
	UNIVERSITI MALAYA POLICY AND PROCEDURE ON LABORATORY BIOSAFETY AND BIOSECURITY		
UNIVERSITI MALAYA BIOSAFETY AND BIOSECURITY COMMITTEE	Document: IBBC-001	Version : 01	Effective Date: Aug 2015

1. List of Abbreviations


BSC	Biological Safety Cabinet
BSL	Biosafety Level
BSO	Biosafety Officer
CWA	CEN Workshop Agreement
GLP	Good Laboratory Practice
GMT	Good Microbiological Technique
ERP	Emergency Response Plan
IBBC	Institutional Biosafety and Biosecurity Committee
NOI	Notice of Intent
OHSAS	Occupational Health and Safety Advisory Services
OSH	Office of Safety and Health
PI	Principal Investigator
SOP	Standard Operating Procedure
UM	Universiti Malaya
UMBC	Universiti Malaya Biosafety Committee
WHO	World Health Organization

2. Definitions

2.1 Activities - research, teaching and services that involve handling, manipulating, working, using, storing, transporting and disposing of infectious and potentially infectious agents/materials and biological toxins.

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- 2.2 Biosafety - the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release. (adapted from: WHO/CDS/EPR/2006.6)
- 2.3 Biosecurity - the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release. (adapted from: WHO/CDS/EPR/2006.6)
- 2.4 Containment zone - a designated area that allows for the containment, confinement and manipulation of animal, plant or organism that harbours infectious and potentially infectious agents/materials and biological toxins, which requires good microbiological techniques within its perimeter. (adapted from: Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline, Ministry of Health Malaysia, 2015, 1st Edition)
- 2.5 Facility - operational unit and associated buildings and equipment used to manage biological agents and toxins.
- NOTE 1: 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. (adapted from: Laboratory Biorisk Management CWA 15793:2011, European Committee for Standardization, ICS 07.100.0)
- 2.6 Good Microbiological Technique - as defined by WHO Laboratory Biosafety Manual 3rd Edition, 2004.
- 2.7 Good Laboratory 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. (adapted from: Handbook: good laboratory practice (GLP): quality practices for regulated non-clinical research and development - 2nd edition, World Health Organization on behalf of the Special Programme for Research and Training in Tropical Diseases 2009)

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2.8 Incidents - an event or occurrence (including near miss) involving infectious material, infected animals, or toxins, including a spill, 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). (adapted from: Canadian Biosafety Standards and Guidelines First Edition, 2013)

2.9 Notice of Intent (NOI) - an application for approval prior to commencement of proposed activity.

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

2.11 Record - document stating results achieved or providing evidence of activities performed. (adapted from: OHSAS 18001:2007)

2.12 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. (adapted from: OHSAS 18001:2007)


3. Scope and Purpose of Policy and Procedure

3.1 Purpose

The purpose of this policy and procedure is to formalize the Universiti Malaya (UM) Institutional Biosafety and Biosecurity Committee (IBBC) obligation in relation to national and international Biosafety and Biosecurity requirements. The IBBC shall:

3.1.1 identify activities which are under the purview of the IBBC.

3.1.2 review and approve any applications related to activities involving the use of infectious and potentially infectious agents/materials and biological toxins in a laboratory and defined containment zone.

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3.1.3 ensure that all activities involving the use of infectious and potentially infectious agents/materials and biological toxins are conducted in accordance to all relevant requirements and guidelines.

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

3.2 Scope

This document consists of the basic concepts and approaches in the form of policy and procedure that govern all activities involving the handling, manipulating, working, using, storing, and disposing of infectious and potentially infectious agents/materials and biological toxins in all forms and sizes of laboratories and containment zone in UM.


3.3 Responsibilities of UM

3.3.1 Establish the IBBC

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

3.3.1.1 Duties of IBBC


- A. Report and be advisory to the Vice Chancellor through the Chairman of the Compliance Committee.
- B. Review the submitted 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.
- C. Notify the Principal Investigator (PI) on the status of submitted NOI.
- D. Periodically review the compliance of all registered activities involving use of infectious and potentially infectious agents/materials and biological toxins.

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- E. Coordinate with the University Malaya Biosafety Committee (UMBC) and Office of Safety and Health (OSH) on the following matters for activities involving use of infectious and potentially infectious agents/materials and biological toxins:
 - a) health and medical surveillance program.
 - b) immunization program where relevant and necessary.
 - c) incidents, corrective and preventive actions to minimize future occurrences.
- F. Establish and evaluate the implementation of a biosafety and biosecurity training program.
- G. Ensure that relevant and appropriate biosecurity measures are implemented. This includes physical security, such as infrastructure, containment zone, and perimeter security. Information security includes protection of the building security plan, passwords, material inventory, and information of storage site of infectious and potentially infectious agents/materials and biological toxins. Laboratory personnel security includes background checks or security clearances. Procedure for accountability and traceability of all materials should be implemented.
- H. Report all incidents to the relevant authorities.
- I. Perform such other duties and functions pertaining to biosafety and biosecurity as may be delegated to the IBBC.
- J. Record keeping.
- K. Perform periodic review of the policy on biosafety and biosecurity, and recommend a subsequent amendment, if required.

