



Institutional Biosafety Committee

Khyber Medical University

# **Rules and regulations for Khyber Medical University – Institutional Biosafety Committee (KMU-IBC)**

Use of potentially biohazardous material in research and diagnostics

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# **1 Introduction**

This document provides detailed guidelines on the purpose, scope, and roles and responsibilities of KMU-IBC.

## **1.1 Purpose**

The purpose of this Institutional Biosafety Committee (IBC) guidelines is to provide guidance to Khyber Medical University (KMU) researchers, faculty members, students and staff members that conduct research or activities involving potentially biohazardous material. The aim of the committee is to encourage laboratory practices that safeguard human health and the environment. Non-compliance to KMU-IBC guidelines may result in:

Suspension, limitation or termination of the noncompliant research project along with other disciplinary actions as recommended to KMU syndicate by KMU IBC against the PI/Supervisor.

## **1.2 Scope**

The KMU-IBC shall ensure that research, diagnostic and clinical work in KMU and its constituents and affiliated institutes is performed in a safe, risk-free environment. It provides guidance in cases of breach of safety and advises corrective action when such happens. The scope of KMU IBC may be extended as deemed necessary after formal approval from the aforementioned bodies.

## **1.3 Definitions**

For the purpose of this document and for matters pertaining to the KMU IBC, the definitions below will apply.

### **1.3.1 Hazards**

All materials that can cause risk to human life and the environment. These include Living modified organisms, recombinant DNA molecules (rDNA), pathogens, potentially contaminated material and hazardous chemicals and reagents, physical and chemical toxic agents such as radiation and heat.

### **1.3.2 LMO**

A Living Modified Organism (LMO) is any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology

### **1.3.3 rDNA**

A recombinant DNA molecule (rDNA) is defined as either: Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or

### **1.3.4 Pathogens**

A biological agent that can cause disease.

### **1.3.5 Potentially Contaminated material**

A physical agent (eg. cloth, soil, wood, plastic) that might be contaminated with pathogens.

### **1.3.6 Hazardous chemical and reagents**

All chemical reagents that may be hazardous to human or environment based on their chemical or physical properties (eg. acids, bases, solvents, DNA damaging agents, corrosives, extremely hot or cold chemicals)

### **1.3.7 Vice Chancellor**

The Vice Chancellor (VC) refers to the Vice Chancellor of the Khyber Medical University.

### **1.3.8 KMU-IBC**

The KMU Institutional Biosafety Committee (KMU-IBC) is a formal expert committee of KMU with approval from Academic Council, Syndicate and Senate.

### **1.3.9 BSO**

The Biosafety Officer (BSO) is the designated officer who assists in assuring compliance to the guidelines of the KMU IBC.

### **1.3.10 PI /Supervisor**

The Principal Investigator (PI) involved in conducting research in (laboratories or field work) KMU or its constituent/affiliated institutes. The PI is accountable to the IBC and must comply with the appropriate research guidelines and all applicable laws and guidelines related to biosafety. In case of a student research project, the term ‘supervisor’ and in case of an individual research project the term ‘PI’ shall be used.

### **1.3.11 RRT**

The Rapid Response Team (RRT), a subcommittee of the KMU IBC, is appointed by the chairman of KMU IBC and is composed of the BSO, IBC Chair, and other relevant members. The purpose of the RRT is to review each incident that involves potentially biohazardous material, within 24 hours of occurrence and to immediately engage the different components of the KMU including the IBC. This committee will also respond in case of a reported incidence of public health outbreak, emergency, and urgent issues pertaining to biosecurity and bioterrorism.

### **1.3.12 Incidence**

This means unintended release, breach of containment, spill or occupational exposure to potentially biohazardous material.

### **1.3.13 Laboratory technologist**

Laboratory technologist refers to KMU employees designated ‘Laboratory Technologist’. Each Laboratory technologist is usually in-charge of daily functions of their designated laboratories.

## **2 INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)**

### **2.1 IBC Membership**

The IBC will be registered with a suitable national or international accreditation agency. In absence of a national biosafety board, membership will be sought from an internationally recognised accreditation body

## **2.2 IBC composition:**

The IBC is composed of members who are appointed by the Registrar KMU after consultation with VC KMU. Members shall represent the organisation and may include representatives from the community. Members will collectively have experience and expertise in research on potentially hazardous material and the capability to assess the safety of research involving potentially biohazardous material and identify any potential risk to public health, animal and plant health or the environment posed by such research.

The IBC should have the following minimum composition:

- a. Chair
- b. BSO
- c. Secretary
- d. Research experts from:
  - I. Basic Medical Sciences
  - II. Clinical sciences
  - III. Public health
- e. Members from community (preferably elected officials, members from judiciary, community leaders, or educators)

The KMU IBC should ideally consult with a national or international accreditation body to address issues pertaining to the organisation's IBC functioning. In absence of such, IBC will seek guidance from a relevant KMU statutory body.

## **2.3 IBC Chair**

### **2.3.1 IBC Chair Appointment**

Vice chancellor will appoint the chair of KMU IBC. A senior faculty member from basic medical sciences should chair the IBC. The Chair should represent the organisation and have knowledge and experience in scientific research pertaining to potentially hazardous material.

### **2.3.2 IBC Chair Responsibilities**

The Chair should preside over the IBC meetings and serve as one of two contacts (in addition to the BSO) with all regulatory agencies to help liaise between the KMU, community and the IBC. The Chair of IBC should designate a member of the IBC to serve as Acting Chair in his/her absence.

## **2.4 BSO**

### **2.4.1 BSO Appointment**

The BSO should be appointed by the VC. The BSO is a member of IBC and shall be experienced in working with potentially hazardous material. The appointed person is recommended to be a permanent BSO of the IBC. In case a permanent faculty member takes additional responsibility of BSO, allowance money shall be allocated for the faculty member. If BSO is appointed on regular basis, their appointed shall be made according to rules and regulations of KMU statutes.

### **2.4.2 BSO Responsibilities**

The BSO is responsible for submitting all applications for approval and notifications and the annual report of IBC. The BSO will be responsible for day-to-day surveillance and monitoring of the laboratory practices. The BSO will be responsible for ensuring the personnel working with potentially hazardous material are trained in safe laboratory practices. BSO will be responsible for taking corrective actions if breach of safety is noticed. The BSO will be responsible for reviewing IBC registration application from (KMU/IBC/Registration\_v1) (Annex-I) for each project and approve the research projects within two weeks after each AASRB committee meeting. BSO will organize trainings for new students/researchers who intend to carry out research in KMU laboratories.

## **2.5 Secretary**

### **2.5.1 Secretary appointment**

The secretary should be appointed by the Chair IBC. The secretary is a member of IBC and must be an employee of KMU.

### **2.5.2 Secretary responsibilities**

The secretary will be responsible for general working of IBC, liaising with syndicate, coordinating trainings, keeping records of incidents and financial record keeping. Issuing of notifications with the approval of IBC chair.

