Biosafety and Ethical Requirements when conducting agricultural research in Uganda

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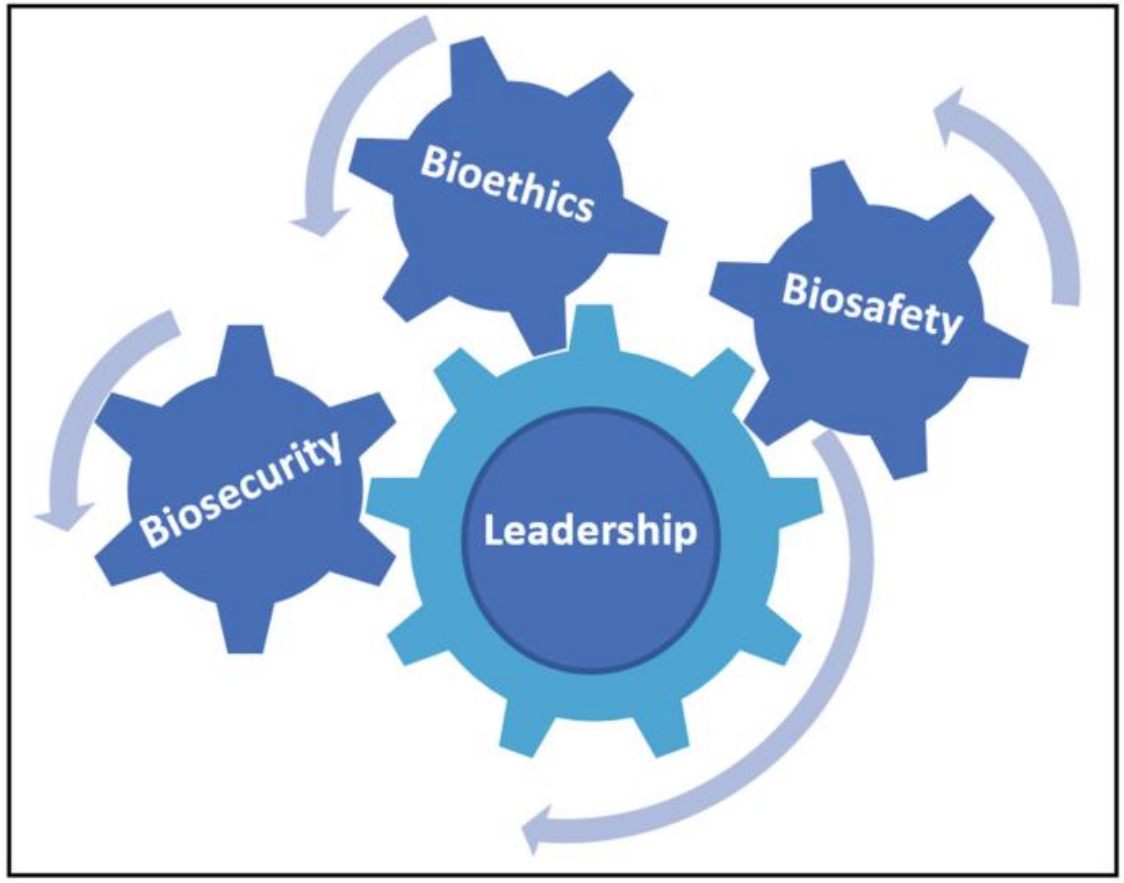
Bio-risk Management

- Bio-risk management is a coordinated effort to identify, assess, and manage risks associated with handling biological materials
- It is crucial for laboratories and facilities involved research, diagnostics, or handling potentially hazardous materials.
- Key Components:
  - Identification: Recognizing potential sources of harm
  - Assessment: Evaluating the likelihood and severity of potential risks
  - Control: Implementing measures to mitigate, reduce and monitor the risks



Key features of Bio-risk Management

- **Biosafety:** Protects personnel and public from unintentional exposure to biohazardous materials.
- **Biosecurity:** Prevents intentional unauthorized access, loss, theft, misuse of biohazardous materials.
- **Bioethics:** Ensure that research and practices involving biological agents are conducted responsibly and ethically.
- Leadership as a driver for the 3



Biological agents

- **Risk Group 1 (RG1) -** Agents that are not associated with disease in healthy adult humans.
- **Risk Group 2 (RG2) -** Agents that represent moderate risk to an individual but a low risk to the community.
- **Risk Group 3 (RG3) -** Agents that represent a high risk to the individual and a low to moderate risk to the community
- **Risk Group 4 (RG4) -** Agents (usually exotic) that represent a high risk to the individual and a high risk to the community.

