

GUIDELINES FOR INSTITUTIONAL BIOSAFETY COMMITTEES

USE OF LIVING MODIFIED ORGANISMS
AND RELATED MATERIALS





GUIDELINES FOR INSTITUTIONAL BIOSAFETY COMMITTEES:

USE OF LIVING MODIFIED ORGANISMS AND RELATED MATERIALS

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For further information, please contact:

Department of Biosafety
Ministry of Natural Resources and Environment
Level 1, Podium 2,
Wisma Sumber Asli, Precinct 4,
62574 Putrajaya, Malaysia

Phone : +603 8886 1580

Fax : +603 8890 4935

Email : biosafety@nre.gov.my

Website: <http://www.biosafety.nre.gov.my>

FOREWORD

It was indeed a significant landmark event when the Malaysian Biosafety Act was passed in the Parliament on 11 July 2007 and received the Royal Assent on 29 August 2007 before it is enforced effective from 1 December 2009. Even though it has been a rugged journey for this Act to be a reality, it is a positive and promising beginning for Malaysia to take proactive approaches towards protecting human health and the environment from the possible adverse effects of the products of modern biotechnology as well as fulfill Malaysia's obligation under the Cartagena Protocol on Biosafety. As part of the initiatives to establish legal and regulatory framework that permits effective implementation of the Act, the Ministry of Natural Resources and Environment has published the Guidelines of Institutional Biosafety Committee (IBC): Use of Living Modified Organism and Related Material.

These guidelines outline the setting up of IBC, role of IBC and processes that must be followed when obtaining, using, transferring, storing or destroying LMO/ rDNA materials. Other information found in this guideline include responsibilities of the biological safety officers and researchers, IBC membership, review done by IBC, actions required for reporting of incidents and spills and other related information. This document was reviewed by Malaysian experts.

It is hoped that these guideline will be useful for all organizations who are involved in conducting research and development of modern biotechnology and to ensure that these activities comply with the Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010 and other related government regulations and policies to safeguard human, plant and animal health and the environment.

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Director General

Department of Biosafety

Ministry of Natural Resources and Environment

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1 INTRODUCTION

1.1 Purpose

The purpose of this guideline is to provide guidance to organisations that conduct research or activities involving LMO/rDNA on the setting up of an Institutional Biosafety Committee (IBC) in compliance with the Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010 and other related government regulations and policies to safeguard human health and the environment.

1.2 Scope

This guideline describes the setting up of the IBCs, its role and functions and also processes that must be followed when obtaining, using, storing, transferring, or destroying LMO/rDNA materials. It also provides an overview of the relevant regulatory requirements.

1.3 Definitions

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

a) 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 (S3, Biosafety Act 2007).

b) rDNA

A recombinant DNA molecule (rDNA) is defined as either:

- i) 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
- ii) Molecules that result from the replication of those described in (i) above

c) Head

The Head refers to the Head of an organisation involved in modern biotechnology, e.g. Vice Chancellor/Rector of a university or other educational institute, Chief Executive Officer (CEO) - usually of a body corporate, Director General/Director/Head of an Agency, Cooperative Research Centre, Department, Division, Institute, Industrial Research and Development Unit or its equivalent.

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d) IBC

The Institutional Biosafety Committee (IBC) is a formal expert committee of an organisation undertaking modern biotechnology work which involves the use of any LMO/rDNA materials. However, the scope of the IBC may be extended as deemed necessary by the respective organisation. The IBC should be chaired by the Head of the organisation or his designate (a suitable senior officer).

e) BSO

The Biological Safety Officer (BSO) is the designated officer who assists in assuring compliance to the Biosafety Act 2007 and the Biosafety (Approval and Notification) Regulations 2010 pertaining to LMO/rDNA research conducted at an organisation.

f) PI

The Principal Investigator (PI) is involved in conducting modern biotechnology research in an organisation/institution. The PI is accountable to the IBC and must comply with the appropriate research guidelines and all applicable laws and guidelines related to biosafety.

g) NBB

The National Biosafety Board (NBB) refers to the Board established under S4(1) of the Biosafety Act 2007.

h) OHSC

The Occupational Health and Safety Committee (OHSC) established under the guidelines of the Occupational Safety and Health Act 1994 ensures that the research carried out protects the safety, health and welfare of personnel and entrants. As a secondary effect, OHSC may also protect co-workers, customers, suppliers, nearby committees and other members of the public impacted by the workplace.

i) RRT

The Rapid Response Team (RRT), a subcommittee of the IBC, is appointed by the Head of the organisation and is composed of the BSO, IBC Chair, and other relevant members. The purpose of the RRT is to review each incident that involves rDNA, within 24 hours of occurrence and to immediately engage the different components of the organisation, including the IBC and OHSC.

j) Incident

This means unintended release, breach of containment, spill or occupational exposure to LMO/rDNA materials.

