INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) GUIDELINES

(Use of potentially biohazardous material in research)

SHAHEED BENAZIR BHUTTO UNIVERSITY

SHERINGAL UPPER DIR, KHYBER PAKHTUNKHWA, PAKISTAN

Contents

ACKNOWLEDGEMENTS

We are grateful to the Department of Biosafety, The Ministry of Natural Resources and Environment Malaysia for allowing us to use their guideline document, "Guidelines for Institutional Biosafety Committees" (ISBN No: 978-967-10117-0-6). We acknowledge that parts of these SOPs have been adapted from Khyber Medical University - Institutional Biosafety Committee (IBC), Peshawar, Pakistan, University of South Dakota Institutional Biosafety Committee guidelines, and Temple University Biosafety registration form.

All practices shall comply with the National Biosafety Rules 2005 and shall be reported to NIH or Ministry of NHSR&C as required.

Secretary,
Institutional Biosafety Committee
Shaheed Benazir Bhutto University Sheringal, Dir (U), Khyber Pakhtunkhwa, Pakistan.

1. INTRODUCTION

This document outlines detailed guidelines regarding the purpose, scope, roles, and responsibilities of the Institutional Biosafety Committee (IBC) at Shaheed Benazir Bhutto University (SBBU), Sheringal.

1.1 Purpose

The purpose of these Institutional Biosafety Committee (IBC) guidelines is to guide researchers, faculty members, students, and staff at SBBU who are involved in research or activities that may involve potentially biohazardous materials. The committee aims to promote laboratory practices that protect human health and the environment within the campus, its surroundings, and areas where research is conducted.

1.2 Scope

These guidelines define the roles, responsibilities, and functions of the SBBU-IBC. They also outline the procedures for the acquisition, use, storage, transfer, and disposal of potentially biohazardous materials. These guidelines apply to all Biological Sciences laboratories at both the main and sub-campuses of SBBU.

1.3 Definitions

The following definitions apply to this document and all matters relating to the SBBU IBC:

1.3.1 Hazards:

Materials that pose a risk to human life or the environment. This includes living modified organisms, recombinant DNA (rDNA) molecules, pathogens, potentially contaminated materials, hazardous chemicals and reagents, and physical or chemical toxic agents such as radiation or extreme temperatures.

1.3.2 LMO:

A *Living Modified Organism* is any living organism that contains a novel combination of genetic material acquired through modern biotechnology.

1.3.3 rDNA:

Recombinant DNA (rDNA) refers to molecules constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules capable of replicating within a living cell.

1.3.4 Pathogens:

Biological agents capable of causing disease.

1.3.5 Potentially Contaminated Material:

Physical materials (e.g., cloth, soil, wood, plastic) that may be contaminated with pathogens.

1.3.6 Hazardous Chemicals and Reagents:

Chemical substances that may pose hazards to humans or the environment due to their physical or chemical properties (e.g., acids, bases, solvents, DNA-damaging agents, corrosives, or substances at extreme temperatures).

1.3.7 Institutional Head:

The Institutional Head refers to the Vice Chancellor of Shaheed Benazir Bhutto University, Sheringal, Dir Upper, Khyber Pakhtunkhwa, Pakistan.

1.3.8 Institutional Biosafety Committee (IBC):

The IBC is an officially approved expert committee established at SBBU for a period of three years. It ensures that research, diagnostic, and clinical activities at SBBU and its affiliated institutions are conducted in a safe and compliant environment. The committee provides guidance in the event of safety breaches and recommends corrective actions. The scope of the committee may be expanded upon formal approval.

1.3.9 Biosafety Officer (BSO):

Appointed by the Vice Chancellor for a term of three years, the BSO is responsible for ensuring institutional compliance with SBBU IBC guidelines.

1.3.10 Principal Investigator (PI)/Supervisor:

The PI is responsible for conducting laboratory or field research at SBBU or its affiliated institutions. Any research involving biohazards, LMOs, rDNA, or pathogens must receive prior IBC approval. The PI is expected to follow all relevant institutional policies and national biosafety regulations.

1.3.11 Incident:

An incident refers to an unintended release, breach of containment, spill, or occupational exposure to potentially biohazardous material.

In case of noncompliance, the IBC will issue standard SOPs along with two written warnings spaced one month apart. If noncompliance continues or the follow-up report is unsatisfactory, the matter shall be referred to the Academic Council through the Office of the Vice Chancellor. Depending on the nature of the incident and the PI's response, the Academic Council may suspend, restrict, or terminate the research project.

2. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

2.1 IBC Responsibilities

The Institutional Biosafety Committee (IBC) at SBBU is established to ensure the safe conduct of laboratory practices that protect human health and the environment during research, teaching, clinical, and diagnostic activities within SBBU laboratories and affiliated institutions, including fieldwork. The IBC's responsibilities include, but are not limited to:

a. Guiding Principal Investigators (PIs) and supervisors on biosafety policies and issues related to hazardous material use in research, including the safety of laboratory personnel and other institutional members.
b. Recommending approval for research projects involving potentially biohazardous materials in accordance with IBC guidelines.
c. Evaluating and monitoring laboratory facilities, procedures, practices, staff training, and expertise in handling hazardous research.
d. Informing PIs of the IBC's decisions regarding the approval or rejection of applications involving potentially hazardous materials.
e. Determining and adjusting containment levels for research involving hazardous materials as necessary.
f. Developing and implementing emergency response plans for accidental spills or personnel exposure to potentially biohazardous materials.
g. Ensuring that application forms (Approval/Notification) are accurate and complete.
h. Recommending to the Academic Council the suspension of research proposals involving hazardous materials if non-compliance is identified or if the activity poses a threat to public or environmental health.