## **2.6 IBC Members**

IBC members are appointed by the VC KMU, and will serve a 3-year term and may be re-appointed. There is no limit to the number of terms a member

may serve as an IBC member. IBC members are responsible for ensuring that research and all other activities which involve potentially hazardous materials are reviewed and approved in a safe and appropriate manner in accordance with biosafety principles. Membership will be annually evaluated by the IBC Chair and endorsed by VC KMU.

## **2.7 Changes in IBC Membership**

IBC members may be replaced by the chair. The IBC Chair notifies the VC and concerned quarters such as KMU syndicate of changes in IBC membership as and when they occur. Such notice should include a revised list of members, contact details and background information on each new member.

### **2.7.1 Use of Consultants/ Ad hoc members**

IBC may use qualified consultants (local or foreign) for advice and information, as and when required but such consultants should not have voting rights. These consultants may be staff of the organisation, consumers, government regulators, environmental groups or stakeholders, and representatives of department of health, KP.

## **2.8 IBC Meetings**

### **2.8.1 Regular Meetings**

The IBC shall meet before each KMU ethics committee meeting to review and approve projects and to conduct project extension review of approved projects.

### **2.8.2 Emergency Meetings**

The Chair may call an emergency meeting of the IBC, as necessary, to address such issues as non-compliance or serious or unexpected events involving potentially hazardous materials in KMU laboratories. The RRT subcommittee may hold emergency meetings to address issues requiring immediate attention (eg. major power breakdown, flooding etc)

### **2.8.3 IBC meeting agenda items**

Prior to the regular meeting, each member should be sent a soft copy of the agenda items being reviewed at the meeting, in addition to other

information to be discussed. Secretary IBC is responsible for dissemination of meeting agenda and documents and writing minutes of meeting

#### **2.8.4 Quorum**

At least 50% of the IBC membership (excluding members with conflict of interest) must be present to conduct business of the IBC. The final approval or disapproval of non-exempt projects of potentially hazardous materials requires a majority (>50% ) vote by IBC members present and eligible to vote. If a quorum is lost at any time during the meeting, the meeting should be adjourned and no further action should be taken by the IBC until a quorum is re-established or a new meeting is appropriately convened. IBC chair will be casting vote.

#### **2.8.5 Attendance**

Attendance of members at IBC meetings is mandatory. Members who are unable to attend a meeting should provide a written prior notification to IBC. The Chair has the authority to call for explanation of absence from the IBC members. Members who fail to attend two consecutive meeting or four meetings in a calendar year or fail to contribute in the research review process will be called to explain for their absence.

### **2.9 Conflict of Interest**

IBC members who have a conflict of interest in the project shall not be present during the IBC's initial or project extension review (i.e. deliberations and voting) on the project. This might be their own proposal, or a proposal in which they are co-investigators, or in which they or a family member has a financial interest. Minutes shall record the information on such members who have declared a conflict of interest. Notwithstanding this, those with a conflict of interest may be requested by the IBC to provide additional information. Member with a conflict of interest may be called in front of the IBC to explain the nature of the project. It will be made clear that the presence of the member is just as PI but not in the capacity of IBC member.

#### **2.9.1 Minutes of Meetings**

Minutes of IBC meetings should include the following information:

- a. Attendance of members and guests.
- b. The status of the IBC's review on all applications and notifications.

- c. IBC actions taken on each project reviewed and any required modifications for IBC approval.
- d. Remarks and plan of action to be taken by PI/supervisor after inspection of laboratory facilities. In case of research being undertaken outside KMU laboratories, a note on whether satisfactory biosafety protocols are in place.
- e. Notation of members who were not present during deliberations and voting, on projects where they had a conflict of interest.
- f. The basis for disapproving any projects on possession and/or use of potentially hazardous material

## **2.10 IBC Records**

The IBC should retain the following records for five years at least.

- a. Confirmed and duly signed IBC meeting minutes, including attendance of IBC members and vote counts.
- b. IBC approved projects and related attachments.
- c. Annual report.
- d. A register of IBC members.
- e. The status of all applications and notifications to the KMU syndicate.

The IBC may also provide relevant information on a separate tab on KMU's website. All official records of the IBC will be kept with the secretary IBC in KMU.

## **2.11 IBC Responsibilities (Also section 3)**

KMU IBC is established to ensure safe laboratory practices, and safeguard human life and the environment in research, teaching, clinical and diagnostic work in KMU laboratories, constituent and affiliated institutions' premises or in the field. The responsibilities of the IBC include, but are not limited to the following:

- a. Provide guidance to PI/supervisor on biosafety policies and issues in the use of hazards in research, including safety of laboratory personnel and other members of the organisation.
- b. Recommend approval of research projects that includes use of potentially biohazardous and periodically reviewing these research projects. BSO will be part of Ethics board and will discuss with ethics board members.

- c. Assess and monitor the facilities, procedures, practices, training and expertise of personnel involved in potentially hazardous research.
- d. Notify the PI of the results of the IBC's review, approval, or rejection of their application for approval and notification of all activities involving the use of potentially hazardous material.
- e. Assess and set containment levels for potentially hazardous material research and modify containment levels as necessary.
- f. Assess field experiments to ensure that the proposed risk assessment, risk management and emergency response plan are sufficient.
- g. Adopt and implement emergency response plan covering accidental spills and personnel contamination, resulting from potentially biohazardous materials research.
- h. Ensure the information provided in the relevant application form (Approval/Notification) is correct and complete.
- i. Recommend suspension of project approval for the possession or use of potentially hazardous material. including research, where the IBC finds non-compliance or that such use or possession poses a threat to the health and safety of the community.

## **2.12 Other related responsibilities**

- a. Advocate formation of institutional biosafety committees in other institutions.
- b. Advocate national legislations towards establishment of a national biosafety board.
- c. Provide training to IBC members from other institutions.
- d. Routinely review the policies and procedures of the IBC and modify them as necessary to ensure appropriate biosafety measures
- e. Collaborate and develop national IBC guidelines and national biorisk management curriculum.
- f. Coordinate with laboratory in-charge technologist to keep up-to-date SOPs.

## **2.13 Research projects that require IBC Approval**

IBC approval is required for activities involving the following:

- a. Use of human material (blood, sputum, CSF etc) in diagnosis and research where the nature of potential risk is not known.