1.4 Compliance with the Malaysian Biosafety Act 2007 and other related Regulations

Any organisation, which undertakes modern biotechnology research and development, shall establish an Institutional Biosafety Committee (IBC) to ensure that any LMO/rDNA research, conducted at or sponsored by the organisation, irrespective of the source of funding, shall comply with the Malaysian Biosafety Act 2007, any other related regulations and Malaysian laws relating to import and export, human, plant and animal health, environment and biological diversity. The IBC shall be registered with the Board by submitting Form G (NBB/IBC/10/FORM G).

Non-compliance may result in:

Suspension, limitation or termination of the noncompliant research project along with other enforcement orders on the organisation, as dealt with in Part VI, Biosafety Act 2007.

2 INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

2.1 IBC Responsibilities

IBC is established under the Biosafety (Approval and Notification) Regulations 2010. The responsibilities of the IBC include, but are not limited to the following:

- a) Provide guidance to PI on biosafety policies and issues in the use of LMO/rDNA research, including safety of laboratory personnel and other members of the organisation.
- b) Recommend approval for LMO/rDNA research projects that are found to conform to Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010 and periodically reviewing these research projects.
- c) Assess and monitor the facilities, procedures, practices, training and expertise of personnel involved in LMO/rDNA 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 LMO/rDNA to the NBB.
- e) Assess and set containment levels for LMO/rDNA 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 LMO/rDNA research.
- h) Review and report to the Head of the organisation and to the NBB any significant problems with non-compliance of the Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010 and any significant research-related accidents or illnesses.
- i) Ensure the information provided in the relevant application form (Approval/Notification) is correct and complete.

2.1.1 Other related responsibilities

- a) Assist in the development of appropriate procedures as required by NBB, to oversee the possession and/or use of LMO/rDNA materials.
- b) Recommend suspension of project approval for the possession or use of LMO/rDNA materials 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. Follow up procedures should include biosafety review with improvements/modification or cessation of project approval with notification to NBB.

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- c) Routinely review the policies and procedures of the IBC and modify them as necessary to ensure appropriate biosafety measures and compliance with Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010.

2.1.2 Modern Biotechnology Experiments that require IBC Approval

IBC approval is required for activities involving the following:

- a) Deliberate transfer of a drug resistance trait to microorganisms.
- b) Deliberate transfer of rDNA or DNA/ RNA derived from rDNA into human research participants (human gene transfer).
- c) 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.
- d) Use of Risk Group 2, Risk Group 3 or Risk Group 4 agents as host-vector systems (refer to Biosafety Guidelines for Contained Use Activity of LMOs).
- e) Cloning of DNA from Risk Group 2 or greater agents (refer to Biosafety Guidelines for Contained Use Activity of LMOs) into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.
- f) Use of infectious or defective Risk Group 2 or greater agents (refer to Biosafety Guidelines for Contained Use Activity of LMOs).
- g) Use of whole animals in which the animal's genome has been altered by stable introduction of rDNA or DNA/ RNA derived from rDNA into a germ-line (transgenic animal).
- h) Viable rDNA-modified microorganism tested on whole animals.
- i) Genetically engineered plants by rDNA methods.
- j) The formation of rDNA material containing two-thirds or more of the genome of a eukaryotic virus.

2.2 IBC Membership

The IBC is registered with the NBB for purpose of LMO/rDNA research. The IBC is composed of members who are appointed by the Head of the organisation. Members should represent the organisation and may include representatives from the community at large. Members will collectively have experience and expertise in LMO/rDNA research and the capability to assess the safety of research involving LMO/rDNA 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

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The IBC may consult with NBB to address issues pertaining to the organisation's IBC, policies, applicable laws (state and federal), and standards of conduct and practice.

2.3 IBC Chair

2.3.1 IBC Chair Appointment

The Head of the organisation or his designate (a suitable senior officer) should chair the IBC. The Chair should represent the organisation and have knowledge and experience in scientific research pertaining to LMO/rDNA.

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 organisation 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 Head of the organisation. The BSO is a member of IBC and must be affiliated with the organisation. The appointed person is recommended to be a permanent BSO of the IBC.

2.4.2 BSO Responsibilities

The BSO is responsible for submitting all applications for approval and notifications and the annual report of IBC to the NBB, on behalf of the organisation.

2.5 IBC Members

IBC members are appointed by the Head of the organisation, and will serve a 1 to 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 LMO/rDNA materials are reviewed and approved in a safe and appropriate manner in accordance with all federal, state and institutional regulations, policies and procedures. Membership will be annually evaluated by the IBC Chair and Head of the organisation, based upon participation.

2.5.1 Changes in IBC Membership

IBC members may be removed or replaced by the Head of the organisation. The IBC Chair notifies NBB 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.

2.5.2 Use of Consultants

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. They may also include representatives from relevant ministries and government agencies e.g. Ministry of Health, Ministry of Agriculture and Agro-Based Industry.

2.6 IBC Meetings

2.6.1 Regular Meetings

The IBC should meet at least once a year to review and approve projects and to conduct project extension review of approved projects.

