1.0 SCOPE

This document consists the policy and procedure that govern all activities involving the handling, manipulating, working, using, storing, and disposing of biological agents/materials including GMO, LMO, rDNA and biological toxins in defined facility and containment zone in UPM. This procedure covers activities in all types of facilities include teaching, research, clinical, veterinary and environmental laboratories. It covers both deliberate use of biological agents and work with material that contain or could contain biological agents.

2.0 REFERENCE DOCUMENTS

Document Code / Reference	Document Title
1 December 2009, P.U. (B) 537/2009	Biosafety Act 2007 (Act 678)
1 November 2010 P.U. (A) 367	Biosafety (Approval and Notification) Regulations 2010
14 February 2018 P.U. (A) 39	Biosafety (Compounding of Offences) Regulations 2018
14 February 2018 P.U. (A) 40	Biosafety (Sampling Procedures) Regulations 2018
-	Exemption by Minister
-	Exemption for Contained Use Activities
ISBN 978-967-0250-24-3	National Policy on Biological Diversity 2016-2025
	National Policy on Biological Diversity 1998
ISBN :978-967-13278-0-7	Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline, Ministry of Health Malaysia 2015, 1st edition
WHO/CDS/EPR/IHR/2007.1	International Health Regulation 2005
Ref. No.: CWA 15793:2011 D/E/F	Laboratory Biorisk Management CWA 15793:2011, European Committee for Standardization, ICS 07.100.0
-	Guidelines on the Handling and Management of Clinical Wastes in Malaysia, Department of Environment, Ministry of Natural Resources & Environment, Third Edition August 2010
[Throughout Malaysia 1 April 1989, P.U. (B)179/1989]	Act 342, Prevention and Control of Infectious Diseases Act 1988 *Incorporating All Amendments Up to 1 January 2006,* the Commissioner of Law Revision, Malaysia Under the Authority of the Revision of Laws Act 1968. Seventh Schedule [Sub regulation 6(1)] of the Prevention and Control of Infectious Diseases Act 1988; Prevention and Control of Infectious Diseases (Importation & Exportation of Human Remains, Human Tissues and Pathogenic Organisms and Substances) Regulations, 2006.
ISBN No: 978-967-10117-0-6	Guideline for Institutional Biosafety Committees: Use of Living Modified Organisms and Related Materials, Ministry of Natural Resources and Environment Malaysia 2010
CWA 15793:2011 D/E/F	Laboratory Biorisk Management CWA 15793:2011 European Committee for Standardization, ICS 07.100.0

https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/	Terrestrial Animal Health Code
https://www.woah.org/en/what-we-do/standards/codes-and-manuals/aquatic-code-online-access/	Aquatic Health Code
http://www.doa.gov.my/index/resources/info_doa/akta_kuarantin_tumbuhan_1976.pd	Plant Quarantine Act 1996
http://www.maqis.gov.my/akta	Malaysian Quarantine and Inspection Services (Quarantine and Inspection) Regulation 2013

3.0 LIST OF ABBREVIATIONS

BAF	: Biosafety Application Form
BSC	: Biological Safety Cabinet
BSL	: Biosafety Laboratory Level
BSO	: Biosafety Officer
BBC	: Biosafety and Biosecurity Coordinator
ERP	: Emergency Response Plan
GLWP	: Good Laboratory Work Practice
GMO	: Genetically Modified Organisms
GMT	: Good Microbiological Technique
IBBC UPM	: Institutional Biosafety and Biosecurity Committee, Universiti Putra Malaysia
JBK NRES	: Department of Biosafety, Ministry of Natural Resources and Environmental Sustainability
LMO	: Living Modified Organisms
NOI	: Notice of Intent
OSH	: Occupational of Safety and Health
PI	: Principal Investigator
rDNA	: Recombinant DNA
SOP	: Standard Operating Procedure
UPM	: Universiti Putra Malaysia
WHO	: World Health Organization

4.0 DEFINITIONS

4.1 Activities - research, teaching and services that involve handling, manipulating, working, using, storing, transporting and disposing of biological materials of infectious and potentially infectious agents/materials including genetically modified organisms (GMO), living modified organisms (LMO), recombinant DNA (rDNA) and biological toxins.