- b. Use of human material (blood, sputum, CSF etc) in diagnosis and research where the nature of potential risk is expected.
- c. Storage of potentially hazardous material in storage areas where others have access to.
- d. Use of animals whereby the project is potentially hazardous to humans.
- e. Deliberate transfer of a drug resistance trait to microorganisms.
- f. Deliberate transfer of rDNA or DNA/ RNA derived from rDNA into human research participants (human gene transfer).
- g. Deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight.
- h. Use of Risk Group 2, Risk Group 3 or Risk Group 4 agents as host-vector systems
- i. Cloning of DNA from Risk Group 2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.
- j. Use of whole animals (immunocompetent or deficient) where pathogens can replicate and risk loss of containment.
- k. Viable rDNA-modified microorganism tested on whole animals.
- l. Genetically engineered plants by rDNA methods.
- m. The formation of rDNA material containing two-thirds or more of the genome of a eukaryotic virus.
- n. Use of archived human tissue where the nature of potential risk is not known.
- o. Use of physical and chemical agents (radiation, corrosives, volatile substances) in research.
- p. Use of agents that may risk certain groups of researchers (pregnant women)

## **2.14 Authority of the IBC**

### **2.14.1 Scope of authority defined**

The KMU IBC has the authority to approve, require modifications in, or disapprove all research, teaching, diagnostic, or outreach activities (whether externally or internally funded) that fall within its jurisdiction.

### **2.14.2 Authority to approve, modify, or disapprove studies**

The KMU IBC approves protocols for up to three years, with annual reviews. After three years the protocol (KMU/IBC/Registration\_v1)

(Annex-I) must be resubmitted. Research that has been reviewed and approved by the KMU-IBC may be subject to further review and disapproval. The KMU-IBC its independent determination whether to approve or disapprove the protocol based upon whether or not biological safety aspects adhere to guidelines. The KMU-IBC has jurisdiction over all research involving potentially hazardous biological materials.

### **2.14.3 Authority to require progress reports from investigators**

Any approved research or protocol is subject to continuing KMU-IBC review. Each protocol will undergo an annual review to ensure that no substantive changes to the protocol have occurred. Protocol resubmission will occur every three years or more frequently if specified by the IBC.

### **2.14.4 Authority to approve/disapprove amendments**

All modifications to currently approved research and other activities are required to have IBC review and approval prior to implementation. Modifications are submitted on . The IBC modification approval is only valid until the end of the original approval period. For example, if a protocol's original approval is issued on January 1, 2017 it will have an expiration date of December 31, 2019. If a modification is approved during this time, the approval still lasts only until December 31, 2019.

### **2.14.5 Authority to suspend or terminate approval of a study**

The KMU IBC has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IBC's requirements or that has been associated with unexpected serious consequences. Any suspension or termination of approval shall include a statement of the reasons for the IBC's action and shall be reported promptly to both the PI and unit head. Information concerning noncompliance or perceived noncompliance with the NIH Guidelines or University policies or procedures may be brought forward by any person and the IBC must recommend appropriate action.

## **2.15 Reporting for Incidents and Spills**

### **2.15.1 Internal Reporting**

It is necessary that any laboratory research incident in the organisation be reported by the PI/laboratory personnel to the IBC through the BSO using the Incident Reporting Form (KMU/IBC\_Registration\_v1) (Annex-II)

within 24 hours. Incidents include non-compliance of the Biosafety rules or any significant research-related accidents and illnesses (e.g. exposure to any uncontained potentially hazardous material materials, any overt exposure in a BSL-2 lab such as a needle-stick injury, splash, or contamination from equipment failure or a potential or overt exposure in the BSL-3 or BSL-4).

A significant event may also occur from a containment breach in the laboratory of an affiliated institute or at the field experiment location, which may be subsequently determined to pose both an overt or potential exposure to individuals and the environment. If necessary, BSO will activate the RRT to respond to the incident.

### **2.15.2 External Reporting**

PI is responsible for reporting any incident by submitting the Incident Reporting Form (KMU/IBC/Incidence/v1) (Annex-III) to an appropriate external body within 48 hours from the incident. This form should be reviewed by BSO before submission. Till a National Biosafety Board for external reporting is established, external reporting will be done to relevant regulatory bodies. These form(s) should be sent to the Chair of IBS through BSO.

If deemed necessary, syndicate may also recommend that IBC inform the incident to external agencies such as the department of health or the National Institute of Health.

## **2.16 Persons Responsible for Compliance**

The responsibility for biosafety at an organisation rests with the Head of the Organisation and PI, who obtains, possesses or uses potentially hazardous materials. IBC and BSO should provide guidance to ensure compliance. Any possession and/or use of these materials at the organisation must be conducted with appropriate safeguards against environmental release.

### **2.16.1 Vice Chancellor**

The VC provides executive leadership, dissemination and implementation of biosafety policies, standards and procedures applicable to the Biosafety rules and other related regulations regarding research using potentially biohazardous material. The VC maintains ultimate responsibility for the biosafe practices

VC the following responsibilities:

- a. Appoint KMU-IBC chair.
- b. Ensure biosafety remains the top priority of KMU research laboratories.
- c. Provide necessary support to KMU IBC.
- d. Have awareness of all requirements regarding compliance with the Biosafety rules and guidelines.
- e. Provide leadership and support at the management level for laboratories.

### **2.16.2 Biological Safety Officer (BSO)**

The BSO should perform the following functions:

- a. Provide biosafety induction and training to all researchers before they begin their research in KMU laboratories.
- b. Periodically inspect all laboratories where research projects are being conducted to monitor that laboratory standards are being followed.
- c. Report to the IBC any significant problems, non-compliance of the Biosafety practice guidelines, and any significant research-related accidents or illnesses of which the BSO becomes aware, unless the BSO determines that a report has already been filed by the PI.
- d. Provide guidance to PI in developing emergency response plan for handling and investigating laboratory accidents involving potentially hazardous materials.
- e. Work with the RRT to provide technical advice on research safety and laboratory security procedures to PI, laboratory personnel and the IBC.
- f. Serve as a liaison officer between the organisation/institution and external regulatory agencies concerning the use of potentially hazardous materials. The BSO is responsible for submitting the annual report of IBC to the KMU syndicate, on behalf of KMU.
- g. Serve as a voting member of the IBC.

### **2.16.3 Principal investigator**

The principal responsibility of PI is risk assessment and selection of appropriate biosafety level of research conducted by them or their students. The PI seeking must make an initial risk assessment of the potentially biohazardous materials. The primary focus of a risk assessment is to prevent or reduce the risk of laboratory-associated infections or accidental or unintentional release of potentially biohazardous materials into the

environment. The assessment of risk is based on the organism's Risk Group and other risk factors and should be utilized to determine the appropriate level of perceived risk and biological and physical containment levels (BSL-1 to BSL-4) prior to possessing or using potentially biohazardous materials.

The responsibilities of PI include but are not limited to the following:

- a. The PI is responsible for submitting complete IBC registration application form. In case of a student project, PI shall ensure the student submits a complete IBC registration form. Prior to the commencement of any activities involving the use of potentially biohazardous materials, the PI must register the potentially biohazardous agents they propose to use with the IBC via the IBC Registration Application Form (KMU/IBC\_Registration\_v1) Annex-II.
- b. The PI is primarily responsible for the people and activities in their laboratories.
- c. They must also ensure strict adherence to biological safety practices and techniques for all work involving potentially biohazardous materials.
- d. It is also the responsibility of the PI to ensure that personnel receive the appropriate training on the potential hazards and precautionary measures applicable to the potentially biohazardous materials. This includes instruction in specific practices and techniques required for safely handling the agents.
- e. They are responsible for implementing an appropriate biological safety program specific for their projects.
- f. They should evaluate all their operations, perform risk assessments, and develop plans for all activities accordingly.
- g. They are responsible for establishing the appropriate biological safety containment levels in consultation with the BSO and ensuring adherence to these levels.