2.6.2 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 LMO/rDNA materials at the organisation.

2.6.3 IBC Materials

Prior to the regular meeting, each member should be sent a copy of the materials being reviewed at the meeting, in addition to other information to be discussed.

2.6.4 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 LMO/rDNA materials requires a majority 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.

2.6.5 Attendance

Attendance of members at IBC meetings is mandatory. Members who are unable to attend a meeting should provide a written summary of their review and any concerns to the IBC. The members also have to provide a show cause letter to explain the absence. Members who fail to attend meetings on a regular basis or fail to contribute in the research review process may be removed from the committee.

2.6.6 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 to be submitted to the NBB.
- 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 after inspection of LMO/rDNA facilities.
- 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 LMO/rDNA materials.

For each project reviewed, IBC meeting minutes will include references to each of the above, as appropriate. The intent of the minutes will be to provide sufficient detail about discussions on these matters and to document the IBC's rationale for particular decisions taken.

2.7 IBC Records

2.7.1 Retention

The IBC should retain the following records for at least six years (unless the IBC is no longer registered with NBB within that period) after completion of the research project (in hard or soft copies):

- 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 NBB.

The IBC may also provide relevant information on the organisation's website. All official records of the IBC will be kept in the organisation.

2.8 Reporting for Incidents and Spills

2.8.1 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 (**IBC/IR/10/ANNEX3**) within 24 hours. Incidents include non-compliance of the Biosafety Act 2007 or any significant research-related accidents and illnesses (e.g. exposure to any uncontained LMO/rDNA 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 GM facility 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 (refer to Annex 1).

If there is any occupational exposure to LMO/rDNA materials, the PI/laboratory personnel will use the Occupational Disease/Exposure Investigation Form (**IBC/OD/10/ANNEX4**) to make a formal report within 24 hours to OHSC, Head of the organisation and IBC.

2.8.2 External Reporting

PI is responsible for reporting any incident by submitting the Incident Reporting Form (**IBC/IR/10/ANNEX3**) to NBB within 48 hours from the incident. This form should be reviewed by BSO before submission. If there is any occupational exposure to LMO/rDNA materials, the Occupational Disease/Exposure Investigation Form (**IBC/OD/10ANNEX4**) should be submitted to NBB within 24 hours from the incident.

These form(s) should be sent to the following address:

The Director General
Department of Biosafety,
Ministry of Natural Resources and Environment,
Level 1, Podium 2,
Wisma Sumber Asli, No. 25, Persiaran Perdana,
Precinct 4, Federal Government Administrative Centre,
62574 Putrajaya, Malaysia.
Fax: 03-8890 4935

2.8.3 Other External Reporting

If deemed necessary, NBB may also recommend that IBC inform the incident to external agencies such as the local public health departments, state agencies, and the relevant funding bodies.

2.9 Conflict of Interest

IBC members who have a conflict of interest in the project should 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 should 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.

2.10 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 LMO/rDNA 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.

2.10.1 Head (Vice Chancellor, Dean, Director, CEO)

The head provides executive leadership, dissemination and implementation of biosafety policies, standards and procedures applicable to the Biosafety Act 2007 and other related regulations regarding LMO/rDNA research. The head maintains ultimate responsibility for the safe conduct of activities involving LMO/rDNA research.

Heads have the following responsibilities:

- a) Have awareness of all requirements regarding compliance with the Biosafety Act 2007 and any related regulations regarding LMO/rDNA materials.
- b) Provide leadership and support at the management level for laboratories.
- c) Ensure that laboratory personnel receive appropriate training prior to the initiation of research projects (i.e. experimental procedures).
- d) Support the work and decisions of IBC in its charge to protect the organisation and staff, reduce liability for the organisation, and be good stewards of public trust in the products of biotechnology.
- e) Ensure that related educational activities are conducted to educate the investigators prior to initiation of research involving LMO/rDNA materials.
- f) Determine that facilities are appropriate and safe for the research proposed if the research involves LMO/rDNA materials.

2.10.2 Biological Safety Officer (BSO)

The BSO should perform the following functions:

- a) Periodically inspect all laboratories where LMO/rDNA research are being conducted to monitor that laboratory standards are being followed.
- b) Report to the IBC any significant problems, non-compliance of the Biosafety Act 2007, 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.
- c) Provide guidance to PI in developing emergency response plan for handling and investigating laboratory accidents involving LMO/rDNA materials.
- d) Work with the RRT to provide technical advice on research safety and laboratory security procedures to PI, laboratory personnel and the IBC.
- e) Serve as a liaison officer between the organisation/institution and external regulatory agencies concerning the use of LMO/rDNA materials. The BSO is responsible for submitting the annual report of IBC to the NBB, on behalf of the organisation.
- f) Serve as a voting member of the IBC.

2.10.3 Principal Investigator (PI)

The PI is accountable to the IBC and is required to comply with the appropriate research guidelines and all applicable laws related to biosafety. Please refer to section 3.2 for more information.

