UGANDA NATIONAL COUNCIL
FOR SCIENCE & TECHNOLOGY

THE REPUBLIC OF UGANDA

STANDARD OPERATING PROCEDURES FOR INSTITUTIONAL BIOSAFETY COMMITTEES IN UGANDA

JANUARY 2021

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CONTENTS

Acknowledgement

These Standard Operating Procedures (SOPs) for Institutional Biosafety Committees in Uganda have been developed to provide guidance to organizations that are undertaking regulated bioscience research and development. They are intended to complement existing biosafety policies and relevant laws of Uganda.

The Uganda National Council for Science and Technology (UNCST), would like to appreciate the valuable technical support, commitment and dedication of the writing and drafting of these guidelines in particular NBC Chairperson Dr. Charles Mugoya and members of the National Biosafety Committee, Dr. Andrew Kiggundu formerly with National Agricultural Research Organization (NARO), Herbert Oloka of Program for Biosafety Systems (PBS), Kwehangana Musa, Beth Mutumba and Hellen Opolot of Uganda National Council for Science and Technology.

The contribution of the Program for Biosafety Systems in supporting these SOPs and cooperation in building an effective and efficient National Biosafety System for Uganda is very much appreciated.

Foreword

All over the world, it is recognized that biotechnology, which refers to a variety of techniques involving living organisms as a means of production, will drive economic development in the 21st century. In Uganda, the Government has embraced biotechnology as a strategy to enhance agricultural productivity and industrialisation, improve health care delivery and preserve the environment. Although biotechnology is beneficial for economic growth and social wellbeing, it may have potential risks because it may involve working with potentially harmful substances or production of unfamiliar genetically modified organisms.

In Uganda, all institutes/organizations handling Genetically Modified Organisms (GMO) products or biological materials are required to establish Institutional Biosafety Committee (IBC), which serves an important role as a point for interaction with the institution to implement the biosafety regulatory framework. The Uganda National Council for Science and Technology (UNCST) within its mandate of research oversight as accorded by the UNCST Act Cap 1990, has therefore developed these Guidelines to support IBCs in observing and adhering to existing biosafety regulatory compliance requirements.

The UNCST is responsible for overseeing research involving GMOs/ Living Modified Organism (LMOs), biological materials and rDNA materials through these IBCs. Therefore, UNCST has taken this initiative to strengthen the functioning of the IBCs.

These Guidelines are not intended to substitute any existing or future legal requirements pertaining to the use of genetically modified organisms in Uganda; rather they are complementary and should be used within the confines of the laws of Uganda.

Uganda is a signatory to the Cartagena Protocol of Biosafety, this Protocol obliges member states to put in place administrative and legal frameworks to ensure safe use of modern biotechnology. These SOPs comply with this international obligation.

Dr. THERESA SENGOOBA

Chairperson, Uganda National Council for Science and Technology Board

List of Acronyms

BSO	Biological Safety Officer
BL	Biosafety Level
BSL	Biological Safety Level
GE	Genetic Engineering
GMO	Genetically Modified Organisms
IBCs	Institutional Biosafety Committees
NCA	National Competent Authority
LMO	Living Modified Organism
NBC	National Biosafety Committee
rDNA	recombinant deoxyribonucleic acid
SOPs	Standard Operating Procedures
UNCST	Uganda National Council for Science and Technology

Definitions

Application: All the documentation that may be required by the NBC for the submission of a request for biosafety approval to conduct research.

Applicant: A party submitting an application for a containment research. Typically, the Applicant is the same as the Authorized Party, or is acting in collaboration with the Authorized Party.

Biosafety: The safe development, transfer and application of biotechnology and its products. Biosafety also means the safe handling of potentially hazardous biological materials

Biotechnology: Any technique that uses living organisms or substances there from to make or modify a product, improve plants or animals, or microorganisms for specific uses.

Containment: Safe methods for managing infectious agents or hazardous compounds in a facility where they are being handled or maintained in order to prevent their escape outside the prescribed spaces.

DNA: Deoxyribonucleic acid is one of two types of molecules that encode genetic information. The other is **RNA**.

Environment: Land, air and water and living organisms supported by any of those media, including any physical, biological or chemical elements of any of the above.

GMO: Genetically modified organism, an organism produced through Recombinant DNA (rDNA) technology. This may involve the introduction of a section of DNA from a "donor" organism to a "recipient" organism or other novel genetic engineering methods.