Once IBC approval has been granted the PI shall:

- a. Not modify the research project involving potentially biohazardous materials such that it requires a change from the BSL and/or Risk Group or change of premise which was already assessed by IBC. When in doubt, the PI should consult the IBC.
- b. Immediately report any significant problems with respect to the implementation of relevant laws, regulations and guideline.
- c. Notify the IBC promptly of any significant research related accidents that have resulted or could result in human illness,

unanticipated plant or animal disease, or in the unintended release of organism under study from an intended confinement.

#### **2.16.4 Laboratory Personnel (Technician, Technologist, Student, Post-doctorate)**

Laboratory personnel must:

- a. Follow all safety practices and establish good laboratory techniques. They must work within the assigned biological safety containment level and use personal protective equipment as recommended by the PI.
- b. Immediately notify the PI or BSO of any health condition that may be due to their work in the laboratory or any health condition that may be compromised prior to the initiation of a research project (i.e. pregnancy, immunosuppression).
- c. Follow all practices and procedures as provided by the PI and BSO, and ensure strict compliance with all required biosafety regulations and guidelines.
- d. Report problems, procedural mistakes, spills, etc. to the PI, and if necessary to the BSO, as soon as they occur.
- e. Report to the PI, BSO or IBC on non-compliance of biosafety guidelines or policies.

#### **2.16.5 Prior to Performing Research Involving potentially hazardous Materials**

Before starting laboratory work involving potentially hazardous materials, the PI should do the following:

- a. Review the applicable guidelines and regulations and become familiar with the safety procedures and requirements related to the potentially biohazardous materials and any other infectious materials involved in the research activity.
- b. Develop standard operating procedures (SOP) incorporating biosafety procedures or a biosafety manual prepared specifically for approved project.
- c. Advise laboratory personnel of special hazards and require them to read and follow instructions on practices and procedures.
- d. Establish policies and procedures to limit access to only individuals who have been advised on the potential hazards and meet specific

- entry requirements (e.g. immunisation, training on use of protective clothing).
- e. Ensure laboratory personnel receive appropriate training on the potential hazards associated with the research, the necessary precautions to prevent exposures, and the exposure evaluation procedures.
  - f. Ensure laboratory personnel follow aseptic techniques and in the biology of the organisms used in the experiments so that the potential risks can be understood and appreciated.
  - g. Ensure laboratory personnel receive accident safety training.
  - h. Ensure an emergency response plan appropriate for the biosafety level of the research laboratory is in place

### **2.16.6 Performing Research Involving LMOs/rDNA Materials**

While performing research on LMO/rDNA materials, the PI should:

- a. Limit or restrict access to the laboratory when work with the LMO/rDNA materials is in progress.
- b. Provide personal protective equipment (PPEs) required for work with the specific LMO/rDNA materials.
- c. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
- d. Follow safety protocols outlined in the emergency response plan approved by the IBC for the specific project and laboratory.
- e. Correct work errors and conditions that may result in the unintended release of LMO/rDNA materials.
- f. Ensure the integrity of the biological and physical containment/ biosafety level.
- g. Ensure the LMO/rDNA materials are kept secure at all times.
- h. Have emergency response plan posted in the designated laboratory.

### **2.16.7 Performing research involving animals**

While performing research on laboratory animals, the PI should

- a.
- b. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
- c. Explain the principles and pathogenesis of zoonosis and ensure workers receive training on zoonosis proof laboratory practices.
- d. Ensure the infection control in animal house
- e. Have emergency response plan posted in the designated laboratories

## **2.16.8 Performing diagnostic/research procedures on human samples**

- a.
- b. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
- c. Explain the principles and pathogenesis of zoonosis and train workers on zoonosis proof laboratory practices.
- d. Ensure the infection control in animal house
- e. Have emergency response plan posted in the designated laboratories

## **2.16.9 Performing research work on biohazardous chemicals**

- a. a. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
- b. Explain the principles and pathogenesis of zoonosis and train workers on zoonosis proof laboratory practices.
- c. Ensure the infection control in animal house
- d. Have emergency response plan posted in the designated laboratories

## **3 INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) RESPONSIBILITIES**

The IBC can address non-compliance to the safe laboratory practices or to KMU's policies and procedures and any other relevant legal requirements. Non-compliance can result in the IBC taking one or more of the following actions:

- a. Suspension of the use of potentially hazardous materials.
- b. Cessation of the approval for use of the potentially hazardous materials.
- c. Confiscation of the potentially hazardous materials.
- d. Destruction of the potentially hazardous materials.
- e. Any other action necessary to protect the public and/or the organisation, including suspending the relevant research activity.

### **3.1 Exemptions**

IBC committee may allow exemptions for some types of research work used. PI who believes that the work falls into any of the exemptions should

nevertheless notify their IBC of the proposed project. An ad-hoc subcommittee should review all submitted research projects to determine their exemption or non-exemption status. Researchers doing qualitative work, epidemiological studies, interview based work might be exempted from IBC purview. However, each research proposal presented to ASRB should be presented to IBC through BSO.

### **3.2 Review of potentially biohazardous material related Activity**

For contained use activity the PI may start the research after receiving an acknowledgement of receipt of the notification from the IBC.

With respect to the review of proposed potentially biohazardous materials research, the IBC should refer to the Biosafety Guidelines and IBC policies and procedures for the organisation.

In particular, the project review should examine the following as described in IBC-Registration\_v1 (Annex I):

- a. Agent characteristics (e.g. virulence, pathogenicity, environmental stability).
- b. Animal characteristics (immunodeficient, genetically modified)
- c. Sample characteristics (healthy individuals, confirmed contagious etc)
- d. Types of manipulations planned.
- e. Sources of the inserted DNA sequences (e.g. species).
- f. Nature of the inserted DNA sequences (e.g. structural gene, oncogene).
- g. Hosts and vectors to be used.
- h. Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced.
- i. Qualification of personnel intended to be involved in the project.
- j. Prior training of the personnel intended to be involved in the project
- k. Containment conditions to be implemented including risk assessment, risk management and emergency response plan.

In addition, the IBC may also conduct an assessment of the facilities, procedures, practices, training, and expertise of personnel involved in the potentially biohazardous work. The IBC may require the PI to provide data reporting and adverse event reporting for the purpose of monitoring the proposed work.

### **3.3 Notice of IBC Action**

The IBC Chair should provide written notification of the IBC's decision to the PI.

### **3.4 Review of protocols**

#### **3.4.1 Review of project duration**

IBC approval of potentially biohazardous materials is valid for two years or longer as determined by the IBC. All IBC approvals of potentially biohazardous materials and infectious agents are subject to an annual review. The first review of the approval will occur within the first 12 months after the initial approval date. Thereafter, the subsequent review will be done after a period of one year, unless the IBC determines that a shorter review period is required.