2.10.4 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.

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- 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.

2.11 Compliance Oversight and Corrective Action

The IBC can address non-compliance to the Biosafety Act 2007 or to the organisation'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 LMO/rDNA materials.
- b) Cessation of the approval for use of the LMO/rDNA materials.
- c) Confiscation of the LMO/rDNA materials.
- d) Destruction of the LMO/rDNA materials.
- e) Any other action necessary to protect the public and/or the organisation, including suspending the relevant research activity.
- f) Reporting to the NBB (refer to Section 2.8.2).

3 PRINCIPAL INVESTIGATOR'S SPECIFIC RESPONSIBILITIES

3.1 Risk Assessment and Selection of Appropriate Biosafety Level

The PI seeking approval for a project which involves the use of LMO/rDNA materials must make an initial risk assessment of the LMO/rDNA 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 LMO/rDNA 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 LMO/rDNA materials.

The IBC will make the final decision as to the level of risk and appropriate biological and physical containment levels for LMO/rDNA materials subject to its review and approval. The BSO may make recommendations to the IBC as to the level of risk and appropriate biological and physical containment levels, according to the Biosafety Guidelines for Contained Use Activity of LMOs.

3.2 Duties of the Principal Investigator

The PI involved in export, import, contained use and field experiment of LMO/rDNA materials shall comply with relevant requirements of the Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010 and other related regulations.

The PI should submit all applications for approval and notification that have been approved by the IBC to the NBB. Once an acknowledgement of receipt has been obtained for contained use or a certificate of approval has been granted for field experiment of LMO/rDNA materials for the research project from the NBB, the PI should:

- a) Not modify the research project involving LMO/rDNA 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.
- d) Complete required training as specified under Section 5.0.
- e) Develop and obtain IBC approval for emergency response plans to handle accidental spills and personnel contamination, and to adhere strictly to such plans.

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- f) Comply with all legislative requirements when conducting research involving LMO/rDNA materials. The PI is responsible for ensuring that the reporting requirements under the Biosafety Act 2007 Part V (Risk Assessment and Risk Management Reports and Emergency Response Plan) are fulfilled.

3.2.1 Prior to Performing Research Involving LMO/rDNA Materials

Prior to initiation of research involving LMO/rDNA 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 LMO/rDNA materials and any other infectious materials involved in the research activity.
- b) Develop standard operating procedures incorporating biosafety procedures or a biosafety manual prepared specifically for the laboratory describing the potential biohazards and the precautions to be taken (e.g. hazards and risks, immunisations, personal protective equipment required, decontamination, storage and disposal, spill procedures). Advise laboratory personnel of special hazards and require them to read and follow instructions on practices and procedures.
- c) 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).
- d) Instruct laboratory personnel on the potential hazards associated with the research, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Ensure that personnel receive annual training updates or additional training as necessary for procedural or policy changes.
- e) Instruct laboratory personnel in aseptic techniques and in the biology of the organisms used in the experiments so that the potential risks can be understood and appreciated.
- f) Instruct and train laboratory personnel in the practices and techniques required to ensure safety and the procedures for dealing with accidents.
- g) Comply with all required occupational health requirements including ensuring laboratory personnel know of the reasons and provisions for precautionary medical practices implemented and ensure that they are offered (at no cost) appropriate immunisations or tests for the LMO/rDNA materials handled or potentially present in the laboratory.
- h) Complete and obtain approval for an emergency response plan appropriate for the biosafety level of the research laboratory.

3.2.2 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 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.

4 INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) REVIEW

4.1 Review of LMO/rDNA Activity

The PI conducting any LMO/rDNA research should submit to the IBC the relevant application forms as prescribed by the NBB. The relevant application forms should be accompanied by the IBC assessment form (**IBC/AP/10/ANNEX2**) and a copy of the document approving the research grant for the LMO/rDNA project. The IBC should review the proposed activity involving LMO/rDNA materials. Once approved by the IBC, the PI should submit the application to the NBB.

For contained use activity the PI may start the research after receiving an acknowledgement of receipt of the notification from the NBB. However, the PI should not start a field experiment until a certificate of approval is granted by the NBB.

With respect to the review of proposed LMO/rDNA research, the IBC should refer to the Biosafety Guidelines for Contained Use Activity of LMOs and other relevant documents, including IBC policies and procedures for the organisation.

In particular, the project review should examine the following:

- a) Agent characteristics (e.g. virulence, pathogenicity, environmental stability).
- b) Types of manipulations planned.
- c) Sources of the inserted DNA sequences (e.g. species).
- d) Nature of the inserted DNA sequences (e.g. structural gene, oncogene).
- e) Hosts and vectors to be used.
- f) Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced.
- h) Qualification of personnel intended to be involved in the project.
- g) 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 LMO/rDNA research. The IBC may require the PI to provide data reporting and adverse event reporting for the purpose of monitoring the proposed LMO/rDNA research.

