



# Research Registration and Clearance Policy and Guidelines

**Uganda National Council for Science and Technology**

July 2016



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**These guidelines are prepared by Uganda National Council for Science and Technology (UNCST).**

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**Recommended citation:**

Uganda National Council for Science and Technology (UNCST). 2016. Research Registration and Clearance Policy and Guidelines. Kampala, Uganda: UNCST

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## List of Acronyms

<b>ACREC</b>	Accreditation Committee for Research Ethics Committees in Uganda
<b>EAC</b>	East African Community
<b>MTA</b>	Material Transfer Agreement
<b>REC</b>	Research Ethics Committee
<b>RC</b>	Research Clearance
<b>R&amp;D</b>	Research and Development
<b>RDC</b>	Resident District Commissioner
<b>RRC</b>	Research Registration and Clearance
<b>RS</b>	Research Secretariat
<b>S&amp;T</b>	Science and Technology
<b>UNCST</b>	Uganda National Council for Science and Technology
<b>USA</b>	United States of America

## 1.0 Introduction

The Uganda National Council for Science and Technology (UNCST) is a semi-autonomous government agency established in 1990 (Cap 209 of the Laws of Uganda) to develop strategies for integrating science and technology (S&T) into the national development planning process, to advise government of Uganda on policy matters necessary for advancing S&T and, to oversee and coordinate research and development (R&D) activities in Uganda.

The UNCST has specific responsibilities for R&D oversight under Sections 4 and 5 of the UNCST Act (Cap 209). The responsibilities are stated as follows:

### Section 4:

- a. To advise and coordinate the formulation of an explicit national policy on all fields of science and technology;
- b. To act as a clearing house for information on research and experimental development taking place in scientific institutions, centres and other enterprises and on the potential applications of their results;
- c. To work in close cooperation with and coordinate all scientific and technological activities of persons, institutions, sectors and organizations;

## Section 5:

- a. To establish specialized committees, research councils, organizations and experimental and developmental activities.

In executing the above functions, the UNCST registers, and with support from the Research Secretariat in the Office of the President, clears all research intended to be carried out in Uganda. In so doing, the UNCST receives and reviews research protocols for their scientific merit, safety and ethical appropriateness, and when satisfied, issues permits to conduct the research in Uganda. The research permit is granted at a national level to facilitate access to research resources within the country. This Policy and Guidelines outlines the process and procedures of carrying out research in Uganda. They are intended to guide all persons who wish to conduct research in Uganda.

## 2.0 Goal

The goal of this Policy and Guidelines is to facilitate the conduct of research and development in Uganda, and to establish a national coordinated framework for research oversight.

### 3.0 Objectives

The overall objective of this Policy and Guidelines is to document research and development activities in all sectors so as to enable research coordination and oversight, research priority setting, the protection of intellectual property and use of research results to guide public policy.

#### The specific objectives are to:

- i. Assist researchers access data for research in Uganda;
- ii. Secure results of research undertaken in Uganda and to provide information on their potential application;
- iii. Document research activities in Uganda and to provide a one stop centre for information on such work;
- iv. Prevent unnecessary duplication of research;
- v. Guard against research misconduct such as plagiarism, falsification and fraud;
- vi. Guard against research projects that are potentially detrimental to human health and the environment;
- vii. Avoid unauthorized collection and transfer of research material and/or information;

- viii. Protect the rights and welfare of research participants/subjects; and
- ix. Guard against clandestine activities which may be undertaken under the cover of research.

### 4.0 Definition of Research

For purposes of this Policy and Guidelines, research shall be defined as, “Any type of systematic investigation, testing and evaluation designed to develop or contribute to generalisable knowledge”. It includes research in all sectors such as industry, medicine, agriculture, humanities and social sciences, natural and physical sciences, as well as experimental development work leading to new designs, products or processes. Examples of research activities include, but may not be limited to, experimental tests and field trials, surveys, censuses, and interviews.

Scientific expeditions (i.e. organized tour of facilities of scientific interest usually for short periods of time) shall not be regarded as research activities. However, where doubt exists as to whether a project is an expedition or a research, it will be treated as a research project.

## 5.0 Scope

This Policy and Guidelines applies to all research activities undertaken in health, agriculture and environmental sciences, physical and biological sciences, humanities and social sciences, industrial and engineering sciences, and information sciences. It also applies to all individuals carrying out research in Uganda, and to research and academic institutions, government ministries, departments and agencies, private companies/enterprises, non-governmental and Intergovernmental organizations, international agencies, and community based organizations.

## 6.0 Registration of Research Protocols

All persons intending to carry out research in Uganda are required to register their research protocols with the UNCST, and obtain UNCST approval of the protocol. Research protocols submitted to UNCST for registration and approval should be well written and fully developed. Draft research protocols shall NOT be accepted for registration. A research protocol should, at the minimum, have a title, names of the investigators and their institutions of affiliation, objective, methodology, significance/justification for the study, ethical considerations, work plan, budget and references. In addition, it is recommended for a research protocol to have a version and date. Data collection

instruments, such as questionnaires, case report forms and informed consent forms should be attached to the protocol. Research protocols received and registered by UNCST are either reviewed internally or externally by Specialized/Research Ethics Committees (RECs), Task Forces (or Ad hoc Technical Committees) and peer reviewers.