2.2 Other Related Responsibilities

a. Promoting the formation of Institutional Biosafety Committees in other institutions.
b. Advocating for national legislation to establish a national biosafety board.
c. Providing training for IBC members from other institutions.
d. Regularly reviewing and revising IBC policies and procedures to maintain effective biosafety standards.

2.3 Research Projects Requiring IBC Approval

IBC approval is mandatory for research activities that involve:

a. Use of human biological material (e.g., blood, sputum, CSF) in research where the potential risk is unknown.
b. Use of human biological material where the potential risk is known or expected.
c. Storage of potentially hazardous materials in shared-access areas.
d. Deliberate transfer of drug resistance traits to microorganisms.

e. Introduction of rDNA or rDNA-derived DNA/RNA into human participants (human gene transfer).
f. Creation of rDNA-containing genes for synthesizing toxins lethal to vertebrates at LD_{50} < 100 ng/kg body weight.
g. Use of Risk Group 2, 3, or 4 agents in host-vector systems.
h. Cloning DNA from Risk Group 2 or higher agents into non-pathogenic hosts.
i. Use of whole animals (immunocompetent or immunodeficient) where pathogens may replicate and escape containment.
j. Testing rDNA-modified viable microorganisms in animals.
k. Genetic modification of plants via rDNA technologies.
l. Formation of rDNA constructs containing two-thirds or more of a eukaryotic virus genome.
m. Use of archived human tissue with unknown risk potential.
n. Use of physical or chemical agents (e.g., radiation, corrosives, volatile substances) in research.
o. Use of agents posing heightened risk to specific researcher groups (e.g., pregnant individuals).

2.4 IBC Membership

The IBC shall be registered with a suitable national or international accreditation body, subject to approval by the competent authority. In the absence of a national biosafety board, affiliation shall be sought through an internationally recognized accrediting organization.

2.5 IBC Composition

The Vice Chancellor of SBBU appoints IBC members and should represent the institution while reflecting a range of relevant expertise. Community representatives may also be included. The members must demonstrate experience in biosafety-related research and the capacity to assess risks to human, animal, and environmental health.

The minimum composition of the IBC should include:

i. Chairperson
ii. Biosafety Officer (BSO)
iii. Secretary
iv. Research experts, including:
    a. A nominee of the Chairperson of Life Sciences
    b. One expert each from the Life Sciences and Chemical Sciences departments
    c. Director of ASRB
v. Director of ORIC
vi. Community representatives (e.g., elected officials, judiciary, educators)
vii. Medical Officer

In addressing institutional biosafety matters, the SBBU IBC should ideally consult with national or international accreditation bodies regarding policies, applicable laws, and standards. In their absence, guidance shall be sought from the SBBU Syndicate.

2.6 IBC Chair

2.6.1 Appointment of IBC Chair

The Vice Chancellor may nominate the Chair of the SBBU Institutional Biosafety Committee (IBC) for a period of three years, on a rotational basis among senior faculty members. The Chair must be a senior faculty member from the life or chemical sciences with expertise in research and development (R&D) activities. They should represent the institution and possess substantial knowledge and experience in scientific research involving potentially hazardous materials.

2.6.2 Responsibilities of the IBC Chair

The Chair is responsible for presiding over IBC meetings and serving as one of two points of contact (alongside the BSO) for regulatory agencies. The Chair also acts as the liaison between SBBU, the community, and the IBC. In the Chair's absence, an Acting Chair—preferably the Secretary—should be designated.

2.7 Biosafety Officer (BSO)

2.7.1 Appointment of BSO

The BSO shall be appointed by the Head of the organization for a term of three years. The BSO must be a faculty member at SBBU, experienced in R&D in a relevant field, preferably biosafety and biosecurity. Additional compensation will be admissible to both the IBC Chair and the BSO, according to university regulations.

2.7.2 Responsibilities of BSO

The BSO shall oversee and streamline all R&D activities at SBBU under the prescribed rules and guidelines. They will provide guidance to researchers to ensure proper biosafety practices across the institution.

2.8 Secretary

2.8.1 Appointment of Secretary

The Secretary shall be appointed by the Vice Chancellor upon the recommendation of the IBC Chair. The Secretary must be a faculty member at SBBU and will also serve as a member of the IBC.

2.8.2 Responsibilities of the Secretary

The Secretary is responsible for the general administration of the IBC, coordination with relevant authorities, training management, record-keeping of incidents, and maintenance of financial records.

2.9 IBC Members

IBC members are appointed by the Vice Chancellor of SBBU for a term of three years. They may be reappointed based on satisfactory performance. Members are tasked with ensuring that all research and activities involving potentially hazardous materials are thoroughly reviewed and comply with biosafety regulations. Membership is reviewed annually by the IBC Chair and subject to endorsement by the Vice Chancellor.