4.2 Exemptions

Biosafety (Approval and Notification) Regulations 2010 allow exemptions for some types of LMO/rDNA used. Exempted work should be carried out under conditions of standard microbiological laboratory practice. Appropriate BSL should be used for the exempted activities and personnel should have

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appropriate training. 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.

4.3 Notice of IBC Action

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

4.4 Approval Period

IBC approval of LMO/rDNA materials is valid for two years or longer as determined by the IBC. All IBC approvals of LMO/rDNA 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.

4.5 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 (**IBC/IR/10/ANNEX3**). If there is any occupational exposure to LMO/rDNA materials, the IBC also needs to review the information submitted through the Occupational Disease/Exposure Investigation Form (**IBC/OD/10/ANNEX4**). 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 NBB may request for a detailed report of the incident if necessary.

4.6 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 and NBB. This includes, but is not limited to, modification of LMO/rDNA 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 NBB through IBC for approval before making any of these changes.

4.7 Project Extension Review of Approved Projects and Notice of Termination

4.7.1 Project Extension Review of Approved Projects

The PI who wishes to extend the time period of the activity with LMO/ rDNA materials must complete and submit the IBC Project Extension Review/ Notice of Termination (**IBC/PE-NT/10/ANNEX5**) 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.

4.7.2 Notice of Termination

The PI will complete an IBC Continuation Review/ Notice of Termination Form (**IBC/CR-NT/10/ANNEX5**) and file it with the IBC Chair when a research project involving registered LMO/rDNA materials is completed or no longer active, or when the LMO/ rDNA materials is properly disposed of or is no longer in the possession of the PI.

The IBC Chair should contact the PI if there are any questions or concerns regarding Termination of Approval.

5 TRAINING

5.1 Mandatory Training of IBC Members

All members of the IBC should receive initial mandatory and refresher training on Biosafety, the Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010 and related regulations and also IBC policies. In addition, IBC members should receive refresher training on any changes to national guidelines. All such training will be organised by IBC with commitment from the organisation and guidance from NBB. It is the responsibility of the IBC Chair to provide this training and BSO to document it.

5.2 Training of the BSO

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

5.3 Training of Laboratory Personnel

General biosafety training is mandatory for all individuals conducting research with LMO/rDNA materials. Such training may be organised by the organisation itself with guidance from NBB. 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.

6 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).

7 OCCUPATIONAL HEALTH AND SAFETY COMMITTEE (OHSC)

The organisation should provide occupational health and safety services coordinated by the organisation's OHSC to ensure appropriate occupational health and safety surveillance for laboratory personnel involved in research approved by the IBC. The PI will use the Occupational Disease/Exposure Investigation Form (IBC/OD/10/ANNEX4) to make a formal report within 24 hours to the OHSC, IBC and NBB if there is any occupational exposure to LMO/rDNA materials.

8 LABORATORY INSPECTIONS AND BIOSAFETY MANUALS

8.1 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.

8.2 Biosafety Manual

The IBC reviews biosafety protocols during inspections. A collection of biosafety protocols and procedures (safety manual) must be available in every laboratory.

9 ACTIVITIES REQUIRING ADDITIONAL PERMITS

Many biological materials and activities require additional permits (such as import permit etc). If such permits are required, the PI is responsible to obtain these permits.

10 FIELD EXPERIMENTS OF LMO

Field experiments of LMO must obtain an approval from NBB [procedures are outlined in Biosafety (Approval and Notification) Regulations 2010]. The application for field experiment should be vetted by the IBC before submission to the NBB.

11 SECURITY 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 PI, 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:
 - Procedures for access to the agent.
 - Procedures for routine cleaning, maintenance, and repairs.
 - Procedures for restricting unauthorised persons.
 - Procedures for addressing loss of keys, passwords and any other secured information and material.
 - Procedures for prevention of loss or theft.

12 DISPOSAL

Potentially hazardous biological materials and LMO/rDNA materials are to be considered “regulated waste” and should be disposed of in a manner consistent with national regulations [such as Environmental Quality Act 1974, Environmental Quality (Scheduled Wastes) Regulations 1989) and Biosafety Act 2007] and related guidelines (e.g. Biosafety Guidelines for the Contained Use Activity of LMOs).

13 PACKAGING AND TRANSPORTATION OF LMO/ rDNA MATERIALS

All regulated LMO/rDNA materials will be packaged and transported in a manner compliant with national and international regulations and related guidelines. (refer to Biosafety Guidelines for the Contained Use Activity of LMOs).