#### **3.4.2 Review of Incidents and Personnel Exposure**

When there is a reporting of incident, IBC will meet and review the information submitted through the Incident Reporting Form (KMU/IBC/Incidence\_v1) (Annex-III). The members of the RRT may include additional information that might be necessary to review the reported incident. Further discussion and action pertaining to the incident should be captured in the minutes of the IBC meeting. The KMU syndicate may request for a detailed report of the incident if necessary.

#### **3.4.3 Modifications to Approved Projects**

The PI should not initiate or implement any significant change or modification to IBC approved projects without the prior review and approval of the IBC. This includes, but is not limited to, modification of potentially biohazardous materials, procedural changes, changes in laboratory personnel, including adding on new personnel and a change in laboratory location, any or all of which may change or increase the Risk Group of the project and/or its BSL. Applicants must submit relevant new application form to IBC through BSO for approval before making any of these changes.

### **3.4.4 Project Extension Review of Approved Projects and Notice of Termination**

The PI who wishes to extend the time period of the activity with Potentially biohazardous materials must complete and submit the IBC Project Extension Review/ Notice of Termination (KMU/IBC/Amendment\_v1) (Annex-IV) Form to the IBC Chair at least one month prior to the next scheduled IBC meeting. The IBC Project Extension Review/ Notice of Termination Form should be submitted at appropriate time intervals as stipulated by the IBC. Review is conducted by the full committee at its regular meetings. The IBC Chair should notify the PI in writing of the IBC's decision.

## **4 TRAINING**

### **4.1 Mandatory Training of IBC Members**

All members of the IBC should receive initial mandatory and refresher training on Biosafety. All such training will be organised by IBC. It is the responsibility of the IBC Chair to provide this training and BSO to document it.

### **4.2 Training of the BSO**

In line with the responsibilities of a BSO, the BSO will attend biosafety trainings with commitment from the organisation. It is the responsibility of the BSO to document the training.

### **4.3 Training of Laboratory Personnel**

General biosafety training is mandatory for all individuals conducting research with potential biohazardous materials. Individual researchers must provide proof to the IBC that they have undergone training or have adequate experience (as recognised by IBC) in Biosafety and Good Laboratory Practices. This includes knowledge in handling and management of incidents/accidents in the facility and information on when and how to report laboratory incidents. Successful completion of training is recommended in order to receive IBC approval, whether with a new application or for a re-application. In addition, individuals proposing to work in BSL-3 containment must have specific BSL-3 laboratory training.

## **5 EMERGENCY RESPONSE PLAN**

When an application for notification/approval of modern biotechnology activity is submitted to the IBC, the PI should also submit an appropriate emergency response plan that they have developed based upon their assessment of the risk group and BSL. The PI should begin with the IBC approved standard emergency response plan and insert appropriate additions for their own protocol and laboratory requirements. This project-specific emergency response plan will be included in the materials to be reviewed and approved by the IBC. It is the role of the IBC to finalise this emergency response plan and take a final vote at a convened meeting of the IBC.

The BSO may provide guidance for the creation of an appropriate template for the emergency response plan pertaining to BSL (BSL 2 and BSL3). It must be tailored to the individual PI's laboratory and use approved protocols. These plans (and any revisions thereof) must be formally adopted by the IBC pursuant to all National Biosafety policies and organisational policies. The emergency response plan will be reviewed periodically based on new information from internal findings and/or external developments (i.e. regulatory, local and international best-practices).

## **6 LABORATORY INSPECTIONS AND BIOSAFETY MANUALS**

### **6.1 Laboratory Inspections**

The IBC will inspect laboratories using checklists. Problems are to be reported to the PI for remedial procedures and, if necessary, to the higher relevant authority in the organisation. Inspection reports should be maintained on file in the IBC.

For routine inspections, relevant authorised personnel, such as IBC members, as well as representatives and officers authorised by the NBB should be allowed access to laboratories that are registered for activities with LMO/ rDNA materials.

### **6.2 Biosafety Manual**

The IBC reviews biosafety protocols during inspections. A collection of biosafety protocols and procedures (safety manual) must be available in each laboratory according to the training provided by IBC.

## **7 BIOSECURITY OF LMO/rDNA MATERIALS**

Authorised access and proper storage of biological materials is very important and should be taken seriously. The PI and all associated personnel must be conscientious in controlling these materials and should be held accountable for them. Access to biological materials should be limited to authorised personnel only.

The laboratory in-charge in coordination with the PI and BSO, depending on the Risk Group the biological agent may pose, should perform a risk vulnerability assessment and develop a plan to protect the security of the material in question.

The plan might include:

- a. Additional locks on laboratory doors, freezers, etc. where biological agents are used or stored.
- b. Chain-of-custody forms within laboratories to track materials.
- c. Inventories of biological materials.
- d. Logs of access to areas where biological materials are in use.
- e. Written security plan for use of biological materials which includes:
- f. Procedures for access to the agent.
- g. Procedures for routine cleaning, maintenance, and repairs.
- h. Procedures for restricting unauthorised persons.
- i. Procedures for addressing loss of keys, passwords and any other secured information and material.
- j. Procedures for prevention of loss or theft.

## **8 DISPOSAL**

The Principal Investigator, faculty member or other person with operational responsibility shall assure compliance with these requirements within his/her laboratory or area of responsibility. KMU shall ensure a mechanism of safe disposal of all biohazardous waste is in place. However, it is important that in the absence of such a centrally managed waste disposal system, the PI ensures safe disposal of waste generated during the project work. This includes:

- Sharp metal waste,
- Non-sharp solid waste,

- Liquid waste,
- Animal carcasses and body parts,
- Animal waste,
- Plastic lab-ware,
- Human pathological waste,
- Biohazardous chemicals and corrosives
- Radio-active agents
- Infectious virus and other living organisms.