2.10 Changes in IBC Membership

Members may be removed or replaced by the Vice Chancellor upon a justified recommendation from the IBC Chair.

2.10.1 Use of Consultants

The IBC may consult qualified experts (local or international) as needed. These consultants may include internal staff, consumers, government regulators, environmental groups, stakeholders, or representatives from the Department of Health, KP. However, consultants will not have voting rights.

2.11 IBC Meetings

2.11.1 Regular Meetings

The IBC shall convene before each SBBU Ethics Committee meeting or whenever necessary to review projects.

2.11.2 Emergency Meetings

The Chair may call an emergency meeting to address urgent issues such as non-compliance or serious incidents involving hazardous materials in SBBU laboratories.

2.11.3 Meeting Materials

All members should receive soft copies of relevant materials ahead of each meeting. The BSO is responsible for distributing the agenda and associated documents.

2.11.4 Quorum

A quorum requires the presence of at least 50% of the IBC membership, excluding members with a conflict of interest. Approval or disapproval of non-exempt projects must be determined by a majority vote of eligible, present members. If quorum is lost during the meeting, it must be adjourned until quorum is re-established or a new meeting is convened.

Conflict of Interest: A member must recuse themselves if they are the PI, a supervisor of the student involved, from the same department, a blood relative or spouse of the PI or student, a neighbor of the student, or have any business relationship with them.

2.11.5 Attendance

Attendance at IBC meetings is mandatory. Members unable to attend must inform the IBC in writing beforehand. The Chair has the authority to seek an explanation for absences. Members who miss two consecutive meetings, three in a calendar year, or fail to contribute meaningfully to project reviews may be removed at the Chair's discretion.

2.11.6 Minutes of Meetings

Meeting minutes must include:

i. Attendance of members and guests (if applicable)
ii. Status of the IBC's review of all applications and notifications
iii. Actions taken and any modifications required for project approval
iv. Observations and action plans following lab inspections; or, for off-site research, a note confirming biosafety protocol adequacy
v. Records of members recused due to conflict of interest
vi. Justifications for any project disapprovals involving hazardous materials

Each project review should be thoroughly documented in the minutes, including rationale behind IBC decisions.

2.12 IBC Records

2.12.1 Retention

The IBC shall retain the following records for a minimum of five years:

a. Confirmed and duly signed IBC meeting minutes, including member attendance and vote counts.
b. IBC-approved projects and related documentation, especially if the project has not been reviewed by the funding agency and no observations have been received.
c. Annual reports.
d. A register of IBC members.
e. The status of all applications and notifications submitted to the SBBU Syndicate.

Relevant information may also be shared via a dedicated section on the SBBU website. All official IBC records shall be maintained by the IBC Secretary at SBBU.

2.13 Authority of the IBC

2.13.1 Scope of Authority

The SBBU IBC holds authority to recommend modifications to all research proposals involving hazardous materials, including LMOs, GMOs, and pathogens.

The committee operates independently and makes its own decisions regarding protocol approval or disapproval based solely on biosafety compliance with applicable regulations, guidelines, and institutional policies. The IBC retains jurisdiction over all research involving regulated or potentially hazardous biological materials, thus offering protection beyond regulatory minimums.

2.13.2 Review and Progress Reports

All approved research remains subject to continuous IBC oversight. Each protocol must undergo an annual review to confirm there have been no substantive changes. Resubmission is required every three years or as otherwise specified by the IBC.

2.13.3 Approval of Amendments

Any modification to an approved protocol must be reviewed and approved by the IBC prior to implementation, using the official Amendment Form. Approval of an amendment is valid only for the remainder of the original protocol's approval period. ***Example: A protocol approved on January 1, 2022, and set to expire on December 31, 2022, would still expire on that date even if an amendment is approved mid-year.***

2.13.4 Suspension or Termination of Study

The IBC may recommend suspension or termination of research to the Academic Council if activities deviate from approved protocols or lead to unexpected serious consequences. Such recommendations must include justification and be reported promptly to the PI and the respective unit head. Concerns about noncompliance may be raised by anyone, and the IBC is responsible for recommending appropriate actions.

2.14 Reporting of Incidents and Spills

2.14.1 Internal Reporting

All research incidents must be reported within 24 hours by the PI or laboratory personnel through the BSO using the Incident Reporting Form (SBBU/IBC/Registration/v1).

Reportable incidents include:

- Noncompliance with biosafety protocols
- Research-related accidents or illnesses
- Exposure to uncontained hazardous material
- Equipment failure leading to exposure in BSL-2, BSL-3, or BSL-4 labs
- Containment breaches at affiliated or field locations

2.14.2 External Reporting

The PI is responsible for submitting the Incident Reporting Form (SBBU/IBC/Incidence/v1) to the appropriate external body within 48 hours. The BSO must review the form prior to submission, which is processed through the Office of the Registrar. These forms must also be submitted to the Chair of

the IBC via the BSO.

