

RESEARCH REGISTRATION AND CLEARANCE POLICY AND GUIDELINES

**Uganda National Council for
Science and Technology**

March 2007

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List of Acronyms

IRC	Institutional Review Committee
MTA	Material Transfer Agreement
RC	Research Clearance
R&D	Research and Development
RDC	Resident District Commissioner
RRC	Research Registration and Clearance
RS	Research Secretariat
S&T	Science and Technology
UNCST	Uganda National Council for Science and Technology
US	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 and implement strategies for integrating science and technology (S&T) into the national development process, provide advice to the government of Uganda on policy matters necessary for advancing S&T and, oversee and coordinate research and development (R&D) activities in Uganda. The UNCST is incorporated under the Ministry of Finance, Planning and Economic Development.

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 clearinghouse 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 co-operation with and co-ordinate 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 or other scientific and technological services;

In executing the above functions, the UNCST registers and together with 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 legitimate 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 provide a national research coordination framework and oversight mechanism.

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 formulation.

The specific objectives are to:

- i. Assist researchers to access data for research within Uganda;
- ii. Secure results of research undertaken in Uganda and to provide information on their potential application;
- iii. Document all research activities in Uganda and to provide a one stop centre for information on such work;

- iv. Prevent duplication of research;
- v. Guard against research misconduct such as plagiarism 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 whose objective is to discover new facts or information and increase the stock of knowledge”. It includes research in industry, medicine, agriculture, social sciences, natural and physical sciences, etc., as well as experimental development work leading to new designs, products or processes. Examples of research activities include, but are not limited to, experimental tests and trials, general purpose data collection, geological surveys, baseline surveys, censuses, market surveys, general purpose interviews, and evaluation exercises.

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.

Consultancies which generate and analyze data shall be considered as research activities, and shall be subject to the provisions of

this Policy. Consultancies, however, exclude professional and other services where the practice involves application of existing knowledge rather than generation and analysis of data.

5.0 Scope

This Policy and Guidelines applies to all research activities undertaken in health, agriculture and allied sciences, physical and biological sciences, social sciences and humanities, 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 departments, private companies/enterprises, non-governmental and Intergovernmental organizations, international agencies, and community based organizations.

6.0 Registration and Approval of Research Projects

All persons intending to carry out research in Uganda are required to register their research activities with the UNCST, and obtain UNCST approval of their activities. Research proposals submitted to UNCST for registration and approval should be well written and fully developed. Draft research proposals shall NOT be accepted for registration. A research proposal should have a title and at least sections on objectives, methodology, significance/justification for the study, work plan and budget and references/bibliography. In addition, the research project proposal should have a version and date, names and brief biographical sketches of the investigators and their institutions of affiliation, and data collection instruments, such as questionnaires. The research proposal must be duly signed by the Principal Investigator.

Research proposals received and registered by the Council are reviewed by the UNCST Specialized/Ethics Committees, Task Forces and peer reviewers.

7.0 Ethical Requirements

All research projects that involve human beings as research participants should undergo ethics review and satisfy the ethical standards for research involving humans as research participants as provided for in the National Guidelines for Research involving Humans as Research Participants (2007), and any other applicable internationally recognized ethics guidance documents. Research involving humans as research participants include: clinical investigations (that is, any experiment or study on one or more persons which involves a test product/ article, whether a drug, treatment, procedure, or device); social-behavioral studies which involve interaction with or observation of people; and basic scientific research to study the biology of persons or organs and specimens thereof.

The most fundamental issues in studies involving humans as research participants are: valid scientific questions and approaches, potential social value, favorable risk-benefit ratio, fair selection of research participants, and adequately administered informed consent process. *(The procedures for ethical review are outlined in the National Guidelines for Research involving Humans as Research Participants, which can be obtained on request from the UNCST).*

8.0 The Process and Procedures for Research Registration and Issuance of Research Permits

An application for a research permit should be made by the lead researcher (i.e. the Principal Investigator) or whereby applicable, a Co-Principal Investigator, to the UNCST using research application forms obtained from the UNCST. The procedure and requirements for submission of application for research permits are as follows:

- a. Two copies of the research project proposal are submitted to UNCST along with completed research application forms obtained from the UNCST. The forms can be collected physically from the UNCST Offices, or downloaded from the UNCST website (www.uncst.go.ug) or they can be mailed electronically, on request. UNCST may request for an electronic submission. The research application forms are:
 - i. UNCST/RC 1 Form, to be completed (one copy) by the Principal Investigator only or where applicable, a co- Principal Investigator;
 - ii. RS 6 Form, to be completed in triplicate (3 copies) by all research assistants and/or co-workers including the Principal Investigator who are actively involved in data collection. Four (4) recent passport size photographs should also be submitted with the filled forms.
- 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. All relevant support letters/documents (for example, ethics approvals, institutional support letters, recommendations, etc) should be attached to the application. Where a research project requires ethical approval by an Institutional Review Committee, such approval, including ethical approvals by foreign based Institutional Review Committees, should be obtained prior to submitting the research protocol to the UNCST.
- c. After the UNCST has approved the research project, it sends two (2) copies of the applicant's RS 6 Form to the Research Secretariat, Office of the President for security verification and clearance. The process of obtaining clearance from the Office of the President is handled by the UNCST. Researchers are NOT expected to follow up their clearance from the Office of the President by themselves.
- d. The research applicant is informed of the status of his/her application within fourteen (14) working days from the date of submission of the application to the UNCST.
- e. After receiving notification of approval of research project, the applicant pays a non-refundable Research Administration and Clearance fee of United States Dollars 300 (Three hundred only) or its equivalent. A research permit shall NOT be issued until the Research Administration and Clearance fee has been paid. All Applicants, except Ugandan students registered for study in local institutions, are eligible and are expected to pay the Research Administration and Clearance fee. The Ugandan students registered in local institutions shall pay a fee of USD\$ 50 (Fifty dollars only). The students must provide documentary proof of their registration as students in the local institution of learning. Applicants should note the following, that:

- i. All payments of Research Administration and Clearance fees are made by the Applicant to UNCST Bank Accounts. The details of the bank account numbers are obtained from the UNCST. One stamped copy of the banking slip is returned to the UNCST, upon which an official receipt will be issued.
 - ii. Applicants are encouraged to make cash payments in the Bank. If a payment must be made by cheque, especially cheques in foreign currency, the applicant shall bear the cost of bank charges.
 - iii. The Research Administration and Clearance fee of US\$ 300 covers a research period up to three (3) years only. A research project that extends beyond two (2) years after the initial 3-year period shall be required to pay US\$ 300 for the extension.
- f. An Applicant, including all research assistants, whose research project has been approved by the UNCST, receives the following documents from the UNCST:
- i. A Research Approval/Clearance Notification Letter copied to the Resident District Commissioner (RDC) of the district(s) in which the research is to be carried out;
 - ii. A Research Permit/Identity Card valid for a period not exceeding one (1) year, but renewable upon submission of a progress report and a specific request for renewal.

9.0 Affiliation to Local Institutions

All researchers who are foreign nationals are required to identify and get affiliated to a local institution appropriate for their type

of research in Uganda. The affiliation is arranged by researchers themselves together with the local institution. Local institutions 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 institutions of affiliation should ensure that they have institutional policies and mechanisms of taking stalk of their research activities.

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

10.0 Institutional Review Committees

All research involving humans as research participants shall be approved by recognized Institutional Review Committees (IRCs). A list of registered IRCS can be obtained from the UNCST. IRCS whose responsibility is to conduct ethical review of research protocols, must ensure that after the IRC approval, Investigators/researchers submit their research protocols to the UNCST. Similarly, other Committees such as Scientific Committees and Institutional Biosafety Committee should do the same. IRCS should include in their approval letters such wording as, “The IRC approval will take effect only after you have registered this research project with the UNCST” or similar wording which refers the applicant to the UNCST to register their research projects. (*The function of IRCS and their relationship with the UNCST are described in detail in the National Guidelines for Research involving Humans as Research Participants*).

11.0 Field Research by College Students

College students registered in an educational institution in Uganda who would like to carry out field research should be introduced to the UNCST by their Head of College/Institution. The Head of College should provide the UNCST with the following: 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).

12.0 Research in Protected Areas

Researchers intending to carry out research in protected areas such as wildlife reserves, forest reserves 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 projects to UNCST for final approval and clearance.

13.0 Evaluation of Research Projects

The UNCST shall have access to data and the research premises, field or location of the research project. The UNCST may, from time to time, visit the research projects sites to ensure compliance with this Policy and Guidelines and the UNCST approved research protocols.

14.0 Termination of Research Permit

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.

15.0 Renewal/Extension of Research Permit

A researcher, who wishes to continue with the research project beyond the expiry date of the research permit, is required to 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, and the Research Identity card previously issued by the UNCST. The progress report should have 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.

16.0 Research Reports

It is the researcher's obligation to submit timely progress reports and 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.

17.0 Access to and Exchange/ Transfer of Materials for Research

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

Any researcher wishing to transfer or export samples 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 Material Transfer Agreement (MTA) between the providing institution in Uganda and the recipient institution abroad.

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

- a. 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;
- b. The Applicant must be a legal resident of Uganda or be affiliated to a local legally recognized institution in Uganda;
- c. A letter to the Executive Secretary of the UNCST requesting for the exchange, transfer or acquisition of research material;
- d. 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;

- e. The Applicant shall receive feedback from the UNCST on the status of his/her request within fourteen (14) 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;
- f. Approval/clearance of the UNCST shall be sufficient to facilitate the exchange, transfer or acquisition of the research material.

18.0 Failure to Register a Research Project with the UNCST

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