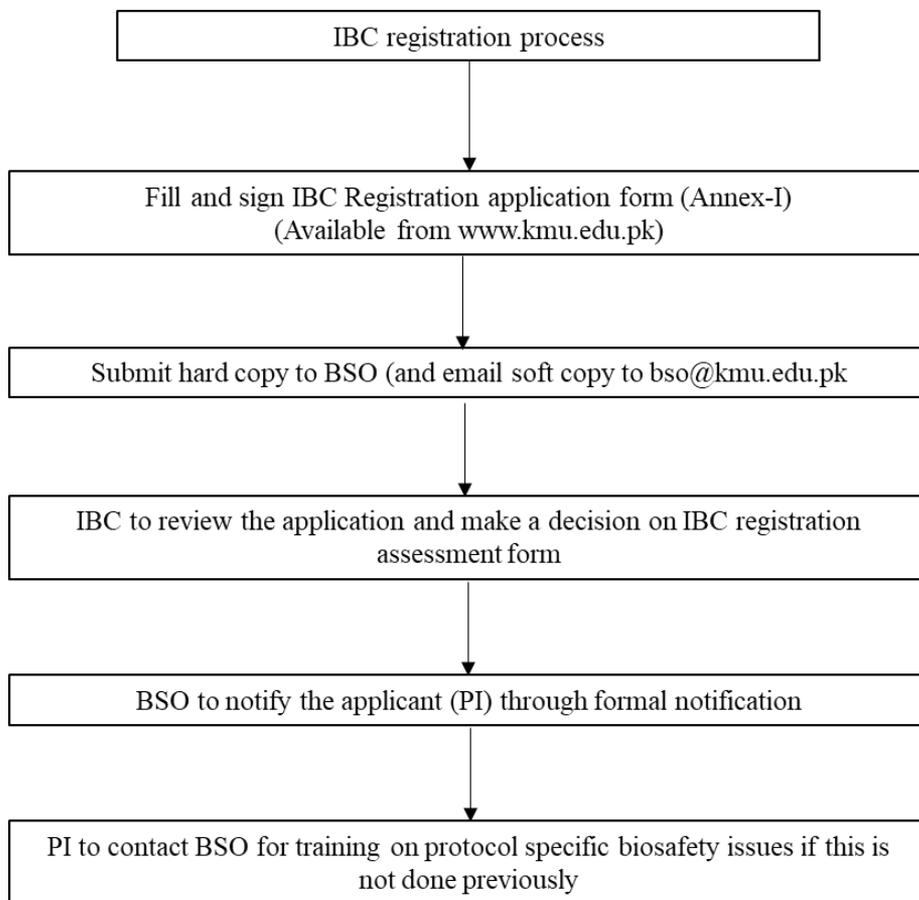
## **9 PACKAGING AND TRANSPORT OF BIOHAZARDOUS MATERIAL**

All regulated biohazardous materials will be packaged and transported in a manner compliant with national and international regulations and related guidelines. IBC has provided an initial batch of shipping and transport containers according to IATA guidelines. However, it is the responsibility of PI to ensure safe transport of biological material.

## 10 FLOW CHARTS

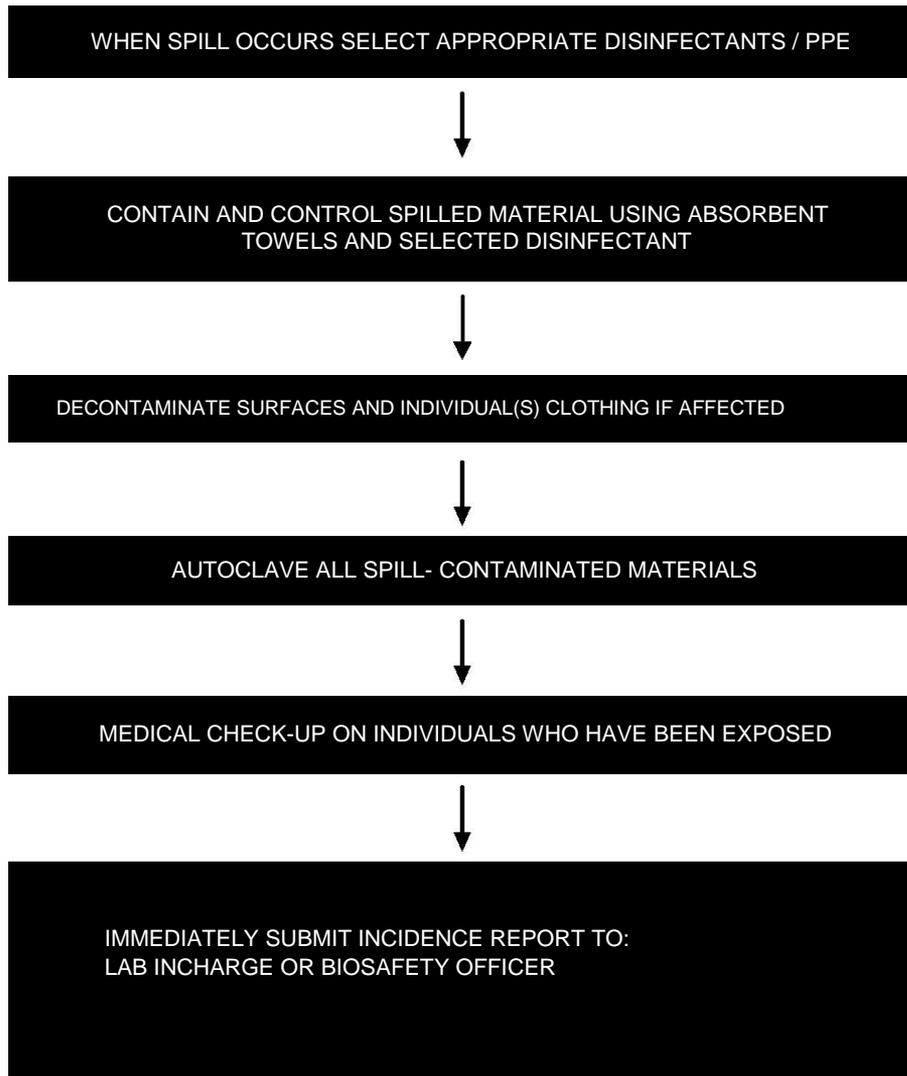
### 10.1 Process of protocol registration with IBC

In case of student research project, IBC application shall be initiated after AASRB approval. In case of an individual project, the application does not require AASRB approval.



