



**UGANDA NATIONAL COUNCIL FOR
SCIENCE AND TECHNOLOGY**



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GUIDELINES FOR ACCREDITATION OF RESEARCH ETHICS COMMITTEES

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1.0 Background

Uganda National Council for Science and Technology (UNCST) is a semi-autonomous government agency established in 1990 by Act of Parliament (CAP 209). UNCST has specific functions for research and development coordination and oversight under Sections 3d, 3h, and 4e of the UNCST Act. In this regard, UNCST conducts registration and approval of all research activities in all sectors intended to be undertaken in Uganda. The National Guidelines for Research Involving Humans as Research Participants, July 2014 provide a national framework for harnessing the benefits of research while ensuring that the rights, interests, values and welfare of people who take part in the research are not compromised. It is a requirement in the guidelines for all Research Ethics Committees (RECs) operating in Uganda to be accredited by UNCST. These guidelines outline the process of REC accreditation in Uganda.

2.0 Objectives

The objectives for accreditation of RECs are to:

- a. improve efficiency and effectiveness of REC operation;
- b. ensure that RECs provide the highest possible ethical standards and protection to research participants;
- c. build public trust and confidence in national ethical review system;

3.0 Benefits of REC Accreditation Scheme

The REC Accreditation Scheme will:

- a. Ensure that RECs are well constituted, and REC members receive training in basic research ethics;
- b. Improve the coordination and networking of RECs in Uganda;
- c. Provide opportunities for increased support to REC functions;

4.0 UNCST Accreditation Committee (AC)

In order to carry out the REC Accreditation, UNCST has established a REC Accreditation Committee. The AC is comprised of five members appointed on individual merit by the Executive Secretary of UNCST. Members of the AC are appointed on a three year renewable term limit.

The AC terms of reference as follows, to:

- a. review REC applications for accreditation in accordance with accreditation standards established by UNCST;
- b. conduct periodic assessment of performance of RECs.

5.0 Stages in REC Accreditation Process

The REC Accreditation process has two stages:

First, the REC should undertake a self-assessment to identify the REC's strengths, achievements and areas that need improvement. During self-assessment, the REC may engage an expert to facilitate the exercise. The REC should submit a report of the self-assessment to UNCST along with an application for accreditation. In conducting a self-assessment, RECs should consider, among other things, the following:

- REC written policies and standard operating procedures
- Extent to which policies and SOPs are followed
- Updated REC membership roster (REC members should normally be given appointment letters);
- CVs of all REC members
- Training for REC members in basic research ethics
- Protocol application forms that researchers use
- Fees policy and structure
- Reviewer checklists
- Consent templates
- Template letters
- REC secretariat and staffing
- Frequency of REC meetings and protocols reviews
- Monitoring of studies

Second, the REC Accreditation Committee (AC) will review the REC's application and will inspect the REC's host institution. During this inspection the REC AC will meet with institution officials responsible for establishing the REC, the REC Chairperson, members and staff. The REC AC will also assess facilities for the REC's operation such as office space, documentation and storage facilities and standard operating procedures.

Accreditation will be granted to a REC for a period of three (3) years. After the 3 years, a REC shall apply for renewal of accreditation, through the same stages as indicated above. Application for renewal shall be three (3) months prior to the expiry date. The AC shall have access to all REC facilities including all relevant records, policies, procedures, minutes, audits reports, research protocols, consent forms, and other materials.

The outcome of the AC reviews and site inspection visits shall be communicated to the REC and host institution within fourteen (14) working days from the date of the site inspection visit.

6.0 Granting Accreditation

The AC has powers to approve or reject a REC's application for Accreditation. In case the REC does not agree with the decision of the AC, the REC or host institution may appeal to the UNCST Executive Secretary within 60 days of receipt of AC's notice of rejection of the REC's application. The UNCST Executive Secretary shall use appropriate UNCST organs to hear the appeal. The decision of the UNCST Executive Secretary's decision on the appeal shall be final.

The AC may grant either Full Accreditation or Provisional Accreditation to a REC.

- a. **Full Accreditation:** AREC granted full accreditation meets all the accreditation requirement as set out by UNCST. The Full Accreditation will be for a period of 3 years. All Accredited RECs will be issued with a Certificate of Accreditation which the REC should display appropriately in their premises.
- b. **Provisional Accreditation:** AREC may be granted provision accreditation if the issues requiring corrective action are minor in the opinion of the AC. Provisional Accreditation

shall be granted for a period of six (6) months only, and may be renewed only once. RECs given provision accreditation shall not receive Accreditation Certificates.

7.0 Revoking Accreditation: The AC may revoke a REC Accreditation at any time if it is determined that the:

- a. REC no longer substantially meets the accreditation requirements as set out by UNCST;
- b. REC will not commit to undertake corrective action identified by the AC;

A REC whose accreditation has been revoked, may re-apply for accreditation.

8.0 Reporting

An Accredited REC shall submit an annual report (January to December) of its activities to the UNCST by 31st January of each year. Failure to submit an annual report within the stipulated period may result in revocation of accreditation. The annual report should be prepared using the template and format provided by the UNCST.

9.0 Confidentiality

Any information the REC shall submit to the AC or UNCST shall be kept confidential. However, the UNCST shall display the Accreditation status of all RECs including listing the REC (but not names of the members) on the UNCST website or other appropriate print media.

10.0 Release and Indemnification

By submitting an application, a REC certifies that the information contained in the application is accurate. The REC agrees to release UNCST, its members, directors, officers, employees and agents from any and all claims, and to indemnify and hold harmless the UNCST representatives from and against any and all liability and costs incurred by them.

11.0 Records Retention

All REC applications, reports, and other documents related to the REC accreditation shall be kept for at least 5 years from the date of accreditation.