ANNEX 1

FIGURE 1: SPILL RESPONSES AND LABORATORY PERSONNEL PROCEDURES

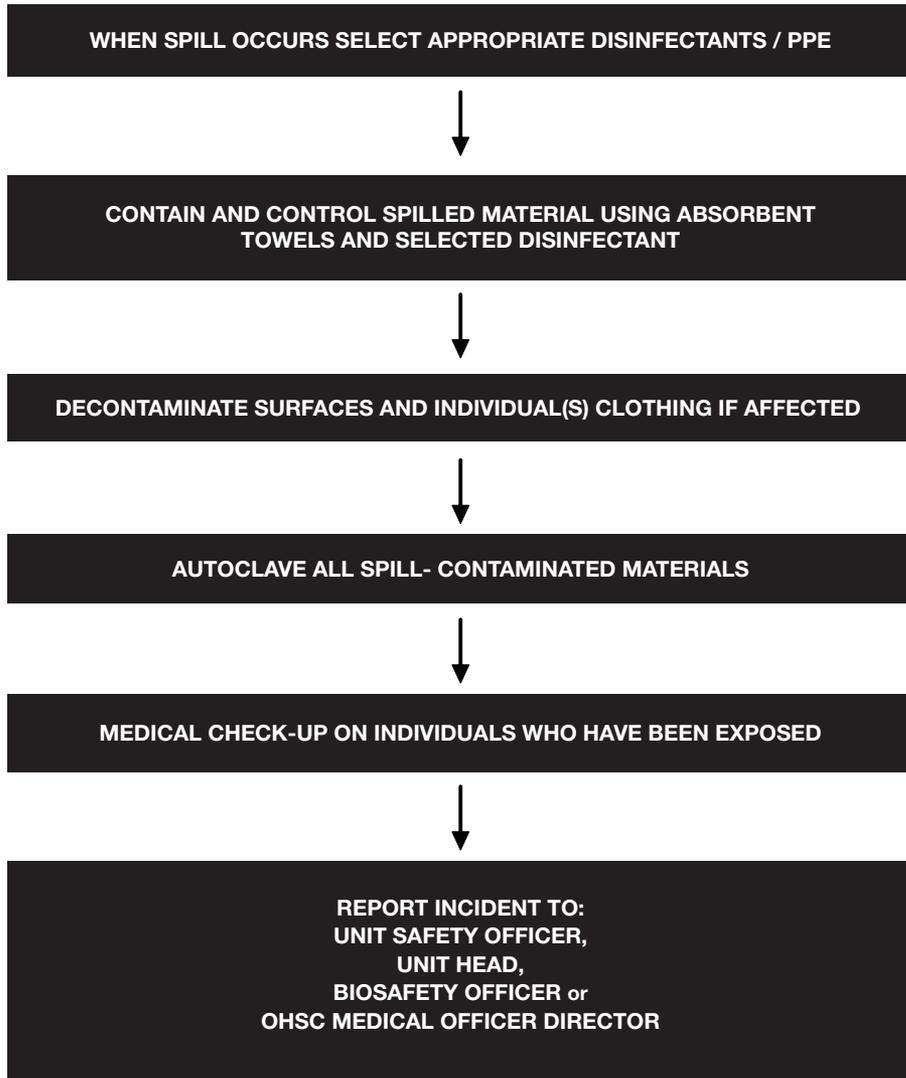
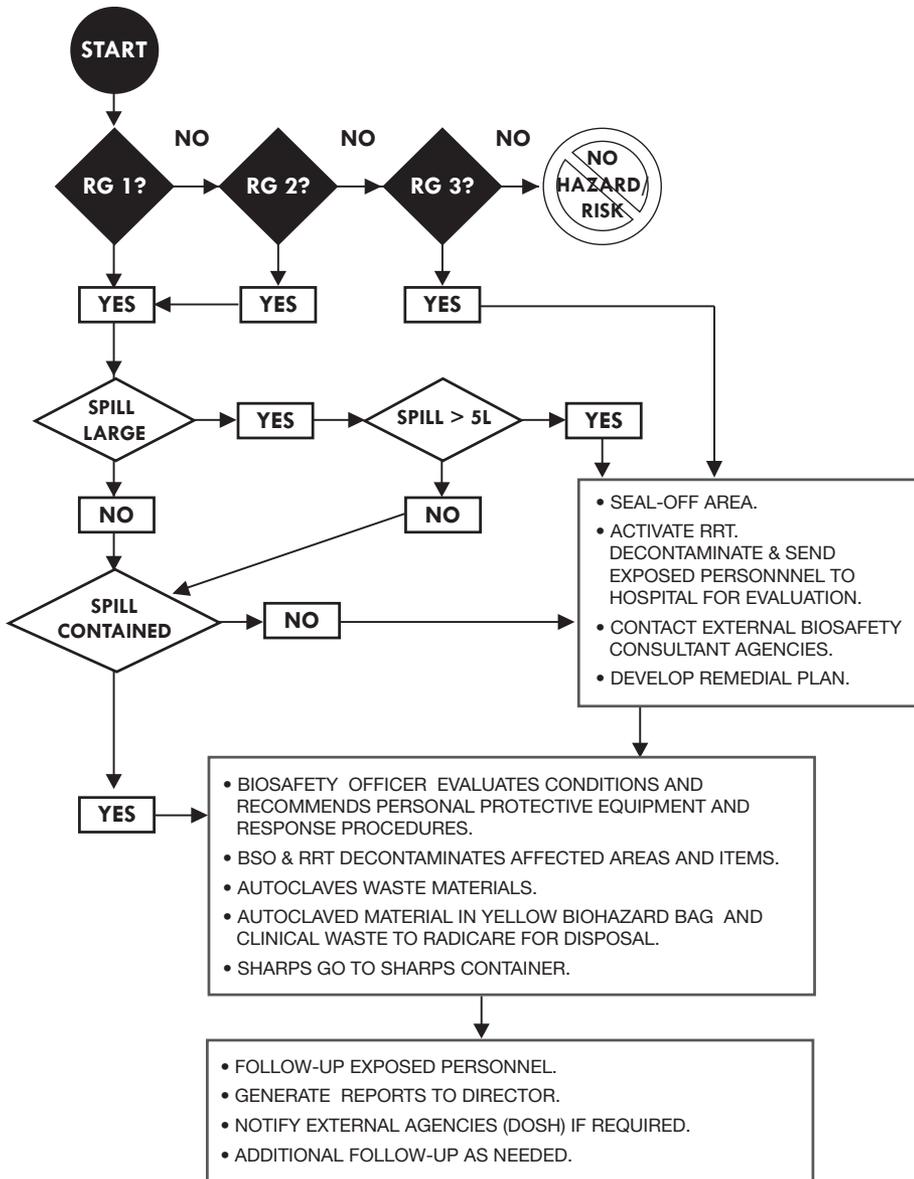