## 10.2 SPILL RESPONSE

### PERSONNEL PROCEDURES



### 10.3 FIGURE 3: SPILL RESPONSE IN CONTAINMENT FACILITY AND EVALUATION OF HAZARDS BY PATHOGEN TYPE

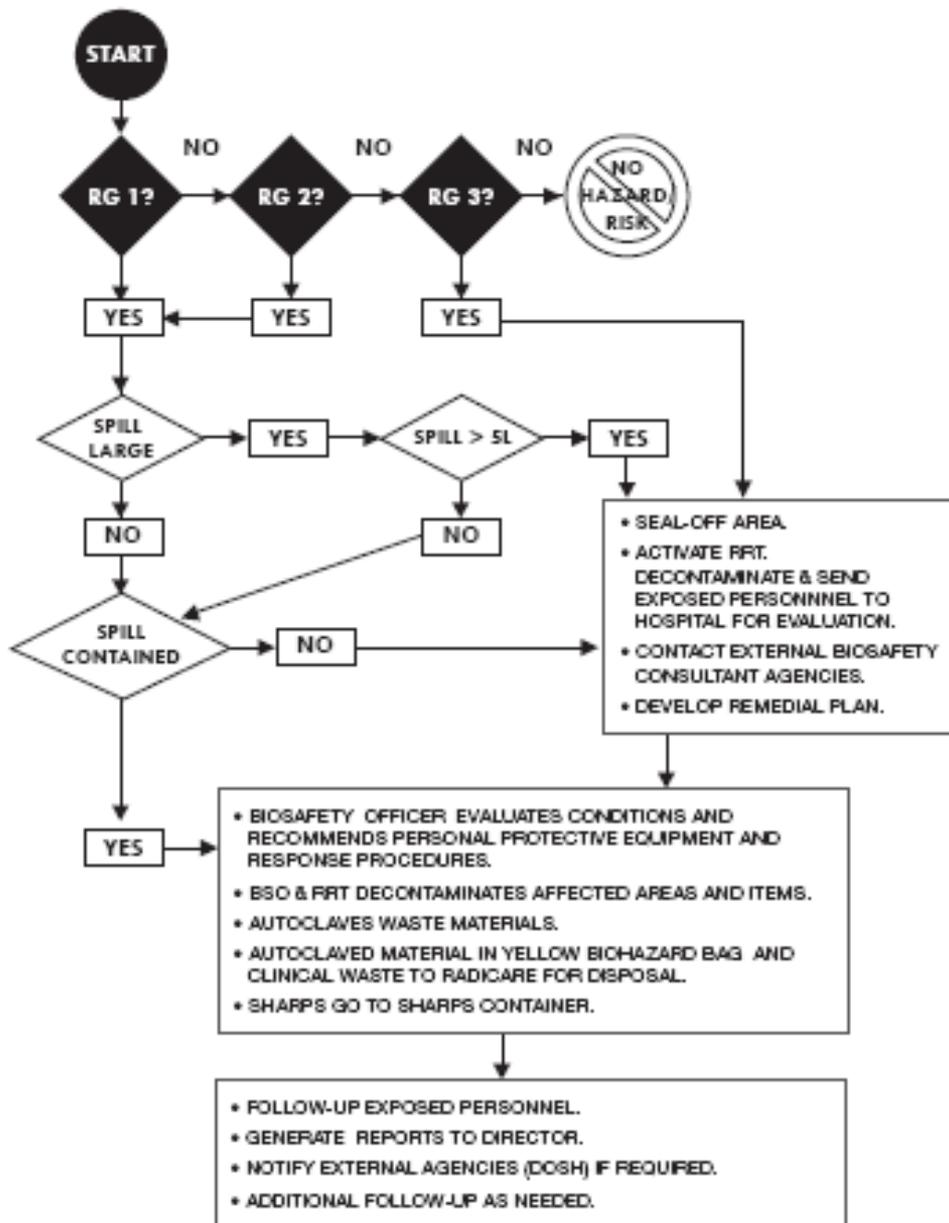


Figure 1: RG: WHO defined Risk Groups

## **11 FORMS**

### **11.1 Guidelines for assessment of Biosafety registration application**

KMU/IBC/Assessment\_form\_v1 is to be used for assessment of a proposal to carry out research on potentially biohazardous material. This form serves to guide the IBC in the consideration and evaluation of the project proposal. Completed IBC assessments should be submitted to the Ethical committee, together with the corresponding application form.

#### **11.1.1 Instructions for Completion of the Form**

The applicant must submit a typed, completed assessment form to the KMU IBC, attached to the corresponding application form, and should retain a copy for record and reference. The assessment form must be signed by the IBC Chair/BSO. A clear and concise explanation is required for the IBC's position on each of the experimental parameters identified in the assessment form (Figure 10.2)

**11.2 Annex-I IBC registration assessment form  
(KMU/IBC/Assessment\_form\_v1)**

# IBC REGISTRATION ASSESSMENT FORM

(KMU/IBC/Assessment\_form\_v1)

Section	Information is complete and biosafety measures addressed appropriately		Comments
1. Applicant information	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
2. Research project	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
3. Safety and protection	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
4. Shipping and transport	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
5. Training	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
6. Occupational health requirement	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
7. Assurance	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
8. Signatures	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
9. Amendments:			
Decision	Approved <input type="checkbox"/>	Approved with amendments <input type="checkbox"/>	Not approved <input type="checkbox"/>

## Signature and stamp:

Name : \_\_\_\_\_

Date : \_\_\_\_\_

**11.3 Annex-II IBC registration form  
(KMU/IBC/Registration\_v1)**

## BIOSAFETY REGISTRATION FORM (KMU/IBC/Registration\_v1)

Please follow all instructions. Use additional paper when necessary. Complete and signed forms should be submitted to KMU Biosafety Officer (BSO)

For official use only:			
IBC application no:			
Ethical approval no:			
Approval date:			
Expiration date:			
Signature and stamp:			
1. Applicant (Principal Investigator/ Student/ Supervisor)			
(1) Name, Degree(s)	(2) Job Role	(3) If student then degree program ( eg. M. Phil/ PhD)	
(4) Department		(5) Phone:	
(6) Interoffice Address:		(7) e-mail address	
b. LIST <b>ALL OTHER PERSONNEL</b> DIRECTLY INVOLVED IN THIS PROJECT			
NAME	PROJECT POSITION(S)	EMAIL ADDRESS	PHONE
(1)			
(2)			
(3)			
(4)			
(5)			

(6)			
<b>2. RESEARCH PROJECT</b>			
<b>a. Applying for</b> (check only one)			
New protocol registration <input type="checkbox"/>	Exemption <input type="checkbox"/>		
<b>b. FUNDING SOURCE</b> (check only one)			
Departmental funds <input type="checkbox"/>	External funds <input type="checkbox"/>	Funding to be applied <input type="checkbox"/>	
<b>c. PROJECT TITLE</b>			
<b>d. RESEARCH INVOLVES</b> (check all that apply)			
In vitro work <input type="checkbox"/>	Whole animals <input type="checkbox"/>	Human subjects <input type="checkbox"/>	
<b>e. SPECIFIC AIMS/OBJECTIVES OF THE RESEARCH PROJECT:</b>			
<b>f. SUMMARY OF THE PROJECT: (in lay terms and not exceeding 250 words)</b>			

--

**g. EXPERIMENTAL PROCEDURES** (Briefly describe in lay terms the methodologies employed in the proposed research relevant to biosafety)

--

**h. MICROORGANISMS USED (VIRUSES, BACTERIA, etc.)**

Strain	Characteristic (eg. pathogenic)	Procedure (eg. culture)	Treatment	Procedure location	Hazard to humans (yes/no)

**i. EXPERIMENTAL ANIMALS**

Animal strain	Characteristic (transgene, immunodeficient)	Procedure (eg. IV, oral)	Drug/ chemical/ exposure	Procedure location	Hazard to human (yes/no)

**j. HUMAN PARTICIPANTS USED** (Briefly describe if participants in your research are healthy, sick, young or old, immunocompetent or immunodeficient)

Participant group (eg. experimental, control)	Characteristic (eg. immunodeficient)	Procedure (eg. IV, oral)	Drug/ chemical/ exposure	Procedure location	Hazard to participant (yes/no)