2.15 Conflict of Interest

IBC members with a conflict of interest may not participate in reviews or voting on related projects. Conflicts may arise if the member is:

- The PI or co-investigator of the project
- Has a family member involved
- Holds a financial interest in the outcome

Such conflicts must be recorded in meeting minutes. However, affected members may be invited to provide clarifications or additional context strictly in their capacity as PIs—not as voting members.

2.16 Responsibilities for Compliance

2.16.1 Institutional Heads (VC/Dean/Director/Chairpersons/HoDs)

Institutional heads provide leadership in implementing and enforcing biosafety policies. Responsibilities include:

a. Prioritizing biosafety in SBBU research laboratories
b. Supporting IBC operations
c. Maintaining awareness of biosafety regulations
d. Providing leadership in laboratory management
e. Ensuring personnel receive biosafety training before starting research
f. Supporting IBC decisions and public trust in biosafety
g. Confirming that research facilities are appropriate for the proposed work

2.16.2 Biological Safety Officer (BSO)

The BSO shall:

a. Deliver biosafety induction and training
b. Conduct regular laboratory inspections
c. Report significant problems, noncompliance, and research-related incidents to the IBC
d. Assist PIs in developing emergency response protocols
e. Serve as liaison with external agencies and submit annual reports to the SBBU Syndicate
f. Serve as a voting IBC member

2.16.3 Principal Investigator (PI)

PIs are responsible for ensuring their research complies with biosafety guidelines and legal obligations. They are accountable to the IBC.

2.16.4 Laboratory Personnel (Technicians, Technologists, Students, Postdocs)

Laboratory personnel must:

a. Follow safety procedures, good lab practices, and required containment levels
b. Notify the PI or BSO of any pre-existing health conditions or symptoms arising from lab work
c. Comply with biosafety protocols as instructed
d. Promptly report incidents, spills, or procedural issues
e. Report any biosafety noncompliance to the PI, BSO, or IBC

2.17 Compliance Oversight and Corrective Action

In cases of noncompliance, the IBC may take any of the following actions:

a. Suspend use of hazardous materials
b. Withdraw approval for material use
c. Confiscate hazardous materials
d. Order the destruction of hazardous materials
e. Take other necessary actions to protect individuals and the organization, including halting the research

3. PRINCIPAL INVESTIGATOR'S SPECIFIC RESPONSIBILITIES

3.1 Risk Assessment and Selection of Appropriate Biosafety Level

Principal Investigators (PIs) seeking approval for projects involving potentially biohazardous materials must conduct an initial risk assessment focused on preventing laboratory-associated infections or the accidental release of hazardous agents into the environment. This assessment should consider the organism's Risk Group along with other risk factors to determine the necessary biosafety and physical containment level (BSL-1 to BSL-4).

The Institutional Biosafety Committee (IBC) will make the final determination on the appropriate level of risk and containment. The Biosafety Officer (BSO) may provide recommendations based on established biosafety guidelines.

PIs are responsible for the following:

a. Submitting a complete IBC Registration Application Form before initiating any work involving potentially biohazardous materials.
b. Ensuring strict compliance with biological safety practices in the laboratory and that all personnel are properly trained in the handling of potentially hazardous agents.
c. Implementing a tailored biosafety program for their research projects.
d. Performing ongoing risk assessments and planning all lab activities accordingly.
e. Establishing and maintaining appropriate biosafety containment levels in collaboration with the BSO.

Once IBC approval has been granted, the PI must:

a. Avoid making changes that affect the BSL, Risk Group, or research location without consulting the IBC.
b. Report any issues related to the implementation of applicable laws, guidelines, or regulations.
c. Promptly notify the IBC of any significant accidents or incidents involving illness, environmental exposure, or release of organisms under study.

3.1.1 Prior to Conducting Research Involving Potentially Hazardous Materials

Before starting lab work, the PI must:

a. Review relevant biosafety guidelines and regulations.
b. Develop Standard Operating Procedures (SOPs) and/or a biosafety manual tailored to the project.
c. Inform lab personnel of specific hazards and ensure they read and follow safety procedures.
d. Restrict laboratory access to authorized personnel trained in biosafety and, where applicable, immunized.
e. Train personnel on hazards, exposure prevention, and incident reporting procedures.
f. Teach aseptic techniques and biological characteristics of the organisms involved.
g. Conduct comprehensive training in safe practices and emergency procedures.
h. Create and maintain an emergency response plan aligned with the laboratory's biosafety level.

3.1.2 Conducting Research Involving LMOs/rDNA Materials

When working with LMOs or recombinant DNA materials, the PI must:

a. Restrict laboratory access during active experiments.
b. Provide and enforce the use of appropriate personal protective equipment (PPE).
c. Monitor laboratory staff for safe work practices.
d. Follow the emergency response protocols approved by the IBC.
e. Correct unsafe conditions that may result in unintended release.
f. Ensure the integrity of biosafety containment systems.
g. Secure all LMOs/rDNA materials at all times.
h. Display an emergency response plan prominently in the laboratory.

3.1.3 Conducting Preclinical Research Involving Animals

In research using animals (e.g., rabbits, mice, rats, dogs, cats, goats, guinea pigs), the PI must:

a. Enforce stringent infection control practices.
b. Supervise staff to ensure biosafety procedures are followed.
c. Educate personnel on zoonotic diseases and laboratory precautions.
d. Maintain biosafety protocols in the animal facility.
e. Ensure an emergency response plan is posted in relevant areas.