FIGURE 2: SPILL RESPONSE IN CONTAINMENT FACILITY AND EVALUATION OF HAZARDS BY PATHOGEN TYPE



IBC/AP/10/ANNEX2

IBC ASSESSMENT OF PROJECT PROPOSAL INVOLVING MODERN BIOTECHNOLOGY ACTIVITIES

IBC/AP/10/ANNEX2 is to be used for assessment of a proposal to carry out modern biotechnology activities. This form serves to guide the IBC in the consideration and evaluation of the project proposal. Completed IBC assessments should be submitted to the National Biosafety Board (NBB), together with the corresponding application form.

Instructions for Completion of the Form

The IBC must submit a typed, completed assessment form to the NBB, 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 and submitted to NBB. A clear and concise explanation is required for the IBC's position on each of the experimental parameters identified in the assessment form.

Some Specific Provisions:

Proposal for Contained Use Activity of LMO/rDNA Material

The IBC may authorise or commission research work immediately, upon obtaining an acknowledgement of receipt for contained use from the NBB. The contained use activity should observe the rudimentary standards, in current or past practice, as appropriate to the particular organism under investigation. The IBC assessment should be attached to the top sheet of the corresponding application form and submitted to the NBB.

Proposal for Field Experiment of LMO/rDNA Material

PI must obtain endorsement from IBC and should not start a field experiment until a certificate of approval is granted by the NBB. Measures for the control and containment of field work must comply with NBB and IBC advice/instruction. The IBC assessments should be attached to the top sheet of the corresponding application form and submitted to the NBB.

Section A General Information

1. Name and Institutional address of applicant.
2. Affiliation:
Indicate names and addresses of the supporting institution, co-operating institutions and supervising Institutional Biosafety Committee
3. Project Title.
4. Experimental Parameters:
Include a concise explanation for IBC assessment/recommendation on each of the following:
 - a) Project objective and methodology.
 - b) Biological system.
 - c) Site or location of contained use activity/ field experiment.
 - d) Period of contained use activity/ field experiment.
 - e) Risk assessment and risk management.
 - f) Emergency response plans.
 - g) Additional IBC recommendation.
 - h) Details of PI:
 - Experience and expertise
 - Training and instruction
 - Health
 - Other (please specify)

Signature (of IBC Chair) and Date,

Name : _____

Date : _____

IBC/IR/10/ANNEX3

INSTITUTIONAL BIOSAFETY COMMITTEE INCIDENT REPORTING FORM

To be completed by the **Principal Investigator/Laboratory personnel** involved in the incident.
This form is to be used by the BSO to report all incidents which did not result in injury.
Please complete and submit to the IBC within 24 hours and to the NBB within 48 hours of the incident.

Reference No.: _____

ORGANISATION :	LABORATORY:	DATE & TIME OF INCIDENT:
FACULTY/DEPARTMENT:		
PI/ LABORATORY PERSONNEL INFORMATION		
PI/ Laboratory Personnel's Name: _____		
Telephone: _____		
The incident was reported on Date: _____ Time: _____		
IDENTIFY THE DIRECT AND CONTRIBUTING CAUSES OF THE INCIDENT		
1. Describe the incident (use appendix if necessary).		