Biohazard

Details available in NIH Guidelines, 2024
https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

Other Biohazards

Type	Description	Example
Human Blood & Blood Products	Bodily fluids, tissues that contain blood, serum, plasma, and other blood components in liquid or semi-liquid form.	HIV, Hepatitis B, Hepatitis C
Animal Waste	Any animal body part or the beddings of infected animals.	Anthrax, Hantavirus, Rabies
Human Bodily Matter	Direct contact with biological hazards such as human bodily matter in the workplace—blood, saliva, urine, and mucus.	Tuberculosis, Influenza, Common cold
Microbiological Waste	Usually found in laboratories, this waste may contain concentrated forms of infectious products, such as blood or bodily fluids that have infectious pathogens, specimen cultures, and viruses.	Ebola, SARS, MERS

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Other Biohazards continues…

Sharp Waste	Belonging to the larger group of infectious waste, this type of biological hazard pertains to syringes, sharp tools, and broken glass that are at risk of pathogenic cross-contamination and piercing through human skin protection.	Needlestick injuries, HIV, Hepatitis B
Molds & Yeasts	These are found in nature, needed for the breakdown of plant debris. Such microorganisms can enter a building directly or their spores can be carried in by the air. For some people, inhalation of the molds, fragments of the molds, or spores can lead to serious health problems or worsen certain health conditions.	Asthma, Allergies, Fungal infections
Organic Material	Workers may also be exposed to rubbish, waste water and sewerage, plant materials, and organic dust.	E. coli, Salmonella, Legionella
Airborne Pathogens	These are microorganisms that can be transmitted through the air, either by droplets or aerosols. They can cause respiratory infections or other diseases.	Influenza, Tuberculosis, Measles
Stinging Insects	These are insects that can inject venom or cause allergic reactions through their stings or bites.	Bees, Wasps, Mosquitoes

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Other Potentials Biohazards

- **Recombinant DNA products** have potential biohazards due to the manipulation of genetic material that may result in emergence of new pathogens, antibiotic and chemical resistance etc.
- **Probiotics** have some potential biohazards, including the possibility of infections, production of harmful substances, and gene transfer.
- **Biotoxins** including mycotoxins (by fungi), zootoxins (by animals), phytotoxins (by plants); they can contaminate food and feeds
- Use of other regulated biotechnology tools, components, and products



BIOSAFETY LEVEL



Low risk to personnel and the environment



Moderate risk to personnel and the environment



Serious disease for human, animal or plant (not spread by casual contact)



Very serious disease for human, animal or plant (often untreatable)

National Biotechnology and Biosafety Policy (2008) and the **2021 Institutional Biosafety Standard Operating Procedures (SOPs)** set forth by the *Uganda National Council for Science and Technology (UNCST)* require institutions handling GMOs and potentially hazardous biological materials to establish an Institutional Biosafety Committee.

- NARO IBC (since 2007)
- UVRI IBC
- Uganda Cancer Institute IBC

Consult UNCST for details on other IBCs

NARO IBC members since Aug 2024

1. Dr. Barbara M. Zawedde, Biosafety, NAROSEC, Chairperson
2. Dr. Henry Wagaba, Plant Biotechnology, NaCORI
3. Dr. Michael H. Otim, Entomology, NaCRRI
4. Dr. Susan D. Kerfua, Molecular Epidemiology and Virology, NaLIRRI
5. Dr. Papius D. Tibihika, Evolutionary Biology- Fisheries, NaFIRRI
6. Dr. Natabirwa Hedwig, Food Science/ Safety, NARL
7. Dr. Sarah Nanyiti, Molecular Biology, NaCRRI
8. Dr. Zziwa Emmanuel, Systems Ecology, FAO Uganda
9. Dr. Mugumya Firminus, Sociologist, Makerere University
10 Dr. Nantongo Judith, Molecular Biology – Forestry, NaFORRI, Secretary, Ex-Officio

Requirements for Scientists

Contained-use research – In closed facility

- Prior to commencing any contained research involving rDNA technology, RG2 and above agents, and other potential biohazards, scientists must obtain no-objection from IBC.
- Applications for contained use research should be submitted to the IBC secretariat in a format specified provided by UNCST.
- IBC will inspect the facility where the contained research is going to be conducted.
- IBC support letter should be submitted together with an application for research approval to UNCST , depending on the Risk Group of the biohazard.
- Project team should work closely with the institute Biological Safety Officer (BSO) to make sure that they complied with the **National Containment Guidelines**
- The BSO will periodically submit a Progress report to IBC

Examples of basic requirements for BSL-2 containment facilities

- Compliance with good laboratory practices:
  - **PPE:** Appropriate personal protective equipment, such as lab coats, gloves, and eye protection, must be worn.
  - **Safe work practices:** Strict adherence to procedures, labelling, proper handling of sharps and waste, record keeping & documentation is crucial.
  - **Regular decontamination** of surfaces and equipment is necessary.
  - **Restricted access:** Only authorized personnel are permitted in the facility with clear and visible signage as well as a log-in and out record.
  - **No eating, drinking, or food storage**
  - **Emergency contact details** must be placed in visible location
  - **Staff health insurance and periodic health monitoring** are necessary

Facility design and equipment

- **Physical barriers** with doors that close and lock
- **Handwashing sinks** must be readily available
- **Eye wash stations** must be accessible for immediate use.
- **Biological safety cabinet (BSC):** A Class II BSC is typically required for procedures that may generate aerosols or splashes.
- **Autoclave or other decontamination method** is essential for management of biohazardous waste
- Clearly labelled waste containers for sharps, biohazardous waste and other materials disposal
- Clearly labelled appropriate storage for hazardous materials

Confined field testing

Before initiating confined field testing of GMOs or other biohazards, approval must be obtained from UNCST.