4.2 Biosafety - the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents including GMO, LMO and toxins, or their accidental release.

4.3 Biosecurity - the protection, control and accountability for biological agents including GMO, LMO and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion, unauthorized access or intentional unauthorized release.

4.4 Containment zone - a designated area that allows for the containment, confinement and manipulation of animal, plant, organism, GMO, LMO or rDNA that harbors infectious and potentially infectious agents/materials and biological toxins, which requires good microbiological practices within its perimeter.

4.5 Facility - operational unit and associated buildings and equipment used to manage biological agents and toxins. This includes the laboratory, together with the supporting infrastructure, equipment and services including ancillary rooms such as airlocks, changing rooms, sterilizing room and storage rooms.

4.6 Good Microbiological Technique - as defined by WHO Laboratory Biosafety Manual 3rd Edition, 2004.

4.7 Good Laboratory Work Practice - a quality system concerned with the organizational process and the conditions, under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived, and reported.

4.8 Incidents - an event or occurrence (including near miss) involving infectious material, infected animals, GMO, LMO, rDNA or toxins, including spillage, exposure, release of infectious material or toxins, animal escape, personnel injury or illness, missing infectious material or toxins, unauthorized entry into the containment zone, power failure, fire, explosion, flood, or other crisis situations (e.g. earthquake, flood). Incidents should also include laboratory acquired infection (LAI).

4.9 Preliminary Assessment Form (PAF) – a preliminary assessment of activities.

4.10 Notice of Intent (NOI) - an application for approval prior to commencement of

proposed activity related to infectious and potentially infectious agents/materials, and biological toxins that are harmful to human, animal and plant.

4.11 Biosafety Application Form (BAF) - an application for approval prior to commencement of proposed activity related to GMO, LMO and rDNA.

4.12 Principal Investigator (PI) - the lead scientist who holds direct responsibility for the technical and/or scientific direction of a project, the relevant course coordinator or service laboratory coordinator.

4.13 Record - document stating results achieved or providing evidence of activities performed.

4.14 Risk assessment - process of evaluating the risk(s) arising from a hazard(s), taking into account the adequacy of any existing controls, and deciding whether or not the risk(s) is acceptable.

5.0 PURPOSE OF POLICY AND PROCEDURE

5.1 PURPOSE

The purpose of this policy and procedure is to formalise the Universiti Putra Malaysia (UPM) Institutional Biosafety and Biosecurity Committee (IBBC) obligation in relation to national and international Biosafety and Biosecurity requirements. The IBBC shall:

5.1.1 Identify activities which are under the purview of the IBBC.

5.1.2 Review and approve all applications related to activities involving the use of infectious and potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins in a defined facility and containment zone.

5.1.3 Ensure that all activities involving the use of infectious and potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins are conducted in accordance to all relevant requirements and guidelines.

5.1.4 Maintain compliance with updated international and national policies, laws, regulations and guidelines related to biosafety and biosecurity.

5.2 RESPONSIBILITIES OF UPM

5.2.1 Establish the IBBC

The IBBC is a UPM entity to oversee all activities involving the handling, manipulating, working, using, storing, transporting, and disposing of infectious and potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins.

5.2.1.1 Duties of IBBC

A. Report and be advisory to the Vice Chancellor.
B. Review the submitted Preliminary Assessment Form (PAF)
C. Review the Notice of Intent (NOI) of any activities involving use of infectious and potentially infectious agents/materials, and biological toxins for the compliance to updated international and national policies, laws, regulations, and guidelines related to biosafety and biosecurity matters.
D. Review the Biosafety Application Form (BAF) of any activities involving use of GMO, LMO or rDNA and inspect the laboratory facilities.
E. Notify the Principal Investigator (PI) on the status of submitted PAF, NOI and the BAF.
F. Periodically review the compliance of all registered activities involving use of infectious and potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins.
G. Coordinate with the office of Occupational Safety and Health (OSH) UPM on the following matters for activities involving use of infectious and potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins:
    a) Health and medical surveillance program where relevantand necessary.
    b) Immunization program where relevant and necessary.
    c) Incidents, preventive and corrective actions to minimize future occurrences.
H. Establish and monitor the implementation of biosafety and biosecurity training programs.
I. Ensure that relevant and appropriate biosecurity measures are implemented. This includes physical security, such as infrastructure, containment zone, and perimeter security.