3.1.4 Conducting Diagnostic or Clinical Research Using Human Samples

For studies involving human biological materials (e.g., clinical trials), the PI must:

a. Practice strict infection control protocols.
b. Supervise adherence to biosafety standards among all research personnel.
c. Educate staff on zoonosis and safe handling of clinical specimens.
d. Monitor biosafety practices in all affiliated laboratory spaces.
e. Maintain and display a clear emergency response plan for the research team.

3.1.5 Performing Research work on Biohazardous Chemicals

For studies involving biohazardous chemicals, the PI must follow the following guidlines

a. **Risk Assessment:** Evaluate chemical hazards and determine appropriate biosafety level (BSL).
b. **Laboratory Setup:** Use fume hoods, proper ventilation, and chemical-resistant surfaces.
c. **PPE:** Ensure lab personnel wear appropriate protective gear (gloves, goggles, lab coats, etc.).
d. **Safe Handling:** Label and store chemicals properly; restrict lab access to trained personnel only.
e. **Training & SOPs:** Provide safety training and maintain clear standard operating procedures.
f. **Waste Disposal:** Follow safe and compliant disposal practices; segregate chemical waste.
g. **Emergency Response:** Maintain spill kits, emergency plans, and ensure all incidents are promptly reported.

4. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) REVIEW

4.1 Review of Potentially Biohazardous Material-Related Activity

For contained-use activities, the Principal Investigator (PI) may begin research upon receiving acknowledgment of receipt of the notification from the IBC.

In reviewing proposed research involving potentially biohazardous materials, the IBC shall adhere to the institutional Biosafety Guidelines and established IBC policies. The review process should specifically examine:

a. Characteristics of the agent (e.g., virulence, pathogenicity, environmental stability)
b. Animal models used (e.g., immunodeficient, genetically modified animals)
c. Nature of biological samples (e.g., from healthy individuals or confirmed contagious cases)
d. Type and extent of laboratory manipulations
e. Origin of the inserted DNA (e.g., source species)
f. Nature of the inserted DNA (e.g., structural gene, oncogene)
g. Hosts and vectors to be used
h. Plans to express foreign genes and the proteins to be produced
i. Qualifications and experience of project personnel
j. Biosafety training history of the involved personnel

k. Containment conditions, including risk assessment, risk management measures, and emergency preparedness plans

The IBC may also assess the facilities, procedures, biosafety practices, and competencies of involved personnel. It may require regular data submission and adverse event reporting to monitor ongoing research.

4.2 Exemptions

The IBC may grant exemptions for certain types of research activities. Such exempt work must be conducted under standard microbiological practices with appropriate Biosafety Level (BSL) conditions. All exempted personnel must be adequately trained.

PIs who believe their work qualifies for exemption must still notify the IBC. An ad hoc subcommittee will determine exemption status. Projects involving qualitative research, epidemiological analysis, or interview-based studies may be considered exempt from IBC review.

4.3 Notice of IBC Action

The IBC Chair shall issue a formal written notification of the committee's decision to the PI.

4.4 Approval Period

IBC approval for projects involving potentially biohazardous materials is valid for two years or a longer period as deemed appropriate by the IBC. All approvals are subject to annual review. The first review must occur within 12 months of the initial approval date. Subsequent reviews will occur annually unless a shorter interval is specified by the IBC.

4.5 Review of Incidents and Personnel Exposure

Upon receiving an incident report through the Incident Reporting Form (SBBU/IBC/Incidence_v1), the IBC shall convene to review the information provided. Additional information may be requested to complete the assessment. The outcome, including any discussions and actions taken, shall be documented in the IBC meeting minutes. The SBBU Syndicate may request a detailed report if necessary.

4.6 Modifications to Approved Projects

No significant changes to IBC-approved projects may be implemented without prior IBC review and approval. This includes modifications to:

- Potentially biohazardous materials used
- Laboratory procedures
- Project personnel (e.g., adding new staff)
- Laboratory location

Such changes may affect the project's Risk Group or BSL classification. Updated application forms must be submitted to the IBC through the BSO for approval before changes can take effect.

5. TRAINING

5.1 Mandatory Training for IBC Members

All IBC members must complete initial biosafety training, followed by periodic refresher sessions.

5.2 Training of the BSO

The BSO is required to attend institutional biosafety training as part of their duties. It is the BSO's responsibility to maintain proper records of this training.

5.3 Training of Laboratory Personnel

All personnel engaged in research involving potentially biohazardous materials must undergo general biosafety training. This training may be conducted internally, with support and oversight from the National Biosafety Body (NBB).

Researchers must provide the IBC with proof of training or demonstrate equivalent experience as recognized by the IBC. Training should cover good laboratory practices, incident response, and the reporting of accidents or violations.

Personnel working in BSL-3 facilities must undergo specialized training in BSL-3 safety procedures before participating in any work.