In order to register a research protocol, the lead researcher (i.e. the Principal Investigator) should complete the necessary research application forms in print obtained from the UNCST website or use the UNCST online research registration platform.

### The procedure and requirements for registration are as follows:

- a. Submit a copy of the research protocol (and all relevant study instruments) along with completed research application forms viz:
  - i. UNCST/RC 1 Form, to be completed (one copy) by the Principal Investigator;
  - ii. RS 6 Form, to be completed in triplicate (3 copies) by all research assistants and/or coworkers including the Principal Investigator, who will be actively involved in data collection.

iii. Four (4) recent passport size photographs should be attached.

**NB.** All sections in the application forms must be completed. Making references to other documents is not acceptable; however, additional sheets of paper may be used, if necessary.

- b. Submit all relevant support letters/documents (for example, ethics approval from a local Research Ethics Committee, biosafety approval from the National Biosafety Committee (where applicable), institutional support letters, recommendations, etc). Where a research protocol requires ethical approval by a foreign based Research Ethic Committee, it is advisable that such approval be obtained prior to submitting the research protocol to the UNCST.
- c. UNCST liaises with the Research Secretariat, Office of the President to obtain security verification and clearance for the researcher. A researcher is NOT expected to follow up directly with the Office of the President.
- d. UNCST provides feedback on the status of registration of the researcher's protocol within ten (10) working days from the date of submission of the research protocol to the UNCST.

e. The researcher pays a Research Administration and Clearance fee of US Dollars 300 (Three hundred only) or its equivalent for the entire period of the research project, but such a period shall not exceed five years. This fee is payable at submission of the protocol for registration. A research protocol may not be registered and a research permit shall NOT be issued unless the Research Administration and Clearance fee has been paid. All Applicants, except Ugandan students and students from the East African Community (EAC), are eligible and are expected to pay the Research Administration and Clearance fee. The Ugandan students and students from the EAC shall pay a fee of US Dollars 50 (Fifty only). The students must provide documentary proof of registration as students (i.e. admission letters) from their institutions of learning. For the avoidance of doubt, students in this regard, include individuals pursuing doctoral, postdoctoral studies and fellowships.

## Research applicants should note the following:

- i. All payments of Research Administration and Clearance fees are made to UNCST Bank Accounts. The details of the bank account numbers are obtained from the UNCST. Evidence of payment in the bank is submitted to the UNCST, upon which an official receipt will be issued.
- ii. Research applicants are encouraged to make cash payments in the Bank. If a payment is made by cheque, or electronic funds transfer, the research applicant should take into account the maturity period and also pay the applicable bank charges.
- iii. The Research Administration and Clearance fee of US\$ 300 covers a research period up to five years only. A research protocol that extends beyond the initial 5 year period shall be required to pay US 300 for the extension.
- f. A researcher whose research protocol is registered and approved by UNCST receives a research permit valid for the entire duration of the study. The researcher may be provided with additional support documents, where necessary.

## 7.0 Ethical and Safety Requirements

All research protocols that involve human beings as research participants should undergo ethics review by a Research Ethics Committee that is fully accredited by the UNCST Accreditation Committee of RECs in Uganda, and should satisfy the ethical requirements and standards set forth in the National Guidelines for Research Involving Humans as Research Participants (current edition), and any other applicable nationally and internationally recognized ethics guidance documents. A list of accredited RECs can be obtained from the UNCST at [www.uncst.go.ug](http://www.uncst.go.ug). RECs whose responsibility is to conduct ethical review of research protocols, must ensure that after the REC approval, Investigators/researchers submit their research protocols to the UNCST for registration and final clearance.

Research protocols involving hazardous materials and genetic modification should undergo biosafety review by a recognised Institutional Biosafety Committee, and where applicable, the National Biosafety Committee or other relevant committees or lead agencies. RECs and other relevant committees should include in their approval letters such wording as, “Please, note that this approval is subject to registration and final clearance of the protocol by UNCST” or similar wording.

## 8.0 Affiliation to Local Organisations

All researchers who are foreign nationals are required to identify and get affiliated to a local organisation appropriate for their type of research in Uganda. The affiliation is arranged by researchers themselves together with the local organisation. The researcher should obtain a letter of recommendation from the local organisation, which they submit to UNCST. Local organisations of affiliation should support the researchers and work, as far as it is practicable, towards building long-term collaborative partnerships with the foreign researchers. Local organisations of affiliation should ensure that they have institutional policies and mechanisms of taking stalk of their research activities, including modalities for sharing data, managing intellectual property and disseminating research results.

Ugandans who do not have formal organisation of affiliation may be permitted to indicate the local administrative/governance units, such as Local Council 1, in their communities as organisations of affiliation.