J. Ensure that laboratory personnel background checks, information security are implemented. Information security includes protection of the building security plan, passwords, material inventory, and information of storage site of infectious and potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins.
K. Ensure that the procedure for accountability and traceability of all materials are implemented.
L. Report all incidents to the relevant authorities.
M. Perform such other duties and functions pertaining to biosafety and biosecurity as may be delegated to the IBBC.
N. Record keeping.
O. Perform periodic review of the policy on biosafety and biosecurity, and recommend a subsequent amendment, if required.

5.2.2 Appoint appropriate members to the IBBC.

5.2.3 Appoint Biosafety Officer/s (BSO) to serve as member of the IBBC.

5.2.3.1 Scope of BSO

A. Qualifications
The BSO shall have relevant background experiences and education related to research, containment/facility, biohazard, microbiology and infectious diseases to make him/her capable to develop and implement the necessary requirements related to biosafety and biosecurity.
B. Duties of BSO
a) Assist in developing and implementing:
i. The IBBC policy of the UPM.
ii. Standard procedures and work systems for activities involving use of infectious and potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins including procurement, storing, transporting, handling, disposal, medical surveillance, incident reporting, and risk assessment.
b) Advise, inform and communicate with PI and relevant laboratory personnel regarding biosafety and biosecurity matters which include:

i. Handling, storage, transport and disposal of biohazardous waste, including appropriate equipment, facilities and work practices to prevent exposure to any harmful biological material, and ensure appropriate containment.
ii. Induction of new laboratory personnel with regards to biosafety and biosecurity.
iii. The availability of immunization against potential biohazards.
iv. Information on biosafety and biosecurity policies andprocedures.

c) Review and ensure the implementation of programs associated with:
   i. Biohazard related Emergency Response Plan (ERP).
   ii. Biosafety and biosecurity training.

d) Manage PAF, NOI and BAF submission processes:
   i. Check and process PAF.
   ii. Check the completeness of submitted NOI.
   iii. Check the completeness of BAF.
   iv. Update and informs PI the status of the submitted PAF, NOI and BAF.

e) Conduct periodic post-approval monitoring to ensure that laboratory activities involving the use of infectious and potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins are within the approved scope of work of the application, and the laboratory activities and facilities where the activities performed are in compliance with appropriate laboratory standards and guidelines as determined by the IBBC.

f) Ensure compliance with the updated international and national policies, laws, regulations and guidelines related to biosafety and biosecurity.

g) Report on compliance failure, policy, guidelines and regulations violations, and any biosafety and biosecurity-related incidents, accidents or illnesses.

h) Maintain updated records of:
   i. Inventory of infectious agents and potentially infectious biological materials, GMO, LMO, rDNA and biological toxins.

ii. NOIs and approved projects.
iii. BAFs and approved projects.
iv. Authorized personnel for activities involving use of infectious and potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins.
v. Health and medical, and immunization status of the authorized personnel.
vi. Occurrence of incidents, accidents and illnesses.
vii. Minutes of all relevant meetings, post-approval monitoring, training and compliance documentation.

i) Communicate with relevant agencies and bodies related to biosafety and biosecurity matters.
j) Submit periodic reports on activities involving use of infectious and potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins to the Vice Chancellor, and any other relevant agencies when necessary and required.
k) Assist the Chairperson in all matters relating to the functions of IBBC.
l) Perform other duties assigned by IBBC.

5.2.4 Appoint Biosafety and Biosecurity Coordinator (BBC).

5.2.4.1 Duty of BBC is to assist BSO in implementation of all activities related to biosafety and biosecurity at respective faculties / institutes.

6.0 MEMBERSHIP AND ORGANIZATION OF THE IBBC

6.1 NUMBER OF IBBC COMMITTEE MEMBERS

Membership consists of at least 6 members. The Vice Chancellor will appoint the Chairperson, Vice Chairperson and members of IBBC for 3-year term.