Hazard: Any harmful/adverse effect on human health and /or environment

Modern Biotechnology: This involves intentional manipulation of genes, cells and living tissue, such as genetic engineering.

Pathogenicity: Indication of whether an organism e.g. bacteria, fungus or virus is able to cause a disease to plants, animals or humans.

Recombinant DNA: DNA which has been altered by joining genetic material from two different sources. It usually involves putting a gene from one organism into the genome of a different organism.

Recombinant DNA technology: Techniques for cutting apart, splicing together, and producing pieces of DNA from different sources.

Risk: A function of the probability of harm and the severity of that harm, consequential to the transport, handling or use of an organism.

Regulated organism: Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genus or taxon known to have plant pests or pathogens, human or animal pathogens, and meets the definition of plant pest or human or animal pathogen, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering.

Unintentional Release: Escape from the constraints of physical containment that are found in a laboratory, greenhouse or other contained structure.

1.0 Introduction

The realization that biosciences research could play a significant role in human sustainable development in the light of rapidly expanding populations has led many countries around the world to embrace bioscience research. Genetic techniques have been used to generate novel varieties of crops, strains and breeds that yield more and better quality industrial, agricultural, environmental and healthcare products with an efficiency that allows sustainable environmental conservation. This has led to the new bio-revolution fueled by the advent of modern biotechnology.

Modern biotechnology just like any other powerful technology, needs to be regulated for safe development and use. 'Biosafety', a term which means adhering to relevant science-based practices put in place to protect human and animal health and the environment from the possible adverse effects, was first applied to the tools of modern biotechnology at the United Nations Conference on the Human Environment and Development in 1972, then in the Rio Earth Summit in 1992. Today, many countries including Uganda, are parties to the Cartagena Protocol on Biosafety that provide a framework for safe transfer, handling, transboundary movement and use of modern biotechnology but have also put place occupational and safety procedures.

During the process of modern biotechnology development two processes are particularly critical; in-vitro techniques, including recombinant deoxyribonucleic acid (rDNA) and direct injection of nucleic acid into cells or organelles as well as subsequent development of products or the fusion of cells to overcome natural reproductive barriers. Within the life sciences, international standards of workplace biosafety have been established with four levels of biohazard classification (BSL1 through BSL4) with specific and pertinent precautions. Core to the process is an understanding that the generation, development and application of these biotechnologies have potential biosafety implications and that investigative research with regulated articles must be carefully managed through an organized institutional setting to promote workplace safety and ensure containment.

Further development into useful products is predicated upon them being deemed safe for use as intended. Relevant to crop biotechnology are the regulatory processes pertinent to stage of development: confined field testing, multi-location testing, general release (breeder seed), and human and animal food/feed use all aligned with policies that protect and promote the environment and health.

PART I: MANDATE, PURPOSE, OBJECTIVES AND SCOPE

2.0 UNCST Mandate under the Cartagena Protocol

Uganda National Council for Science and Technology was designated as the Competent National Authority (CNA) for biosafety matters under the Cartagena protocol. It is for this reason and purpose that the Uganda National Council for Science and Technology (UNCST) developed an interim framework to allow for the research and development of modern biotechnology to be regulated at institutional level by an Institutional Biosafety Committee (IBC) and at national level by the National Biosafety Committee (NBC) which was established in 1996. Research governance, clearance, and relevant oversight are major functions of UNCST under the Sections 4 and 5 of the UNCST Act (Cap 209).

3.0 Purpose

a. The purpose of these standard operating procedures (SOPs) is to provide guidance to organizations that are undertaking bioscience research and development for which an Institutional Biosafety Committee (IBC) is required.

b. These SOPs are intended to complement existing biosafety policies and relevant laws of Uganda.

4.0 Objectives

The objectives of these SOPs are to:

a. Ensure compliance with national biosafety regulations, guidelines, policies and relevant laws of Uganda;

b. Guide the establishment and operationalization of IBCs;

c. Provide a framework for reviewing applications for contained research and development of genetically modified organisms;

d. Provide cooperation mechanisms between UNCST and institutions conducting biological science research.