3.3.2 Appoint appropriate members to the IBBC.

3.3.3 Appoint a Biosafety Officer (BSO) to serve as a member of the IBBC.

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3.3.3.1 Scope of BSO

A. Qualifications

The BSO shall have 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 UM.
- ii. standard procedures and work systems for activities involving use of infectious and potentially infectious agents/materials and biological toxins in UM including procurement, storing, transporting, handling, disposal, medical surveillance, incident reporting, and risk assessment.

b) Advise, inform and communicate with 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 and procedures.

c) Review and ensure the implementation of programs associated with

- i. biohazard related Emergency Response Plan (ERP).
- ii. biosafety and biosecurity training.

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- d) Manage NOI submission process:
 - i. review the completeness of submitted NOI.
 - ii. update and informs the status of the submitted NOI.
- e) Conduct periodic post-approval monitoring to ensure that laboratory activities involving the use of infectious and potentially infectious agents/materials and biological toxins are within the approved scope of work of the NOI, and the laboratory activities and facilities where the activities are 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 reference materials.
 - ii. NOIs and approved projects.
 - iii. authorized personnel for activities involving use of infectious and potentially infectious agents/materials and biological toxins.
 - iv. health and medical, and immunization status of the authorized personnel.
 - v. occurrence of incidents, accidents and illnesses.
 - vi. 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.

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- j) Submit periodic reports on activities involving use of infectious and potentially infectious agents/materials and biological toxins to the Vice Chancellor, Chairman of Compliance Committee, UMBC, 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.

4. Membership and Organization of the IBBC

4.1 Number of IBBC Committee Members

Membership consists of at least three (3) members. The Vice Chancellor will appoint the Chairperson and the Deputy Vice Chancellor (Research and Innovation) will appoint the members of IBBC for a two (2) year term.

4.2 Qualifications of Members

4.2.1 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 and biological toxins. Membership may include scientists, researchers, academics, medical personnel, veterinarian, engineer, representative of technical staff, and representative of laboratory management.

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

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


4.3 IBBC Executive Secretary

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

4.3.1 keep the updated details of members.

4.3.2 record of the attendance of each meeting.

4.3.3 ensure minimum quorum is met for each meeting.

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4.3.4 record and keep accurate minutes of each meeting.

4.3.5 prepare and submit reports to the Vice Chancellor, Chairman of Compliance Committee, UMBC and any other relevant agencies when necessary and required.

4.3.6 serve as the contact person for the IBBC.

4.3.7 establish, review and maintain all documents and records of the IBBC.

4.4 Meetings

4.4.1 Meeting schedule

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

4.4.1.2 Quorum: At least fifty percent (50%) of the members (excluding any member with a conflict of interest) must be present during the IBBC meeting.

4.5 Conflict of Interest


4.5.1 Any IBBC member who have declared a conflict of interest shall not participate in the review and approval of the respective NOI.

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

5. Submission of NOI to the IBBC and the Review Process

5.1 Submission of an NOI

5.1.1 All PIs in UM shall notify using **UM/IBBC/FORM B** 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 any activities conducted on the premises of UM and/or facilities under the governance of UM that involve both UM and non-UM PIs. IBBC approval must also be obtained for activities conducted by UM PIs at non-UM facilities. PIs shall complete **UM/IBBC/FORM B** and submit it to the IBBC, accompanied with:

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5.1.1.1 Biological Risk Assessment Form (**UM/IBBC/ANNEX 1**).

5.1.1.2 Laboratory Self-Inspection Form Biosafety Level 1/2/3 Checklist (**UM/IBBC/ANNEX 2/3/4**), whichever applicable.

5.1.1.3 Personnel Biosecurity Registration Form (**UM/IBBC/ANNEX 5**)

5.1.1.4 Records of personnel training related to laboratory biosafety (refer to section 6.1.4)

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

5.2 NOI Review Process

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


5.2.2 IBBC members will review all NOI submissions in an IBBC meeting with a quorum of at least fifty percent (50%) of its members present. The NOI will only be approved when the majority of the IBBC members decided that the intended activities, personnel and biosafety and biosecurity requirements are deemed meeting the IBBC requirements.

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

5.3 Outcomes of NOI Review

5.3.1 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 three (3) years, unless a shorter time is specified by the IBBC.

5.3.2 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

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within one (1) month of the latest review outcome and an “Approved” status is granted for the NOI by the IBBC.

5.3.3 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.

5.3.4 Withhold approval: The NOI is withheld if it has not adequately addressed the applicable principles of biosafety and biosecurity. The decision outcome of the IBBC cannot be overruled by any other institutional authority and/or bodies. Resubmission of the NOI can be made within three (3) months of the latest review outcome; otherwise the PI must submit a new NOI.


5.4 Amendments to approved NOI

PIs shall complete and submit form **UM/IBBC/FORM C** to the IBBC if there are any amendments to their approved NOI. Examples of modifications which requires 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.