6.2 QUALIFICATIONS OF MEMBERS

6.2.1 The IBBC members shall comprise of persons with experience, expertise, and the capability to assess the safety and any potential risk in handling of infectious and potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins. Membership may include scientists, researchers, academics, medical personnel, veterinarian, engineer, representative of technical staff, and representative of laboratory management.

6.2.2 The BSO also serves as the executive secretary for the IBBC.

6.2.3 Qualified ad-hoc consultants may be invited when other expertise is required.

6.3 IBBC EXECUTIVE SECRETARY

BSO will be acting as the IBBC Executive Secretary and is responsible for performingthe following duties:

6.3.1 Keep the updated details of members.

6.3.2 Record of the attendance of each meeting.

6.3.3 Ensure minimum quorum is met for each meeting.

6.3.4 Record and keep accurate minutes of each meeting.

6.3.5 Prepare and submit reports to the Vice Chancellor and any other relevant agencies when necessary and required.

6.3.6 Serve as the contact person for the IBBC.

6.3.7 Establish, review and maintain all documents and records of the IBBC.

6.4 MEETINGS

6.4.1 Meeting schedule

6.4.1.1 The IBBC shall meet at least two (2) times of each year or whenever necessary.

6.4.1.2 Quorum: At least fifty percent (50%) of the members (excluding any

member with a conflict of interest) must be present during the IBBC meeting.

6.5 CONFLICT OF INTEREST

6.5.1 Any IBBC member who have declared a conflict of interest shall not participate in the review and approval of the respective NOI and application related to infectious and potentially infectious agents/materials, GMO, LMO, rDNA activities and biological toxins.

6.5.2 Minutes of the meeting must record the information on any IBBC member who has declared a conflict of interest.

7.0 SUBMISSION OF PAF TO THE IBBC AND THE REVIEW PROCESS

7.1 SUBMISSION OF PAF

7.1.1 All PIs in UPM shall complete the PAF form (UPM/IBBC/PAF) for all activities that involve the use of infectious and potentially infectious agents/materials and biological toxins in their natural unmodified and genetically modified. This includes activities conducted on the premises of UPM/or facilities under the governance of UPM that involve both UPM and non-UPMPIs. PIs shall submit the completed form to the IBBC by email or hard copy.

7.2 PAF REVIEW PROCESS

7.2.1 IBBC shall review the PAF within 1 month upon receipt of the form.

7.2.2 PIs shall be informed in writing of the PAF review outcome. All communications must be recorded and documented by the BSO and/or the IBBC committee.

7.3 OUTCOMES OF THE PAF REVIEW

7.3.1 **NOI submission required**.
PIs are required to complete the NOI form (step 8.0)

7.3.2 Exempted from NOI submission.
Activities are approved to be conducted. NOI form submission is not required. Each approved PAF is valid for a maximum of five (5) years. PIs are required to re-submit a new PAF form **at least 3 months** before expiry date.

7.3.3 Biosafety Application Form (BAF) submission required

PIs are required to complete the BAF form (step 9.0)

7.3.4 Exempted from Biosafety Application Form (BAF) submission

BAF form submission is not required. Exempted from Biosafety Application Form (BAF) submission (GML/LMO)(Exemption based on User's Guide to the Biosafety Act and Regulations).

7.3.5 Further clarification from Department of Biosafety is required

Biosafety Officer will contact Department of Biosafety on the application within 1 week for further clarification.

8.0 SUBMISSION OF NOI TO THE IBBC AND THE REVIEW PROCESS

8.1 SUBMISSION OF NOI

8.1.1 All PIs in UPM shall notify using Notice of Intent Form (UPM/IBBC/NOI) and obtain approval from the IBBC before the initiation of any activities that involve the handling, manipulating, working, using, storing, transporting and disposing of infectious and potentially infectious agents/materials, and biological toxins. This includes activities conducted on the premises of UPM and/or facilities under the governance of UPM that involve both UPM and non-UPM PIs. PIs shall complete UPM/IBBC/NOI and submit it to the IBBC, accompanied with:

8.1.1.1 Biological Risk Assessment Form (UPM/IBBC/BRAF).

8.1.1.2 Laboratory Self-Inspection Form Biosafety Level 1/2/3 Checklist (UPM/IBBC/BSL 1/BSL2/BSL3), whichever applicable.