5.0 Scope

These SOPs apply to institutions and persons conducting or intending to conduct research and development activities which involve:

a. using modern biotechnology tools, components and products;

b. research, handling, and general release of genetically modified organisms

c. handling of potentially infectious microorganisms;

d. handling biologically hazardous materials including corrosives and acids.

PART II: ESTABLISHMENT AND FUNCTIONS OF INSTITUTIONAL BIOSAFETY COMMITTEES

6.0 Establishment of an IBC

a. An institution that intends to conduct regulated biosciences and development activities as spelt out in section 5 shall establish an IBC or shall have an affiliation with an existing IBC with similar or closely related expertise and mandate.

b. The IBC should be composed of members drawn from the diverse fields of biological sciences and shall consist of not less than seven persons at least three of whom shall have relevant expertise in biosafety.

c. The IBC may co-opt external expertise for a specified and defined period of time selected based on their area of expertise.

d. A recommendation on an external expertise can be made by a IBC member or IBC chairperson in accordance with the policies of the institution that has established the IBC.

7.0 Functions of an IBC

7.1. An IBC shall perform the following functions:

a. Review and approve, laboratory experiments, contained use of GMOs, and regulated biological materials;

b. Regularly review, monitor and assess laboratory experiments, conditions of contained use, and adherence to relevant biosafety containment requirements;

c. Review applications to conduct confined testing, deliberate and controlled release, confined field trials, and general release and forward pertinent recommendations to UNCST or other national regulatory agencies as applicable;

d. Ensure that any information provided by applicants at institutional level for their consideration is correct and complete, before forwarding the application to the NBC / UNCST for consideration;

e. Conduct inspection or facility audit to ensure that conditions of contained use, lab conduct, confined field conduct align and comply with relevant national laws, regulations and pertinent terms and conditions of authorization;

f. Assess field experiments to ensure that proposed risk assessment and risk management as well as emergency response measures are sufficient;

g. Provide interim and final reports every six-months for all active authorized regulated activities;

h. Maintain a record / database of all biotechnology and biosafety activities of the institution;

i. Liaise with national biosafety regulatory institutions and act as a contact point for biosafety regulatory procedures within the institution;

j. Advise the institution on biosafety capacity development needs;

k. To liaise with relevant research regulatory entities in the conduct of their roles;

7.2. In the performance of its functions under SOP (7.1) above, the IBC may constitute sub-committees for any purpose except in decision making on an application received;

7.3. For avoidance of doubt, an activity falling under any of the following categories shall require prior review by a relevant IBC and approval of the Competent National Authority:

a. Field trials genetically modified plants with rDNA techniques;

b. Use of Risk group 2 or greater agents as host-vector systems,

c. Deliberate transfer of a drug resistance trait to microorganisms,

d. Deliberate formation of rDNA containing genes for the bio-synthesis of toxin molecules lethal to vertebrates at an LD-50 of less than 100 nanograms per kg body weight;

e. Cloning of DNA from Risk Group 2 or greater agents into non-pathogenic Prokaryotes or lower Eukaryotic host-vector systems;

f. Use of whole animals in which the animal's genome has been altered by stable introduction of rDNA or DNA/RNA derived from rDNA into a germ-line (transgenic animal);

g. Viable rDNA-modified microorganisms tested on whole animals;

h. Formation of rDNA material containing two-thirds or more of the genome of a eukaryotic virus;

8.0 Appointment of IBC members

a. Members of the IBC shall be appointed for a period of 5 years by the responsible officer/ head of the institution and shall be eligible for reappointment in accordance with policies of the institution.

b. The appointing authority shall, when appointing members to the IBC, designate one member as a chairperson of the committee.

c. The Chairperson of the IBC shall have the education, credentials, knowledge and experience in scientific research pertaining to applied biosciences, living modified organisms, genome editing, recombinant DNA, or genetics.

d. A member of the IBC shall be appointed on their individual merit but with due consideration of the expertise and experience within the institution.

e. The IBC shall have a minimum membership of 7 members.

f. The chairperson and members of the IBC shall be of high moral standing.

g. A Biological Safety Officer (BSO) under SOP (9) shall be an ex-officio member of the IBC and shall serve as the secretary to the committee.

9.0 Resignation and Replacement of IBC Member

A member of the IBC may resign or be replaced in accordance with policies of the institution appointing the committee.