6. EMERGENCY RESPONSE PLAN

When submitting a notification or request for approval of activities involving modern biotechnology, the PI must also submit a project-specific Emergency Response Plan. This plan should be based on a standard IBC-approved template and tailored to reflect the specific risk group and biosafety level (BSL) of the proposed activity.

The IBC is responsible for finalizing and formally approving the plan during a convened meeting. The BSO may provide support by developing a template for emergency response plans for BSL-2 and BSL-3 research.

All Emergency Response Plans must:

- Be tailored to the PI's laboratory and experimental setup
- Be based on approved protocols
- Be formally adopted by the IBC
- Comply with National Biosafety policies and institutional requirements

These plans will be periodically reviewed and updated in light of new information, either from internal findings or changes in regulatory guidance and international best practices.

7. LABORATORY INSPECTIONS AND BIOSAFETY MANUALS

7.1 Laboratory Inspections

The IBC shall conduct inspections of laboratories involved in research using hazardous materials, utilizing standardized checklists. Any identified issues must be reported to the Principal Investigator (PI) for corrective action and, if necessary, to higher authorities within the organization. All inspection reports should be securely filed by the IBC.

Authorized personnel, including IBC members and representatives designated by the National Biosafety Body (NBB), shall have access to laboratories registered for activities involving LMOs/rDNA materials during routine inspections.

7.2 Biosafety Manual

The IBC will review biosafety protocols during laboratory inspections. Each laboratory must maintain a readily accessible biosafety manual that includes all relevant safety procedures and protocols.

8. ACTIVITIES REQUIRING ADDITIONAL PERMITS

Certain biological materials and research activities require special permits (e.g., import permits). It is the responsibility of the PI to ensure that all required permits are obtained prior to commencing such activities.

9. SECURITY OF LMO/rDNA MATERIALS

Strict control and secure storage of biological materials are essential. The PI and associated personnel must manage these materials responsibly and are accountable for their security. Access should be restricted to authorized personnel only.

Depending on the Risk Group of the biological agent, the PI must conduct a vulnerability assessment and develop a security plan, which may include:

a. Additional locks for laboratory doors, freezers, or storage units
b. Chain-of-custody documentation for materials
c. Inventories of biological agents
d. Access logs for restricted areas
e. A comprehensive written security plan, including:

- Procedures for agent access
- Procedures for maintenance and cleaning
- Restrictions for unauthorized individuals
- Measures for reporting lost keys, passwords, or credentials
- Protocols for preventing theft or unauthorized removal

10. DISPOSAL

All potentially hazardous biological materials and LMO/rDNA materials are considered ***regulated waste*** and must be disposed of in accordance with applicable national regulations (e.g., Environmental Quality Act 1974, Environmental Quality (Scheduled Wastes) Regulations 1989, Biosafety Act 2007) and related biosafety guidelines.

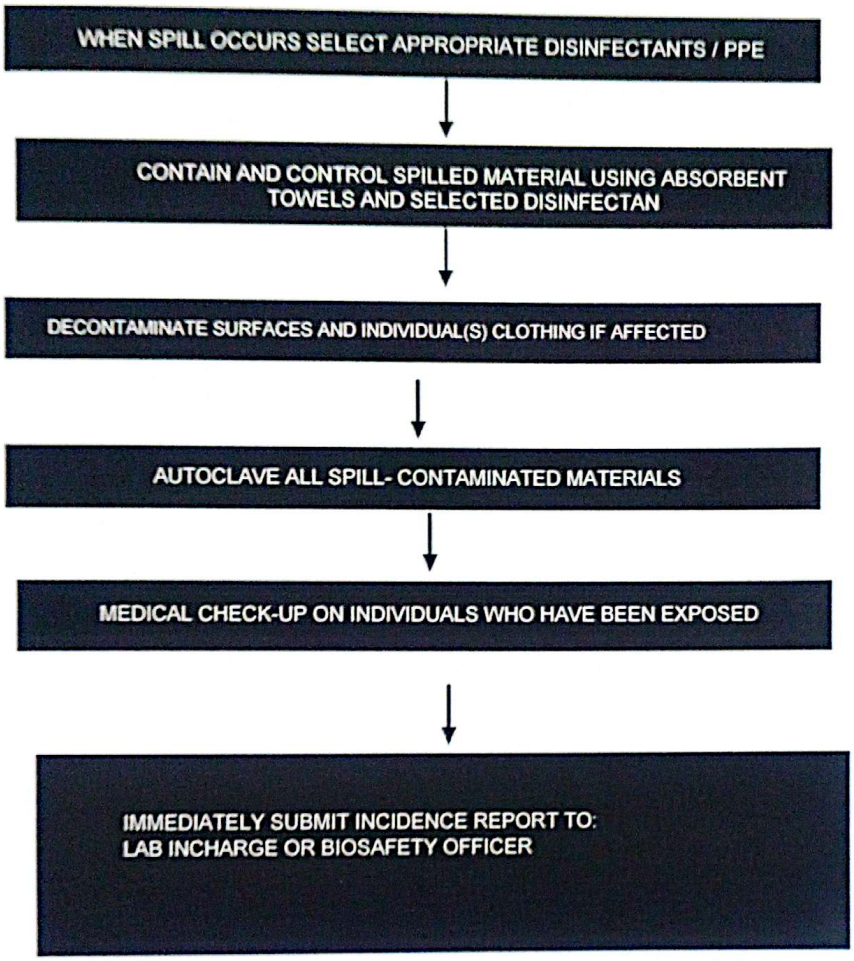
11. PACKAGING AND TRANSPORT OF BIOHAZARDOUS MATERIAL

All regulated LMO/rDNA materials must be packaged and transported in compliance with national and international regulations and relevant biosafety guidelines to ensure containment and safety during transit.