8.1.1.3 Personnel Biosecurity Registration Form (UPM/IBBC/PBR)

8.1.1.4 Biosafety and Biosecurity Training Form (UPM/IBBC/BBTF) (refer to section 9.1.5).

8.1.1.5 Additional documents including SOPs relevant to biosafety, and records of maintenance and certification/calibration of relevant equipment, will have to be submitted upon request.

8.2 NOI REVIEW PROCESS

8.2.1 Upon submission, BSO will ensure that all required documents are complete. In the instance where documents are incomplete, the applicant will be clearly notified, and the application will have to be resubmitted together with the required documents.

8.2.2 IBBC Chairperson will appoint suitable IBBC member(s) to review the NOI submissions. The NOI will only be approved when the intended activities personnel and biosafety and biosecurity requirements fulfil the IBBC requirements.

8.2.3 PIs shall be informed in writing of the NOI review outcome. All the communications must be recorded and documented by the BSO and/or the IBBC committee.

8.3 OUTCOMES OF NOI REVIEW

8.3.1 **Approved**

This status is given to NOI that satisfactorily addresses all issues pertaining to biosafety and biosecurity. No additional amendments or changes to the NOI are required. The approved NOI is valid for a maximum of five (5) years, unless a shorter time is specified by the IBBC.

8.3.2 **Approved pending minor modifications**

Minor revisions are required to the NOI. Work under the NOI can only be initiated when the PI addresses all issues raised by the IBBC within one (1) month of the latest review outcome and an “Approved” status is granted for the NOI by the IBBC.

8.3.3 **Deferred**

The NOI is deferred when consultation from an external body is required due to the IBBC members’ limited experience and/or expertise in the proposed field of study and/or technical procedures involved in the study.

8.3.4 **Withhold approval**

The NOI is withheld if it has not adequately addressed the applicable principles of biosafety and biosecurity. Resubmission of the NOI can be made within three (3) months of the latest review outcome; otherwise, the PI must submit a new NOI.

8.4 AMENDMENTS TO APPROVED NOI

PIs shall complete and submit Amendment Form (UPM/IBBC/AMENDMENT) to the IBBC if there are any amendments to their approved NOI. Examples of modifications which require an Amendment Form to be submitted include, but are not limited to, changes in the potentially infectious agents/materials and biological toxins used, changes in the experimental design, changes in personnel, changes in location and/or changes that may increase the Risk Group of the potentially infectious agents/materials and biological toxins and/or the Biosafety Level. The amendment(s) must be reviewed and approved by the IBBC before any work under the NOI can be continued.

8.5 EXTENSION OF APPROVED NOI

Each approved NOI is valid for a maximum of five (5) years. PIs are required to submit the form UPM/IBBC/EXTENSION for application of NOI extension at least **three (3) months** before the expiry date.

8.6 POST-APPROVAL MONITORING

The IBBC may visit laboratories and facilities where IBBC approved activities are conducted to ensure biosafety and biosecurity compliance according to international, national and institutional policies, regulations and guidelines. The visit will be communicated to the PI. Any non-compliance will result in immediate suspension of approval. The BSO or officials performing the visit will submit the inspection report toboth IBBC and the PI concerned.

8.7 NOTIFICATION OF NOI EXPIRY

The expiration of an NOI will be notified to the PI, in writing, at least **four (4) months** before the expiry date.

9.0 SUBMISSION OF BIOSAFETY APPLICATION FORM (BAF) TO THE IBBC AND THE REVIEW PROCESS

9.1 SUBMISSION OF BAF

9.1.1 All PIs in UPM shall notify using relevant Biosafety Application Form (BAF) (https://osh.upm.edu.my/faildokumen) related to the scope of the activities and obtain approval from the IBBC before the initiation of any activities that involve the handling, manipulating, working, using, storing, transporting and disposing of GMO, LMO and rDNA. This includes any activities conducted on the premises of UPM and/or facilities under the governance of UPM that involve both UPM and non-UPM PIs. The scope of the activities includes Notification / Contained Use (Form E) and approval (Form A, B, C, D) depending on the scope of activities. PIs shall complete the relevant application form and submit it to the IBBC, accompanied with:

9.1.1.1 Research proposal.

9.1.1.2 Supporting documents such as grant offer letter, etc.

9.1.1.3 Brief CV of research participants.

9.1.1.4 Laboratory Self-Inspection Form Biosafety Level 1/2/3 Checklist (UPM/IBBC/BSL1/BSL2/BSL3), whichever applicable.

9.1.1.5 Personnel Biosecurity Registration Form (UPM/IBBC/PBR).

9.1.1.6 Biosafety and Biosecurity Training Form (UPM/IBBC/BBTF) (refer to section 10.1.5).

9.1.1.7 Additional documents including SOPs relevant to biosafety, and records of maintenance and certification/calibration of relevant equipment, will have to be submitted upon request.

9.2 BAF APPLICATION REVIEW PROCESS

9.2.1 Upon submission, BSO will ensure that all required documents are complete. In the instance where documents are incomplete, the applicant will be clearly notified and the application will need to be resubmitted together with the required documents.

9.2.2 IBBC Chairperson will appoint suitable IBBC member(s) to review the application submissions. The application will only be approved when the intended activities, personnel and biosafety and biosecurity requirements

aremeet the IBBC requirements.

9.2.3 PIs shall be informed in writing of the application review outcome. All communications must be recorded and documented by the BSO and/or the IBBC committee.

9.3 OUTCOMES OF BAF APPLICATION REVIEW

9.3.1 Approved

This status is given to application that satisfactorily addresses all issues pertaining to biosafety and biosecurity. No additional amendments or changes to the application are required prior submission to JBK NRES.

9.3.2 Approved pending minor modifications

Minor revisions are required to the application. Work under the application can only be initiated when the PI addresses all issues raised by the IBBC within one (1) month of the latest review outcome and an "Approved" status is granted for the application by the IBBC for submission to JBK NRES.

9.3.3 Deferred

The application is deferred when consultation from an external body is required due to the IBBC members' limited experience and/or expertise in the proposed field of study and/or technical procedures involved in the study.

9.3.4 Withhold approval

The application is withheld if it has not adequately addressed the applicable principles of biosafety and biosecurity. Resubmission of the application can be made within three (3) months of the latest review outcome; otherwise the PI must submit a new application.

9.4 AMENDMENTS TO APPROVED BAF

PIs shall complete and submit Amendment Form (UPM/IBBC/AMENDMENT) to the IBBC if there are any amendments to their approved BAF application. Examples of modifications which requires an amendment form to be submitted include, but are not limited to, changes in the potentially infectious agents/materials, GMO, LMO and biological toxins used, changes in the experimental design, changes in personnel, changes in location and/or changes that may increase the Risk Group of the potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins and/or the Biosafety Level. The amendment(s) must be reviewed and approved by the IBBC before any work under the NOI can be continued.

9.5 EXTENSION/NOTICE OF TERMINATION OF APPROVED APPLICATION

PIs are required to submit the extension form/notice of termination (ANNEX 5) from JBK NRES for application of extension at least three (3) months before the expiry date.

9.6 POST-APPROVAL MONITORING

The JBK NRES may visit laboratories and facilities where IBBC approved activities are conducted to ensure biosafety and biosecurity compliance according to international, national and institutional policies, regulations and guidelines. The inspection will be communicated to the PI. Any non-compliance may result in immediate suspension of approval. The BSO or officials performing the visit will prepare a report of the findings to be submitted to both the IBBC and the PI concerned.

10.0 RESPONSIBILITIES OF PI

10.1 PI shall register all activities involving use of infectious and potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins by submitting the Preliminary Assessment Form (UPM/IBBC/PAF).

10.2 PI shall submit NOI upon request, and the NOI will be reviewed and approved by IBBC prior to commencement of the project.

10.3 PI shall submit BAF application form related to GMO LMO and rDNA activities upon request, and the application will be reviewed by IBBC and approved by JBK KASA prior to commencement of the project.

10.4 The PI is responsible to ensure that all activities involving use of infectious and potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins comply with international, national and institutional policies, guidelines and regulations related to biosafety and biosecurity.