10.0 The Biological Safety Officer

1. An institution conducting Genetic Engineering (GE) research and research with regulated organisms (infectious) that require specific containment conditions at the relevant levels of BL2, BL3 or BL4 or, as appropriate, large-scale microbial research (i.e. greater than 10-liter batch size or deliberate controlled releases greater than 0.5 ha), shall appoint or designate one staff member as a biological safety officer.
2. The responsible officer / Head of the institution will identify and appoint the BSO in accordance with the policies of the institution.
3. A BSO shall perform the following functions:

    a. Provide liaison between researchers within the institution, IBC, and relevant regulatory agencies;

    b. Assist and establish relevant biosafety best practices as required by research approval permits or authorization;

    c. Organise biosafety inspections to independently assess conduct and containment status supporting on-going or planned regulatory research authorizations;

    d. Regularly assess the institutional biosafety capacity to support GE research and development and research on infectious agents and biohazardous materials;

    e. Inform and advise applicants and interested researchers of applicable biosafety laws, regulations, guidelines, processes, and procedures;

f. Maintain active communication with applicants, ensuring timely and complete submission of applications for IBC review and feedback on the review process;

g. Organize and facilitate meetings of the IBC, including the distribution of relevant documentation to members, scheduling of meetings, and ensuring the quorum;

h. Liaise with the IBC Chairperson in preparation of annual and periodic reports of IBC activities;

i. Ensure proper keeping of records, including approved applications, and all correspondences in relation to IBC activities;

j. Facilitate access to biosafety scientific literature and relevant educational programmes useful to the IBC and researchers within the institution;

k. Update information about IBC membership, including declarations of potential conflicts of interest.

l. Oversee the secretariat of the IBC.

11.0 Registration of an IBC by the Competent Authority

a. A responsible officer of an institution shall, on appointment of an IBC, promptly notify the Competent National Authority of the appointment.

b. The notification shall include a roster of members and their curriculum vitae detailing relevant expertise, education and qualifications.

c. The Competent Authority shall review the roster of members to the IBC and if satisfied as to the competence of the members, approve the entire membership or specific members, ensuring replacement of those that may have not qualified for approval.

d. The Competent Authority shall issue a certificate of registration valid once it is satisfied as to the completeness and competence of the IBC membership.

e. A certificate issued by the competent authority shall be valid for a period of five years unless amended, withdrawn or revoked by the issuing authority.

f. A change in membership to a registered IBC shall communicated to the Competent Authority in a manner prescribed under this SOP and an amended certificate issued to the institution if the change reflects less than half of the members of the IBC.

g. A change in more than half the membership of a registered IBC shall require a new registration certificate.

PART III: MEETINGS OF INSTITUTIONAL BIOSAFETY COMMITTEES

12.0 Meetings of the Institutional Biosafety Committees

a. The IBC shall hold at least four (4) formal meetings a year.

b. A meeting of the IBC may be conducted electronically (via web meeting, tele–conference), if approved by the IBC Chairperson in advance and or permitted by institutional policies.

c. The BSO, shall in consultation with IBC chairperson, schedule a meeting of the IBC.

d. The BSO shall notify members at least fourteen (14) working days' notice in advance of a formal meeting.

e. The BSO shall provide IBC members with a meeting agenda, relevant materials for IBC review, and meeting venue details at least seven (7) days in advance of the meeting.

f. IBC members shall take personal responsibility to adequately prepare for IBC meetings.

g. Materials circulated by the BSO in advance of IBC meetings are to be considered sensitive and premature for general circulation unless notified otherwise by the IBC chairperson.

13.0 Meeting Agenda

1. Standing items on the IBC agenda include:

    a. Call to order by the IBC chairperson.

    b. Roll call of members.

    c. Review and approval of minutes of previous IBC meeting.

    d. Presentation of a report on IBC activities and observations from the previous reporting period.

    e. Presentation (where applicable) of progress or inspection reports on on-going approved research activities that were previously reviewed by the IBC.

    f. Review and consideration (approval or rejection) of new applications for research or general release (where applicable).

    g. Review and recommendation of reports (when applicable) to the Competent Authority.

    h. Consideration of periodic plans of work for the IBC.

2. The chairperson of an IBC shall preside at meetings of the committee and in his or her absence, a meeting chair shall be elected from among members present.

3. The chairperson of an IBC can limit, lengthen, or stop at any time during the meeting any or all discussions if deemed to be in the best interests of the IBC.