## 9.0 Research in Protected Areas

Researchers intending to carry out research in protected areas such as wildlife reserves, forest reserves, museums, antiquities and monuments or other conservation sites under the jurisdiction of Uganda Wildlife Authority, National Forestry Authority, or any other authorized lead agency are required to obtain access permits from those agencies prior to submitting their research protocols to UNCST for registration and final clearance.

## 10.0 Research by Students

Research by students (i.e. college, undergraduate and masters) registered in an educational institution in Uganda, which presents no more than minimal risk to humans and the environment, should be appropriately documented and reviewed by the student's supervisors/head of department and, where applicable, a local REC. Student research that presents more than minimal risk to humans and the environment, and which may involve hazardous substances, should be registered with and approved by UNCST. For the avoidance of doubt, this section does not apply to doctoral and post doctoral students and students pursuing other forms of study such as fellowships.

The local REC and or the students' Head of Department shall submit to UNCST a list of all approved students' research

protocols prior to commencement of the studies. The list shall include: Name(s) of student(s), subject of research assignments, area in which research is to be done, duration of the research, estimated budget and source of funds, and Name(s) of supervisor(s).

## **11.0 Monitoring of Research Sites**

The UNCST shall have access to data and the research premises, field or research site. The UNCST may, from time to time, visit the research sites to ensure compliance with this Policy and Guidelines and the UNCST approved research protocols. The visits may be announced or impromptu.

## **12.0 Termination of Research**

The UNCST reserves the right to terminate, suspend or revoke a research permit in the event of gross misconduct or violation of the provision of this Policy and Guidelines or when deemed necessary in the prevailing circumstance without giving notice to the researcher.

## **13.0 Renewal/Extension of Research Permit**

A researcher who wishes to continue with the research protocol beyond the expiry date of the research permit should make a written request for an extension or renewal of the permit to the Executive Secretary of the UNCST. The request should be accompanied by a progress report, REC and other institutional approvals (where applicable). The research report should include a title of the study, UNCST study reference number, study area/site, brief background and objective of the study, progress in the reporting period, constraints/problems encountered and implementation plan for the period requested. The researcher may provide any other pertinent information as he/she deems fit.

## **14.0 Research Reports**

### **14.1 Progress reports**

Annual renewal of the study is not required from UNCST. However, the researcher should electronically submit annual progress reports to UNCST within four weeks after every 12 months of the study for information only. Failure to do so may result in termination of the research.

## 14.2 Amendments

Any changes, amendments, and addenda to the research protocol, research instruments or the consent form (where applicable) must be submitted to the designated local REC or Lead Agency for review and approval prior to implementing the changes. UNCST should only be notified of the REC or lead agency approved changes within ten working days.

## 14.3 Serious Adverse Events Reporting

For clinical trials, all serious adverse events must be reported promptly to the designated local REC for review as stipulated in the National Guidelines for Research Involving Humans as Research Participants, (current edition).

## 14.4 Final reports

It is the researcher's obligation to submit final reports of their research projects to the UNCST. Researchers are free to adopt any format for writing a final report, but the report should have an abstract, a section on results, discussion of the results and recommendations. Researchers who are foreign nationals are required to submit a study completion report before returning to their countries. Researchers are encouraged to share their research findings with the communities who participated in their research or with any

target group likely to use/benefit from the results of the research.

## 15.0 Transfer of Materials for Research

Experimental analyses and investigational procedures should be undertaken within Uganda. However, where it is proven that no capacity for a given investigation exists in Uganda, or where exchange of research material is needed for quality assurance purposes or other justifiable reasons, research materials may be transferred to, exported to or exchanged with more advanced facilities abroad.

Any researcher wishing to transfer or export research materials abroad for research purposes, shall make a request for the transfer or export to the Executive Secretary of the UNCST. The request should be accompanied by a Materials Transfer Agreement (MTA) between the providing organisation in Uganda and the recipient organisation abroad. Guidelines for preparing MTAs can be obtained from UNCST.

## **The following are the necessary steps for the transfer or export of materials for research purposes:**

1. The research activity that involves the exchange, transfer or acquisition of material shall first be registered and approved by the UNCST in accordance with this Policy and Guidelines;
2. The Applicant must be a legal resident of Uganda or be affiliated to a local legally recognized institution in Uganda;
3. A letter to the Executive Secretary of the UNCST requesting for the exchange, transfer or acquisition of research material;
4. A MTA and any other document related to the exchange, transfer or acquisition of material shall accompany the request for the exchange, transfer or acquisition of the research material;
5. The research applicant shall receive feedback from the UNCST on the status of his/her request within ten working days from the date of submitting the written request. The feedback may be an approval/clearance, reject/disapproval or comments to improve the quality

of the application for the exchange, transfer or acquisition of the research material;

6. Approval/clearance of the UNCST shall be sufficient to facilitate the exchange, transfer or acquisition of the research material.

## **16.0 Failure to Register a Research Protocol with the UNCST**

Any person who does not register his/her research protocol with the UNCST, shall not be exonerated from action against him/her and the legal consequences of non-compliance with this Policy and Guidelines.









## Contact Information

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