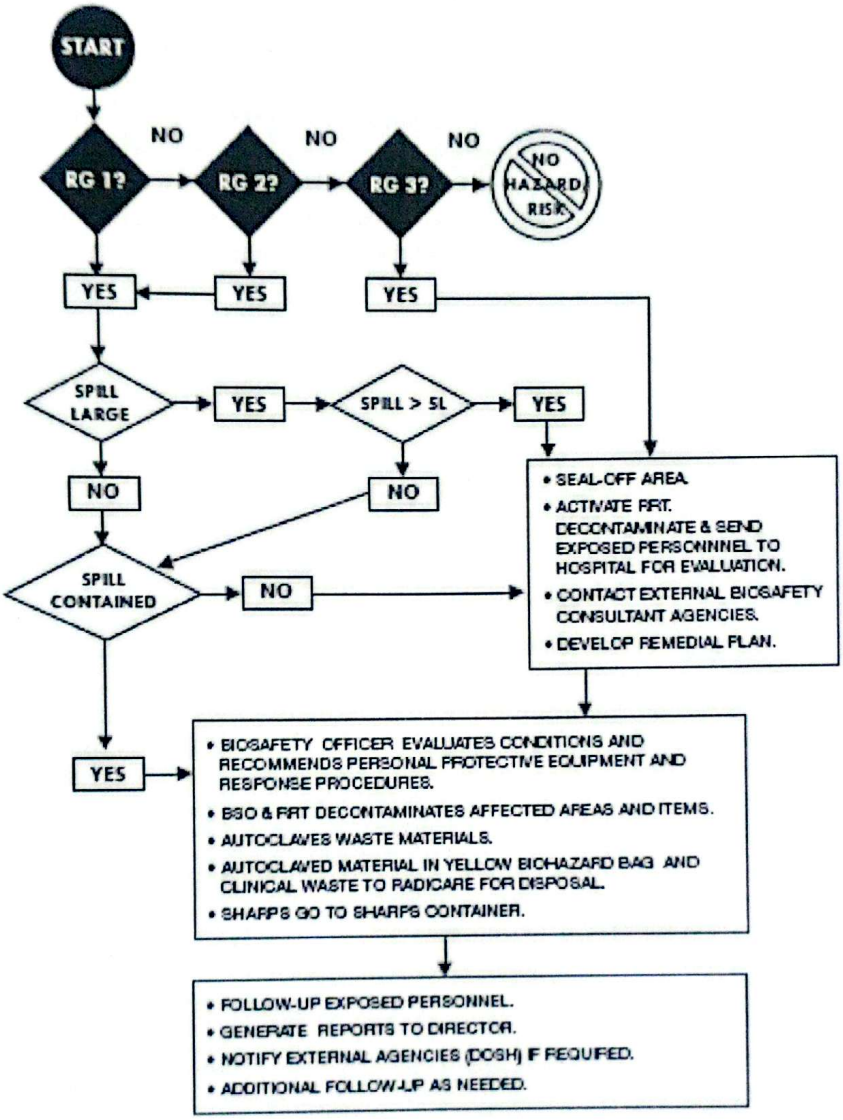
13. FLOW CHARTS

13.1 Spill Responses and Laboratory

PERSONNEL PROCEDURES



13.2 Spill response in containment facility and evaluation of hazards by pathogen type



14. CONFIDENTIALITY AND PRIVACY

All committee members are responsible for maintaining the **confidentiality, privacy, ethical standards, copyright, and intellectual property rights** of the researcher and the institution.

In cases where such matters arise, the issue shall be referred to the Advanced Studies and Research Board (ASRB) for necessary approval. If a penalty or disciplinary action is warranted, a recommendation shall be made to the university syndicate for appropriate action.

Note: An officer within the Office of Research, Innovation and Commercialization (ORIC) shall be designated to manage intellectual property rights (IPR). The IPR officer must hold an LLB degree and possess expertise in the relevant domain.

15. TRAINING

Training is mandatory for all supervisors and their students conducting research involving hazardous materials, microbes, or laboratory animals.

Students must obtain a certificate of training in biosafety and bioethics prior to submitting their research synopsis to the ASRB for approval.

16. FORMS

16.1 Guidelines for Assessment of Biosafety Registration Application

The designated form *SBBU/IBC/Assessment_form_v1* shall be used to assess proposals involving potentially biohazardous materials. This form guides the IBC in evaluating the project's biosafety elements. A completed assessment, along with the corresponding application, must be submitted to the Ethical Committee for further processing.