14.0 Quorum

The quorum for an IBC meeting shall be at least fifty percent (50%) of members of the IBC, excluding ex-officio members or co-opted experts.

15.0 Decision Making

Decisions of the IBC shall be by consensus and if consensus cannot be achieved, decisions shall be made by at least a seventy–five percent majority vote of the voting members present.

16.0 Minutes

1. The minutes of an IBC meeting will reflect date, time, and place of the meeting, individuals in attendance and roles, whether minutes of the prior meeting were approved, all motions, reviews conducted and recommendations made, and the time of adjournment.

2. Trade related secret information, confidential business information the disclosure of which would directly compromise the business potential of the applicant shall be redacted in the minutes.

17.0 Conflict of Interest

1. A member of an IBC may not be involved (except to provide information) in the review or approval of an application in which he /she has been or expects to be engaged or has direct financial or other material interest.

2. A member of an IBC shall recuse himself or herself from the review and decision making on applications in which he or she expects to be engaged or in which they have a direct financial or other material interest.

3. At each meeting of the IBC, members shall be given an opportunity to identify any conflicts of interest pertaining to items on the agenda.

18.0 Confidentiality

1. A member of the IBC shall protect all information given to them in confidence in the course of their work, including confidential business (or propriety) information as may be indicated by an applicant.

2. Every member of the IBC shall, on appointment, sign a confidentiality agreement on appointment to the IBC.

3. A member of the IBC shall not use information provided to him or her in the course of performance of committee work for personal gain.

19.0 Funding of IBC Activities and Allowances for Members

1. Financing for IBC operations shall be the sole responsibility of the institution appointing the IBC and can be based on cost recovery basis from fees payable by applicants for IBC reviews under SOP 26.0.

2. The National Competent Authority shall require a written funding commitment for operations of the IBC from the institution appointing an IBC.

3. Members of the IBC may be paid honorarium for the detailed review of applications and reimbursement for reasonable expenses incurred during discharge of their official IBC duties.

4. Reimbursements shall cover meals, travel, and accommodation in accordance with the institution's financial policies.

5. A BSO shall maintain an annual budget for efficient operations of the IBC.

PART IV: REVIEW AND APPROVAL OF AN APPLICATION AND MONITORING OF RESEARCH ACTIVITIES

20.0 Application for Contained Use Research

1. A person shall not commence contained research involving genetically modified organism or rDNA and other infectious/hazardous materials without a written approval from the IBC.

2. An application for contained use research shall be submitted to the IBC secretariat in a format published by the competent authority.

3. The IBC may give approval for contained use in writing to the applicant with copies of the approval letter and summary of minutes of the meeting that reviewed and approved the work to the competent authority.

21.0 Application for Confined Use Research

1. A person shall not commence a confined field experimentation of genetically modified organisms without approval from the competent authority.

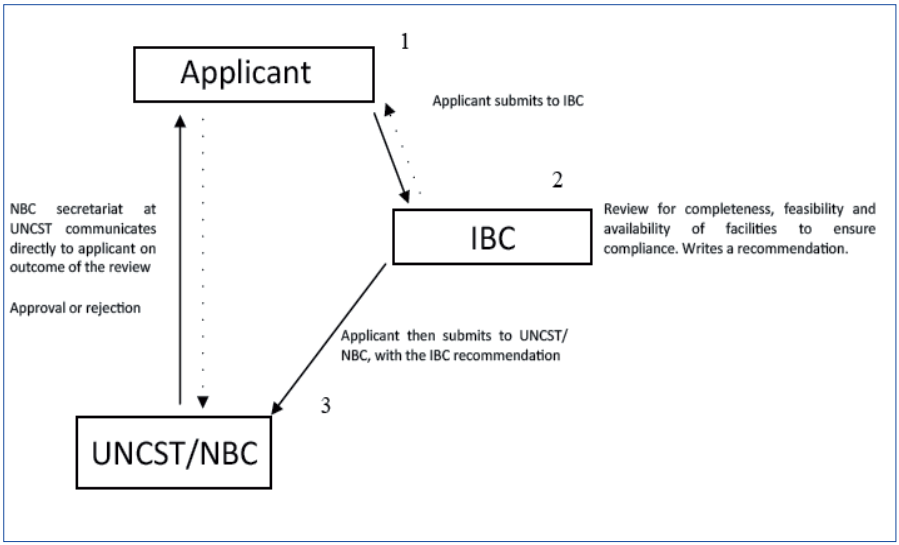
2. An application to conduct a confined field experiment shall be on a format published by the competent authority.

