPs so as to be in tandem with the relevant national regulatory requirements that are in force from time to time.

1.6 For an institution that wants to establish a REC, the institution should write NCST indicating when SOPs and Guidelines of the intended REC would be developed and submitted to NCST for approval. Get a copy of them if SOPs are available. If not available, discuss when and how these would be developed. A REC shall only be allowed to operate if SOPs and guidelines are available and approved by NCST

1.7 Are guidelines and SOPs referred to in sections 1.4 to 1.6 approved/endorsed by the NCST? NCST official should demand evidence of written approval.

1.8 Composition of the Secretariat. A secretariat should have at least a REC Administrator, Compliance Officer and Secretary/Typist. Does the Secretariat of this REC have these portfolios. The NCST official shall perform a verification of the availability of these portfolios.

2.0 **Membership of the REC**

[The NCST official makes an assessment against the following]

2.1 What is the composition of this REC in relation to the nationally stipulated regulatory requirements and the NCST approved SOPs and Guidelines for a REC?

2.2 How are the Chairperson and Vice elected in reference to the NCST approved Guidelines and SOPs for a REC?

2.3 Is the method of election within the realm of protection of human research participants?

2.4 How are members appointed? Is their appointment within the realm of protection of human research participants?

2.5 Mandatory Declaration by Newly Appointed REC Members

- **Sections 3.7 and 4.6** of the National Policy Measures and Requirements for the Improvement of Health Research Co-ordination in Malawi (November, 2012) respectively state that "Membership of NHSRC shall exclude research project directors, trustees and owners of research institutions or projects" and "Membership of COMREC **shall exclude directors, trustees/owners of research projects/affiliates, institutions or organizations"**
- To ensure that the appointment of the members is in tandem with the provisions of this particular requirement so as to avoid first level potential conflict of interest, a newly appointed member within a given term of the reconstituted REC shall be required to make a regulatory declaration at the member's first meeting of a REC or at the newly appointed member's first appearance on a REC **stating individually in the presence of the NCST Regulatory Affairs Official, REC Administrator and other appointed members that the appointed member is none of those in the category specified to be excluded from REC membership.**

- The NCST official or in his/her absence, the REC Administrator representing the NCST official shall administer the declaration statement to each of the appointed members. Before administering the Statement, the administering officer i.e: the Regulatory Official or REC Administrator shall first audibly read the provisions of sections 3.7 and 4.6 referred above. Then ask a member to state the following Statement after the Regulatory Official or REC Administrator or any officer in designation .

STATEMENT OF DECLARATION

"I, (name of member), who has been appointed member of (name of REC) openly and truthfully declare that I am none of those in the category specified in the national regulatory requirements to be excluded from [name of REC) membership. I also declare that if in the course of my membership I become one, I shall immediately cease to be member".

- The declaration shall be minuted and signed for and shall form part of the regulatory records required by NCST
- Any appointed member who has not made this regulatory declaration shall not be a member
- The NCST shall cause to inspect any declarations administered by a REC Administrator or an officer other than the NCST regulatory official

2.6 In case of resignation of a member, how is replacement conceived to be made?

2.7 State the term of office of the constituted REC membership

2.8 Does the REC have an opportunity for providing continued education and training of its members?

3.0 Meetings of REC

3.1 State the frequency of meetings

3.2 Does the REC meet on stipulated schedules? If the schedule of meetings is available, get a copy of it

3.3 What is the quorum of any meeting/

3.4 How are decisions made at the meeting i.e Is there a specific SOP on decision making?

3.5 How is conflict of interest managed by this REC?

4.0 Proposal/Protocol Review Procedures and Criteria

4.1 State the application requirements for review of the protocol by this REC

- Application requirements for new studies;
- Application requirements for amendments/modifications to the already approved study;

- Application requirements for annual continuing review

4.2 Does the secretariat screen applications before putting them on the agenda for review by the REC?

4.3 What are the levels of review of proposals/protocols (does the REC have the following review levels?

- Convened full REC meeting
- Expedited Review

4.4 How are review levels in 4.3 determined? Does the REC have a particular SOP on how to determine these levels of review?

4.5 What are the specific elements of review of a proposal/protocol by this REC?

5.0 Consent Form

5.1 Does the REC have a standard consent form?

5.2 What are the elements of a consent form for this REC? If available, get a copy of the form with its elements, and examine if these elements are adequate to promote safety, rights and well-being of research participants.

6.0 Special Protections for Vulnerable Research Participants

6.1 What mechanisms are in place by this REC to in protect vulnerable research participants?

7.0 Inspection/Monitoring of Approved Studies

7.1 State procedures that are in place, if any, for undertaking inspection/monitoring of approved studies.

7.2 If not available, discuss when these procedures would be developed for use by the REC

8.0 Examination of Documents and Materials by the NCST Official

The NCST officer will examine documents related to the business of a REC. Such documents may include;

- Minutes of meetings of a REC

- Agenda of REC meetings
- Study files kept at the secretariat Office
- Study inspection reports
- REC approved Consent forms Etc

9.0 Assessment of a REC's Adherence to the National Regulatory Requirements As Stipulated by NCST

A REC's adherence to the regulatory requirements shall be assessed by the NCST official in terms of the specific regulatory requirements governing RECs whether in the health or the social sciences and humanities sectors.

The elements specified in these national regulatory requirements shall form the basis of the assessment by the official.

10.0 General Problems Faced by the REC

10.1 Ask the REC to state any problems/challenges/impediments that it is facing in transacting its business

10.2 Ask how they intend to overcome such problems/challenges/impediments

10.3 What is the support/commitment from the management of the institution in overcoming such problems/challenges/impediments

11.0 General Recommendation by the NCST Official

In light of the information obtained from sections 1 to 10 above, the NCST officer will make a debriefing summary, conclusion or recommendation and a final report to be shared with the administration and management of a given REC for consequent action or for information and another copy to be kept on file at NCST for regulatory records. The report shall describe the degree of a REC's adherence to the ethical and regulatory affairs.