5.5 Extension of Approved NOI

Each approved NOI is valid for a maximum of three (3) years. PIs are required to submit the form **UM/IBBC/FORM D** for application of NOI extension at least three (3) months before the expiry date. NOI extension applications will be reviewed by the IBBC before it is approved. The maximum period of extension is one (1) year only.

5.6 Post-Approval Monitoring

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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 prepare a report of the findings to be submitted to both the IBBC and the PI concerned.

5.7 Notification of NOI Expiry

The expiry of an NOI will be related to the PI, in writing, **three (3) months** before the actual expiry date.

6. Responsibilities of PI

6.1 General Responsibilities

6.1.1 PI shall register all activities involving use of infectious and potentially infectious agents/materials and biological toxins by submitting the Preliminary Assessment Form **(UM/IBBC/FORM A)**.


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

6.1.3 The PI is responsible to ensure that all activities involving use of infectious and potentially infectious agents/materials and biological toxins comply with international, national and institutional policies, guidelines and regulations related to biosafety and biosecurity. Failure to comply may result in immediate suspension of NOI approval.

6.1.4 The PI shall ensure that his/her personnel working with infectious and potentially infectious agents/materials and biological toxins are trained in laboratory biosafety and biosecurity, including Good Microbiological Technique (GMT), Good Laboratory Practices (GLP) and other relevant practices.

Proposed laboratory biosafety and biosecurity training must include:

6.1.4.1 institutional specific training

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6.1.4.2 basic laboratory biosafety and biosecurity.

6.1.4.3 agent-specific laboratory biosafety and biosecurity.

6.1.4.4 job-specific laboratory biosafety and biosecurity such as the proper use of biological safety cabinet, waste disposal management, equipment handling, etc.

6.2 Responsibilities to the IBBC

6.2.1 For the submission of application, PI shall:

6.2.1.1 submit the Preliminary Assessment form (**UM/IBBC/FORM A**). PI will be notified on the registration and the status on the requirement for NOI submission.

6.2.1.2 submit the full application that includes NOI Form (**UM/IBBC/FORM B**), and the following documents:

A. Biological risk assessment form (**UM/IBBC/ANNEX 1**).

B. Laboratory Self-Inspection Form Biosafety Level 1/2/3 Checklist (**UM/IBBC/ANNEX 2/3/4**), whichever applicable.

C. Personnel Biosecurity Registration Form (**UM/IBBC/ANNEX 5**)


D. Records of personnel training related to biosafety (refer to section 6.1.4)

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

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

6.2.1.4 report and notify any significant incidents or potential exposure (Incident Reporting Form **UM/IBBC/ANNEX 6**) that can cause human illness, potential plant or animal disease outbreak, or unintended release of infectious agents/materials and biological toxin.

6.2.1.5 submit updated inventory of infectious agents and potentially infectious biological reference materials upon request.

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6.2.1.6 submit the **UM/IBBC/FORM C** if there are any amendments or changes required to the approved NOI.

6.2.1.7 submit the **UM/IBBC/FORM D** if an extension of the approved NOI is required.

6.3 Responsibilities with regards to SOPs/Conduct of the Activities

The PIs shall:

6.3.1 provide relevant SOPs to the personnel.

6.3.2 inform the personnel of the potential hazards associated with the activities, the exposure evaluation procedures and appropriate exposure precautions.

6.3.3 ensure that personnel receive adequate job specific training which includes the proper use of biological safety cabinet (BSC), waste disposal management, equipment handling and maintenance, and other relevant activities. 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.

6.3.4 ensure that the laboratory biosafety practices of the personnel are adhered to the required SOPs.

6.3.5 maintain the integrity of the physical and bio-containment/Biosafety Level (BSL) used for the activities.


7 Record Keeping

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


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

8 Relevant Documents and References

- i. Policies and Procedures of the Emory University Institutional Biosafety Committee, Version:2, Environmental Health and Safety Office, Emory University, March 12, 2014.

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- iv. Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition, U.S. Department of Health and Human Services, Public Health Service Centers for Disease Control and Prevention, National Institutes of Health, HHS Publication No. (CDC) 21-1112, Revised December 2009 (<http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf>).
- v. Laboratory Biorisk Management CWA 15793:2011, European Committee For Standardization, ICS 07.100.0
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- vi. Canadian Biosafety Standards and Guideline, 1st Edition, 2013, ISBN: 978-1-100-22266-0
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- viii. Guidance on regulations for the Transport of Infectious Substances 2007– 2008, World Health Organization, Applicable as from 1 January 2007.
- ix. International Health Regulations (2005) IHR Core Capacity Monitoring Framework: Questionnaire For Monitoring Progress In The Implementation Of IHR Core Capacities In States Parties 2011 Questionnaire.
- x. 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, In Collaboration With Percetakan Nasional Malaysia Bhd 2006.

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- xii. Guideline for Institutional Biosafety Committees, use of living modified organisms and related materials, Ministry of Natural Resources and Environment Malaysia 2010.
- xiii. The University of Chicago Institutional Biosafety Committee (IBC) and Select Agent (SA)-IBC Policy and Procedure Manual, 2014,
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