10.5 The PI shall inform the personnel of the potential hazards associated with the activities, the exposure evaluation procedures and appropriate exposure precautions and ensure that his/her personnel working with infectious and potentially infectious agents/materials, GMO, LMO, rDNA and biological toxins are trained in laboratory biosafety and biosecurity, including Good Microbiological Technique (GMT), Good Laboratory Work Practices (GLWP) and otherrelevant practices. The training can be formal or informal, but it must be documented. The PI is responsible for the competency of the personnel in the conduct of the activities. Proposed laboratory biosafety and biosecurity training must include:

10.5.1 Institutional specific training.

10.5.2 Basic laboratory biosafety and biosecurity.

10.5.3 Agent-specific laboratory biosafety and biosecurity.

10.5.4 Job-specific laboratory biosafety and biosecurity such as the proper use of biological safety cabinet (BSC), waste disposal management, equipment handling, etc.

10.6 The PI is responsible for maintaining an up-to-date Biological Material Inventory (BMI).

10.7 The PI shall submit a new PAF application (for PAF approved project), IBBC Extension/Notice of Termination form (for NOI approved project) or Annex 5A/Annex 5B Form (for BAF approved project) at least 3 months before the expiry date to IBBC.

10.8 For the submission of application, PI shall:

10.8.1 Submit the Preliminary Assessment Form (UPM/IBBC/PAF). PI will be notified on the registration and the status on the requirement for NOI submission.

10.8.2 For activities involving the use of infectious and potentially infectious agents/materials, and biological toxins, submit the full application that includes the following documents:

10.8.2.1 NOI Form (UPM/IBBC/NOI),

10.8.2.2 Biological Risk Assessment Form (UPM/IBBC/BRAF),

10.8.2.3 Laboratory Self-Inspection Form Biosafety Level 1/2/3 (UPM/IBBC/BSL 1/2/3), whichever applicable,

10.8.2.4 Personnel Biosecurity Registration Form (UPM/IBBC/PBR),

10.8.2.5 Biosafety and Biosecurity Training Form (UPM/IBBC/BBTF) (refer to section 10.1.5). Additional documents including SOPs relevant to biosafety, and records of maintenance and certification/calibration of relevant

equipment, will have to be submitted upon request.

10.8.3 For GMO/LMO activities, submit the full application that includes thefollowing documents:

10.8.3.1 Biosafety Application Form (BAF) (Forms A, B, C, D, E), whichever applicable together with the relevant supporting documents. Refer toJBK KASA guideline (https://osh.upm.edu.my/faildokumen).,

10.8.3.2 Laboratory Self-Inspection Form Biosafety Level 1/2/3 Checklist (UPM/IBBC/BSL 1/2/3), whichever applicable,

10.8.3.3 Personnel Biosecurity Registration Form (UPM/IBBC/PBR),

10.8.3.4 Biosafety and Biosecurity Training Form (UPM/IBBC/BBTF) (refer to section 9.1.5),

10.8.3.5 Additional documents including SOPs relevant to biosafety, and records of maintenance and certification/calibration of relevant equipment, will have to be submitted upon request.

10.8.4 PI maintain communication with IBBC throughout the conduct of activities until completion.

10.8.5 Report and notify any significant incidents or potential exposure that can cause human illness, potential plant or animal disease outbreak, or unintended release of infectious agents/materials and biological toxin:

i. For GMO/LMO/rDNA activities – submit the Incident Reporting Form (IBBC/IR/10/ANNEX 3) - JBK NRES.

ii. For infectious and potentially infectious

agents/materials and biological toxins – submit the Incident Reporting Form (UPM/IBBC/INCIDENT).

10.8.6 Submit updated Biological Material Inventory Form (UPM/IBBC/BMI) of infectious agents and potentially infectious biological reference materials upon request.

10.8.7 Submit the Amendment Form (UPM/IBBC/AMENDMENT) if there are any amendments or changes required.

10.8.8 The PI shall submit a new PAF application (for PAF approved project) **at least 3 months** before the expiry date to IBBC.

10.8.9 For extension

i. For GMO/LMO/rDNA - submit the Extension/notice of termination(IBBC/PE-NT/10/ANNEX 5A) **at least 3 months** before the expiry date to IBBC.

ii. For infectious and potentially infectious agents/materials and biological toxins - submit the Extension Form (UPM/IBBC/EXTENSION) **at least 3 months** before the expiry date to IBBC.