3. Application forms can be obtainable from the official website of the competent authority .

4. An applicant shall first submit an application for confined experiment to the IBC for a no objection before submission to the competent authority (Figure 1).

5. An application to the competent authority shall be accompanied with the IBC decision document, approval letter or minute extract that endorsed the application.

Figure 1: Application process for confined field trial and linkages with Competent National Authority



22.0 Receiving and Reviewing of an Application

1. The IBC shall within seven days after receipt of a complete application for contained testing notify the Competent Authority of the application.

2. The Competent Authority may within seven days after receipt of the notice from the IBC give directions to the institutional biosafety committee regarding the application for research.

3. Members of the IBC shall receive a copy of a complete application and requisite documents at least seven (7) calendar days prior to an IBC meeting.

4. The IBC secretariat shall ensure that applications and documents are made available to the IBC members before a scheduled meeting.

5. The IBC secretariat shall notify the applicant in writing on receipt of a complete application and may invite an applicant to give a presentation at a scheduled IBC meeting and to receive comments from the IBC members.

6. The applicant may be given a chance to respond to the comments during the meetings.

7. IBC members shall critically review applications prior to and during IBC meetings.

8. The IBC may conduct an inspection of research facilities to ensure that the proposed work can be safely undertaken at the proposed facilities.

9. In review of applications, the IBC shall critically review the following aspects:

    a. Competence of the team and training plans;

    b. Suitability of facilities;

    c. Scientific thoroughness and feasibility of the gene technology and development processes undertaken to develop the product;

    d. Risk of the work to personnel and the environment around the work;

    e. Completeness of proposed biological and physical containment/ confinement;

f. Completeness of the proposed emergency plan.

10. The IBC shall make a decision on a complete application within twenty–one (21) working days from the date of receipt of the application.

11. The period specified in SOP 22 (10) includes the time it takes the applicant to revise the application and provide any additional documentation as may have been requested by the IBC. The IBC shall on case by case basis advise on the timelines for additional information requirements not subject to SOP 22(10).

23.0 Appeal against IBC decision

1. An applicant who is dissatisfied with the decision of the IBC may appeal to the responsible officer / Head of the institution.

2. The responsible officer may, if satisfied as to the merits of the appeal, forward the application to National Competent Authority for consideration.

24.0 Laboratory and other Facility Inspections

1. The IBC shall inspect laboratories and other research facilities where a regulated activity, involving LMO/rDNA and infectious biological agents, is being undertaken.

2. Inspections shall be conducted using checklists and approved inspections forms as provided within the national containment and confinement guidelines and standard procedures.

3. The IBC shall prepare and file a report within the IBC secretariat for each inspection undertaken.

4. An inspection report prepared under 24.0 (3) shall include relevant information such as:

    a. Compliance infractions

    b. Breach of containment

    c. Proposed remedial measures

5. The Competent Authority may request the IBC to conduct any specified inspection at any time.

6. Research scientists shall not deny IBC members or a BSO entry to research facilities to conduct inspection

25.0 Un-intentional Release and Emergency Measures

1. A person authorized to conduct research involving rDNA technology or infectious diseases and agents shall submit a report to the IBC and the competent authority within twenty–four hours after discovery of the un–intended release or breach to confinement or containment.

2. For purposes of this SOP, the authorized person shall report any intrusive acts of civil disobedience, protests, vandalism, theft or loss of experimental genetic material or agents.

3. The BSO shall immediately prescribe emergency remedial measures to prevent further loss of regulated material, including where necessary, notification of authorities to recover lost materials.

4. The IBC shall ensure that a person authorized to conduct research follows emergency guidelines published in the National Containment Guidelines 2007 in cases of emergencies in containment research and other infectious/hazardous materials.

5. The IBC and BSO shall ensure that a person authorized to conduct research submits a record of corrective action in the relevant forms published in the field trial and containment guidelines.

26.0 Fees

1. An application to the IBC for laboratory testing, contained testing, preliminary confined field testing, advanced field testing and general release of genetically engineered organisms may be subject to a fee that shall be determined by the institution's policies.