Application forms for confined field experiments are available in a format published by UNCST

Applicants should first submit the application to the IBC for a no-objection before forwarding it to UNCST

IBC will support the applicant in application process and biosafety compliance before submission to UNCST

Submission to UNCST should be accompanied by the IBC recommendation

Project team must work closely with BSO to ensure compliance with the **Field Trials Guidelines** by UNCST

Examples of basic requirements for BSL-2 confinement facilities

- Physical barriers with clear signage
- Restricted access with log-in and out record
- Storage facility
- Accessible toilet
- PPE: Overalls, gumboots, gloves or hair covers where necessary
- Proper data management, record keeping and reporting
- Periodic training for personnel
- Contingency plan
- Communication plan

Ethical Considerations

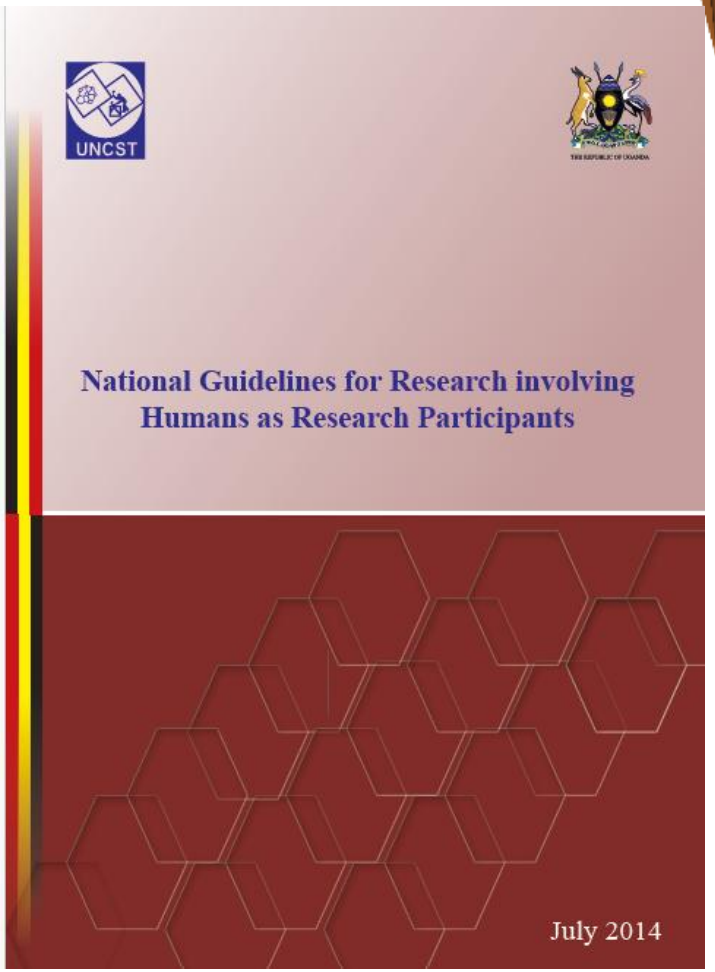


Some key Ethical considerations

- Bioethics review helps determine whether a research/project should proceed, and how to mitigate potential risks.
- Any research involving humans as subjects or participants must obtain **Ethical Approval** prior to conducting the research.
- **Informed consent:** It's pertinent to obtain informed consent (preferably in writing) from participants and respect their autonomy.
- **Confidentiality:** As much as possible, it is crucial to respect the privacy of the participants unless empirical consent is obtained.
- **Data sharing:** Decisions about whether and how to share research data should involve ethical considerations.

Ethical Approval

- Ethical Approval is given by an Accredited Research Ethics Committee (REC)
- Details about accredited RECs can be obtained from UNCST
- NARO has established a REC that is in the process of Accreditation
- Details on Ethical Approval process and other ethical consideration available in *National Guidelines for Research Involving Humans as Research Participants* (2014)



The NARO REC will organize a detailed presentation, once accredited

Take home message

Biosafety and Bioethics compliance is increasingly becoming a requirement by funders, and when you want to publish in several peer reviewed journals.

The role of IBC and REC is to support the project team to ensure compliance with the biosafety and ethical requirements, respectively

The Secretariat for both committees is in the Office of the Deputy Director General, Research Coordination
researchcoordination@naro.go.ug

Thank you!