10.8.10 For termination:

i. For GMO/LMO/rDNA - submit the Extension/Notice of Termination (IBBC/PE-NT/10/ANNEX 5B) **at least 3 months** before the expiry date to IBBC.

ii. For infectious and potentially infectious agents/materials and biological toxins – submit the Notice of Termination Form (UPM/IBBC/NOT) **at least 3 months** before the expiry date to IBBC.

11.0 RECORD KEEPING

11.1 IBBC shall maintain security and confidentiality of data records of registrations, documents, laboratory personnel details and copies of all documented correspondences.

11.2 All records shall be kept for **seven (7)** years as required by the IBBC and regulatory bodies.

LIST OF FORMS FOR GMO, LMO, rDNA RELATED ACTIVITIES

DOCUMENT CODE	FORM NAME
UPM/IBBC/PAF	Preliminary Assessment Form
UPM/PPKKP/IBBC/FORM IBBC(E1)	Notification of Exempted Living Modified Organism Contained Use Activities
NBB/A/ER/10/FORM A	Approval for Release Activities of Living Modified Organism (LMO) (Research and Development Purposes in All Field Experiments) Or Importation of LMO That Is Higher Plant
NBB/A/ER/10/FORM B	Approval for Release Activities of Living Modified Organism (LMO) (Research and Development Purposes in All Field Experiments) Or Importation of LMO Other Than Higher Plants
NBB/A/ER/23/FORM C	Approval for Release Activities (Second Schedule 2-6) Or Importation of Living Modified Organism (LMO) That Is A Higher Plant and Product of Such Organism
NBB/A/ER/10/FORM D	Approval for Release Activities (Second Schedule 2-6) Of Living Modified Organism (LMO) Other Than A Higher Plant and Product of Such Organism
NBB/N/CU/22/FORM E	Notification for Contained Use and Import for Contained Use Activities Involving Living Modified Organism (LMO) for Biosafety Levels 1,2,3 and 4
NBB/N/Ex/23/FORM F	Notification for Export of Living Modified Organism (LMO)
UPM/IBBC/BSL 1/BSL2/BSL3	Laboratory Self-Inspection Form Biosafety Level 1/2/3 Checklist
UPM/IBBC/PBR	Personnel Biosecurity Registration Form
IBC/AP/20/ANNEX 2	IBBC Assessment of Project Proposal Involving Modern Biotechnology Activities
IBC/IR/20/ANNEX 3	Incident Reporting Form
IBC/OD/20/ANNEX4	Occupational Disease / Exposure Investigation Form
IBC/PE/20/ANNEX 5A	Project Extension Form
IBC/NT/20/ANNEX 5B	Notice of Termination Form
IBC/TR/23/ANNEX 5C	Notice of Transfer of LMO in Storage Form
UPM/IBBC/BMI	Biological Material Inventory Form
UPM/IBBC/BBTF	Biosafety and Biosecurity Training Form
SOP TEMPLATE	Standard Operating Procedure
UPM/IBBC/BSCLF	Biosafety Submission Checklist Form

LIST OF FORMS FOR NON-GENETICALLY MODIFIED MICRORGANISMA RELATED ACTIVITES

DOCUMENT CODE	FORM NAME
UPM/IBBC/PAF	Preliminary Assessment Form
UPM/IBBC/NOI	Notice of Intent Form
UPM/IBBC/BRAF	Biological Risk Assessment Form
UPM/IBBC/BSL 1/BSL2/BSL3	Laboratory Self-Inspection Form Biosafety Level 1/2/3 Checklist
UPM/IBBC/PBR	Personnel Biosecurity Registration Form
UPM/IBBC/INCIDENT	Incident Reporting Form
UPM/IBBC/AMENDMENT	Amendment Form
UPM/IBBC/EXTENSION	Extension Form
UPM/IBBC/NOT	Notice of Termination Form
UPM/IBBC/BMI	Biological Material Inventory Form
UPM/IBBC/BBTF	Biosafety and Biosecurity Training Form
SOP TEMPLATE	Standard Operating Procedure
UPM/IBBC/BBSCLF	Biosafety & Biosecurity Submission Checklist Form