**k. TYPES OF HUMAN TISSUE USED** (Briefly describe if archived samples are used eg. Paraffin embedded tissues)

--

Sample type	Characteristic (eg. Potentially hazardous)	Procedure (eg. DNA extraction)	Further treatment (eg. PCR amplification)	Procedure location	Hazard to human (yes/no)

**l. TYPES OF RADIATION EXPOSURE:** (Briefly describe if research project involves radiation exposure eg. X-ray, radio-isotopes)

--

**m. TYPES OF RECOMBINANT MATERIAL USED** (Briefly describe the origin of recombinant insert or transgene, and vector. Also describe if these can be of potential hazard to the researcher or environment)

--

#### 4. SAFETY AND PROTECTION

<b>a. Standard operating procedures (SOP) written and approved by the PI/Supervisor?</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
--	------------------------------	-----------------------------

**b. Which buildings/laboratories will be used in your research?** (Research projects with a particular biosafety requirement must be conducted in building/laboratory with required biosafety level)

Laboratory	Biosafety level available

**5. SHIPPING AND TRANSPORT:** (Briefly describe if the biohazardous material will be transported to a local, national or international laboratory. Describe what measures will be undertaken to ensure safe transport)

--

**6. TRAINING:** (Briefly describe if the researchers working on this project have received appropriate biosafety training. If no, a training with biosafety office must be arranged before start of the project)

Name of researcher	Biosafety level required	Training received:	
		Yes <input type="checkbox"/>	No <input type="checkbox"/>

		Yes <input type="checkbox"/>	No <input type="checkbox"/>
		Yes <input type="checkbox"/>	No <input type="checkbox"/>
		Yes <input type="checkbox"/>	No <input type="checkbox"/>

**6. OCCUPATIONAL HEALTH REQUIREMENTS:**

	Yes <input type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
i. Have you ensured safe disposal of solid sharp waste generated in this project?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
ii. Have you ensured safe disposal of non-sharp solid waste generated in this project?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
iii. Have you ensured safe disposal of liquid waste generated in this project?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>

**7. WASTE DISPOSAL:**

i. Are there any special groups of workers at risk of infection or disease from the use of the biohazard(s)/ hazardous drug(s) (e.g. pregnant, immuno-compromised, allergic, etc.)? If yes, describe below:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
ii. Are any special immunizations necessary for personnel involved in the research (e.g. Hepatitis B, Tetanus/Tdap, etc.)? If yes, describe below:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
Is there a need to monitor the health of personnel involved (e.g. testing)? If yes, describe below:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>

**6. ASSURANCE:**

<b>a. PRINCIPAL INVESTIGATOR/ STUDENT/SUPERVISOR</b>	<b>INITIALS</b>
I certify the information provided in the KMU IBC registration form is complete and accurate and understand my responsibilities as noted in it.	
No changes will be made without advance approval from the KMU Institutional Biosafety committee.	
I acknowledge my responsibility for the safe conduct of this research in accordance with KMU IBC guidelines	
Involving Recombinant DNA Molecules. I will inform all associated personnel of the nature and risks of this work, as well as necessary precautions and safe practices.	

I also agree to comply with the requirements for the shipment and transfer of recombinant DNA materials.	
<b>I further acknowledge my responsibility to ensure compliance with the following:</b>	
(1) Work surfaces will be appropriately decontaminated at least daily and immediately after working with biohazardous materials.	
(2) All personnel involved will wash thoroughly with soap and water. Clothing will be changed as needed.	
(3) All contaminated materials will be discarded appropriately according to KMU IBC guidelines (e.g. as Biohazard waste, as Hazardous drug waste, as Chemotherapeutic waste).	
(4) BSO (KMU IBC) will be immediately notified of all spill or incidents occurred at biosafety level 2 and up laboratories.	
(5) In the event of an incident where there is a risk of infection or other consequences to incident, affected personnel will be counselled to seek appropriated medical attention.	
<b>SIGNATURE:</b>	<b>Date:</b>
<b>b. CO- INVESTIGATOR</b>	
I certify that I have reviewed this Biosafety Registration form and that the information provided in it is complete and accurate.	
SIGNATURE OF CO- INVESTIGATOR	<b>Date:</b>
<b>c. ENDORSEMENT OF HEAD OF INSTITUTION</b> (not needed for KMU students/supervisors/PIs who have received ASRB approval)	
In addition to endorsing the PI's certification, if the experiments are supported primarily by department or university funds, I certify that I have reviewed the protocol and it is judged to be of scientific merit.	
SIGNATURE AND STAMP OF THE HEAD OF INSTITUTION	<b>Date:</b>



**11.4 Annex-III Incidence report form  
(KMU/IBC/Incidence\_report\_v1)**

**INSTITUTIONAL BIOSAFETY COMMITTEE INCIDENT  
REPORTING FORM (KMU/IBC/Incidence\_report\_v1)**

*To be completed by the user involved in/reporting 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)		
<b>IDENTIFY THE DIRECT AND CONTRIBUTING CAUSES OF THE INCIDENT</b>		
1. Describe the incident:		
2. Probable cause or causes of incident (tick 1 or more boxes for appropriate answers).		
<input type="checkbox"/> Fault of equipment	<input type="checkbox"/> Inadequate workspace	
<input type="checkbox"/> Equipment unavailable	<input type="checkbox"/> Lack of training	
<input type="checkbox"/> Poor storage	<input type="checkbox"/> Poor access	
<input type="checkbox"/> Weather	<input type="checkbox"/> Unknown	
<input type="checkbox"/> Assistance unavailable	<input type="checkbox"/> Assistance unavailable	
<input type="checkbox"/> Electrical fault	<input type="checkbox"/> Electrical fault	
<input type="checkbox"/> Carelessness	<input type="checkbox"/> Incorrect method / work practices	
<input type="checkbox"/> Terrain	<input type="checkbox"/> Others*	
*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, failed 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, counselling, training, policies, procedures, etc.)?
7. Who is responsible to implement corrective actions?

Signature of reporting person

Name:

Date:

For official use only:
------------------------

**11.5 Annex-IV Project extension/ renewal/ modification  
(KMU/IBC/amendment\_v1)**

**INSTITUTIONAL BIOSAFETY COMMITTEE PROJECT  
EXTENTION APPLICATION (KMU/IBC/Extension\_termination\_v1)**

*To be completed by Principal Investigator. 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 prior to 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 <input type="checkbox"/>	Modification <input type="checkbox"/>
2. General information		
Will the PI change?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Will the Risk Group (RG) change?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Will the Biosafety Level (BSL) change?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Will the type/amount of hazardous materials change?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If the answer to any of the above questions is yes, you must submit 'IBC registration application form (KMU/IBC/Registration_v1)		
3. Certification		

I certify that the above information accurately describes the current status of the modern biotechnology activities that was previously approved by the IBC. I understand that I must resubmit a new 'IBC registration application form (KMU/IBC/Registration\_v1)

Signature of Principal Investigator  
Name:

Signature of Biosafety Officer  
Name:

Date:

Date:

Signature of IBC Chair
------------------------