2. The review fee is nonrefundable and shall be paid prior to submission of an application to the IBC.

3. For guidance purposes, UNCST proposes the following fees:

    a. Application for laboratory research and contained testing, Uganda Shillings five hundred thousand

    b. Application for preliminary confined field testing, Uganda Shillings one million five hundred thousand

    c. Application for advanced field testing, Uganda shillings two million five hundred thousand

    d. Application for general release, Uganda shillings three million five hundred thousand.

PART V: REPORTS, CAPACITY BUILDING, IBC ASSESSMENT AND AMENDMENT TO SOPS

27.0 Submission of Reports to the Competent Authority

1. The IBC shall prepare and submit a formal report of its activities to the Competent Authority every six months.
2. The reports shall be due on the 31st July for the preceding period of 1st January to 30th June and 31st of January every year for the preceding period of 1st July to 31st December.
3. The reports shall be prepared in the format in Schedule 1.
4. Reports to the competent authority may be submitted electronically.

28.0 Records

1. The IBC shall maintain a hard copy file and an electronic copy for each application securely at the IBC secretariat.
2. The application file shall contain a reference number, activity proposal document, reviewer comments, copies of approval letters and other correspondences, inspection reports, and correspondences from IBC members regarding specific applications and activities.
3. The application file shall be kept at the IBC secretariat for a period of at least three years after completion of the research activity.

29.0 Training of IBC Members

Each institution establishing an IBC shall ensure that new members are adequately trained on the roles and responsibilities of the IBC.

30.0 Performance Assessment of IBC

1. The responsible officer/appointing authority of the IBC shall ensure an annual independent assessment of the performance of the IBC
2. A report of the performance assessment shall be provided to the National Competent Authority.

SCHEDULES

Schedule 1: Semi-Annual Report Format

The semi-annual report of the IBC shall contain:

a. The membership and competence of the institutional biosafety committee.

b. Research approved by the institutional biosafety committee.

c. Activities of the institutional biosafety committee during the reporting period.

d. Biotechnology and biosafety capacity of the research institution including the human resources and infrastructure.

e. Training and capacity building activities for the members of the IBC.

Schedule 2: Confidentiality Agreement For IBC Members

As a member of the Institutional Biosafety Committee (IBC) constituted by the

_____ (Name of Organization) as per provisions of Uganda National Council for Science and Technology.

I hereby declare that I am aware of my obligations to respect confidentiality of applications, issues and other matters placed before the IBC and discussed thereupon, during my entire tenure of membership of IBC. I hereby solemnly agree and undertake to maintain the confidentially of the proposals and other related information made available to me for review, reference or discussion. I hereby further agree and undertake not to divulge any confidential or Intellectual Property (IP) or commercial business information (CBI) of the organization/institute acquired as a result of my review of such proposals and subsequent discussions arising there from.

That I shall also respect the confidential nature of the opinions expressed by other IBC members or experts during discussions in meetings or provided in written form and would not divulge the same to any person, press or media. That I also agree that I would avoid any conflict of interest such as financial or material interest and providing any consultancy, advice, services as an individual/scientist to any applicant except of the academic, scientific and intellectual nature.

Executed at: _____

Date: _____

Witnessed by: .....

This can be downloaded from the UNCST website

Schedule 3: Application for Registration of an Institutional Biosafety Committee

1. Name and address of the Organization: (Please provide contact details including postal address, phone, and e-mail) _____
2. Head of the Organization: (Please provide contact details including postal address, phone, fax and e-mail) _____
3. Contact Person/ (Proposed Member Secretary): (Please provide contact details including postal address, phone, fax and e-mail)

   _____
4. Proposed activities/projects to be undertaken:

   _____
5. Indicate the list of organisms/genetically engineered organisms/ biological materials to be used if known: _____
6. Category of biosafety level as per the National guidelines for Containment issued by UNCST: _____
7. Proposed facilities and infrastructure for rDNA activities/biological materials handling:
   a. Laboratory set up_____
   b. Greenhouse/net house (Details may include structure, size, size of the mesh etc.):

      _____
   c. Any other specialized facility: _____

10. Proposed composition of IBC(minimum of seven), their CVs, and responsibilities:

_____

Signature

Head of the Organization:…… Date: ……

UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

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