16.1.1 Instructions for Completing the Form

- The IBC is required to submit a **typed and signed** assessment form to the SBBU Ethical Committee, attached to the related application form.
- A **copy of the completed assessment** must be retained for internal records and future reference.
- The form must bear the signature of either the IBC Chair or the BSO.
- Each response should include a clear and concise justification for the committee's position on the specified experimental parameters.

17. *RESOLUTION OF AMBIGUITIES*

1. *Any query regarding the interpretation of these guidelines shall be referred to the Vice Chancellor, whose decision shall be final.*

b. Disputes related to the implementation of the guidelines shall be resolved by the Vice Chancellor in consultation with the Academic Council, ensuring alignment with existing policies.
c. If a guideline requires action but lacks clarity regarding authority, timeline, or procedures, the Vice Chancellor shall determine these specifics in consultation with the Academic Council.

IBC REGISTRATION ASSESSMENT FORM

(SBBU/IBC/Assessment_form_v1)

Section	Information is complete and biosafety measures are addressed appropriately		Comments
1. Applicant information	Yes ☐	No ☐	
2. Research project	Yes ☐	No ☐	
3. Safety and protection	Yes ☐	No ☐	
4. Shipping and transport	Yes ☐	No ☐	
5. Training	Yes ☐	No ☐	
6. Occupational health requirement	Yes ☐	No ☐	
7. Assurance	Yes ☐	No ☐	
8. Signatures	Yes ☐	No ☐	
9. Amendments:			

Decision	Approved ☐	Approved with amendments ☐	Not approved ☐

Signature and stamp:
Name : _____

Date : _____

IBC registration form (SBBU/IBC/Registration_v1)

Incidence report form (SBBU/IBC/Incidence_report_v1)

INSTITUTIONAL BIOSAFETY COMMITTEE INCIDENT

REPORTING FORM (SBBU/IBC/Incidence_report_v1)

To be completed by the Principal Investigator/Laboratory personnel involved in the incident. This form is to be used by the BSO to report all incidents which did not result in injury.
Please complete and submit to the IBC within 24 hours

Reference No.: _____

ORGANISATION :	LABORATORY:	DATE & TIME OF
		INCIDENT:
FACULTY/DEPARTMENT:		

PI/ Laboratory Personnel Information	
PI/ Laboratory Personnel's Name	
Telephone:	
Incidence time (00:00 am/pm)	
Incidence date (dd/mm/yyyy)	

IDENTIFY THE DIRECT AND CONTRIBUTING CAUSES OF THE INCIDENT

1. Describe the incident:

2. Probable cause or causes of an incident (tick 1 or more boxes for appropriate answers).

☐ Fault of equipment	☐ Inadequate workspace
☐ Equipment unavailable	☐ Lack of training
☐ Poor storage	☐ Poor access
☐ Weather	☐ Unknown
☐ Assistance unavailable	☐ Assistance unavailable
☐ Electrical fault	☐ Electrical fault
☐ Carelessness	☐ Incorrect method/work practices
☐ Terrain	☐ None of the above*

*State cause if not listed above:

3. Did the incident contribute to any release or dispersal of potentially biohazardous materials outside the

containment/ field experiment area? If "Yes", please state the emergency response plan taken.
4. What act(s) by the staff and/or others contributed to the incident (e.g. wrong tool or equipment, improper position or placement, work rule violation, failure to follow instructions, etc.)?
5. What personal factors contributed to the incident (e.g. improper attitude, fatigue, inattention, substance abuse, failing to wear PPE, etc.)?
6. What corrective actions have been or will be taken to prevent a recurrence of this type of incident (e.g. repair / modify/replace equipment, counseling, training, policies, procedures, etc.)?
7. Who is responsible for implementing corrective actions?

Signature of Principal Investigator Name:

Date:

Signature of Biosafety Officer Name:

Date:

Signature of IBC Chair

Project extension/ notice of termination (SBBU/IBC/extension_termination_v1)

INSTITUTIONAL BIOSAFETY COMMITTEE PROJECT EXTENTION/ NOTICE OF TERMINATION

(SBBU/IBC/Extension_termination_v1)

To be completed by the Principal Investigator. The completed form should be submitted to the NBB.

Project Extension: If you wish to continue your modern biotechnology activities you must complete this form and submit it to the IBC at least one month before the end of the current approval period of the project. Termination: If at any time you wish to terminate your modern biotechnology activities, complete this form and submit it to the IBC.

1. Identification		
Name of Principal Investigator		
E-mail:		
Faculty/Department		
Tel		
IBC Reference No.		
Project Title		
Request for	Extension ☐	Termination ☐

2. General information		
Will the PI change?	Yes ☐	No ☐
Will the Risk Group (RG) change?	Yes ☐	No ☐
Will the Biosafety Level (BSL) change?	Yes ☐	No ☐
Will the type/amount of hazardous materials change?	Yes ☐	No ☐
If the answer to any of the above questions is yes, you must submit 'IBC registration application		

form (SBBU/IBC/Registration_v1)

3. Certification

I certify that the above information accurately describes the current status of the modern biotechnology activities that were previously approved by the IBC. I understand that I must resubmit a new 'IBC registration application form (SBBU/IBC/Registration_v1)

Signature of Principal Investigator Name:

Date:

Signature of Biosafety Officer Name:

Date:

Signature of IBC Chair