



**UGANDA NATIONAL COUNCIL FOR
SCIENCE AND TECHNOLOGY**



**GUIDELINES FOR ACCREDITATION OF
INSTITUTIONAL REVIEW COMMITTEES**

Version 1.0; May 2009

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. In March 2007, UNCST issued revised National Guidelines for Research Involving Humans as Research Participants in Uganda. The guidelines 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 Institutional Review Committees (IRCs) operating in Uganda to be accredited by UNCST.. These guidelines outline the process of IRC accreditation in Uganda.

2.0 Objectives

The objectives for accreditation of IRCs are to:

- a. improve efficiency and effectiveness of IRC operation;
- b. ensure that IRCs 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 IRC Accreditation Scheme

The IRC Accreditation Scheme will:

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

4.0 UNCST Accreditation Committee (AC)

In order to carry out the IRC Accreditation, UNCST has established an IRC 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 IRC applications for accreditation in accordance with accreditation standards established by UNCST;
- b. conduct periodic assessment of performance of IRCs.

5.0 Stages in IRC Accreditation Process

The IRC Accreditation process has two stages:

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

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

- Monitoring of studies

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

Accreditation will be granted to an IRC for a period of three (3) years. After the 3 years, an IRC 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 IRC 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 IRC 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 an IRC's application for Accreditation. In case the IRC does not agree with the decision of the AC, the IRC or host institution may appeal to the UNCST Executive Secretary within 60 days of receipt of AC's notice of rejection of the IRC'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 an IRC.

- Full Accreditation:** An IRC 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 IRCs will be issued with a Certificate of Accreditation which the IRC should display appropriately in their premises.

- b. **Provisional Accreditation:** An IRC 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. IRCs given provision accreditation shall not receive Accreditation Certificates.

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

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

An IRC whose accreditation has been revoked, may re-apply for accreditation.

8.0 Reporting

An Accredited IRC shall submit an annual report (January to December) of its activities to the UNCST by 31st March 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 IRC shall submit to the AC or UNCST shall be kept confidential. However, the UNCST shall display the Accreditation status of all IRCs including listing the IRC (but not names of the members) on the UNCST website or other appropriate print media.

10.0 Release and Indemnification

By submitting an application, an IRC certifies that the information contained in the application is accurate. The IRC 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 IRC applications, reports, and other documents related to the IRC accreditation shall be kept for at least 5 years from the date of accreditation.