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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"/> Fault and maintenance staff / engineer |
| <input type="checkbox"/> Electrical fault | <input type="checkbox"/> Lack of attention / supervision |
| <input type="checkbox"/> Carelessness | <input type="checkbox"/> Incorrect method / work practices |
| <input type="checkbox"/> Terrain | <input type="checkbox"/> None of the above* |

* State cause if not listed above:

3. Did the incident contribute to any release or dispersal of LMO/rDNA 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.)?

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6. What corrective actions have been or will be taken to prevent a recurrence of this type of incident (e.g. repair / modify / replace equipment, counseling, training, policies, procedures, etc.)?

7. Who is responsible to implement corrective actions?

Signature of Principal Investigator

Name:

Date:

Signature of Biosafety Officer

Name:

Date:

Signature of IBC Chair

Name:

Date:

Send a copy to NBB,
Department of Biosafety,
Ministry of Natural Resources & Environment,
Level 1, Podium 2,
Precinct 4, 62574 Putrajaya.
Tel: 03-88861580 Fax: 03-88904935

IBC/OD/10/ANNEX4

INSTITUTIONAL BIOSAFETY COMMITTEE OCCUPATIONAL DISEASE / EXPOSURE INVESTIGATION FORM

To be completed by **Principal Investigator/ Laboratory Personnel** involved.

This form is to be used to report all occupational exposure to LMO/rDNA materials and to document the investigation by the BSO. Please **complete and submit to the OHSC, IBC and NBB within 24 hours of the accident.**

Reference No: _____

1. INFORMATION OF PERSONNEL INVOLVED IN OCCUPATIONAL DISEASE	
Name : _____	
NRIC : _____	Contact no : _____
Age : _____	Office : _____
Race : _____	Ext : _____
Employment Details	
Job Title : _____	
Faculty/Department: _____	
Employment Status: <input type="checkbox"/> Permanent <input type="checkbox"/> Contract	
Duration of Current Job: _____ months/years	
2. DESCRIPTION OF OCCUPATIONAL DISEASE / EXPOSURE TO LMO/rDNA MATERIALS	
Location in the department of occupational exposure to LMO/rDNA materials occurred: _____	
Date : ____ / ____ / ____	Time : ____ ____ am/pm

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<p>Diagnosis/Provisional Diagnosis :</p> <p>Particulars of Treatment</p> <p><input type="checkbox"/> Nil <input type="checkbox"/> Outpatient Treatment</p> <p><input type="checkbox"/> First Aid <input type="checkbox"/> Admission to Hospital</p> <p>Medical Certificate given <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Duration of MC: _____ days</p>
<p>Description of events (Describe tasks being performed and sequence of events. Use Appendix if necessary)</p> <p>a) What kind of work did the personnel do which may be associated with the disease? (Describe work activities)</p>
<p>b) What was the hazard or agent being exposed to the personnel?</p>
<p>c) How long had the personnel been exposed to the hazard or agent?</p>
<p>d) What are the symptoms and how long had the personnel been experiencing the symptoms?</p>

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Signature of Principal Investigator

Name:

Date:

Signature of Biosafety Officer

Name:

Date:

Signature of IBC Chair

Name:

Date:

Send a copy to NBB,
Department of Biosafety,
Ministry of Natural Resources & Environment,
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Precinct 4, 62574 Putrajaya.
Tel: 03-88861580 Fax: 03-88904935

IBC/PE-NT/10/ANNEX5

PROJECT EXTENSION & NOTICE OF TERMINATION

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

- a) Name of Principal Investigator: _____
- b) E-mail: _____
- c) Faculty/Department: _____
- d) Tel: _____
- e) IBC Reference No.: _____
- f) NBB Reference No. (if applicable): _____
- g) Project Title: _____
- h) Identify LMO/rDNA materials: _____

2. Request for Project Extension/Notice of Termination

- I request **extend IBC approval** of my use/possession of the LMO/rDNA materials described above. (Complete Sections C, and D below)

OR

- I request **termination** of IBC approval. **Describe when and how the LMO/rDNA materials identified above will be disposed of:**

3. General Information

- a) Will the Principal Investigator change?
 Yes No
- b) Will the Risk Group (RG) change?
 Yes No
- c) Will the Biosafety Level (BSL) change?
 Yes No
- d) Will the type or amount of LMO/rDNA materials change?
 Yes No
- e) Will the LMO/rDNA materials be moved to another laboratory?
 Yes No
- f) Will the use of the LMO/rDNA materials change?
 Yes No

If the answer to any of the above questions (1–6) is Yes, you must submit an application form **NBB/N/CU/10/ANNEX 5** (Notification for contained use and import for contained use activities for classes 1, 2, 3 and 4) to the NBB through IBC for approval before making any of these changes.

4. Adverse Events

- a) Have any adverse events occurred since the project approval or last request for project extension approval?
 Yes No

- b) If so, was an Incident Reporting Form submitted to the IBC as required by the IBC regulation?
 Yes No

5. 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 **NBB/N/CU/10/ANNEX 5** (Notification for contained use and import for contained use activities for classes 1, 2, 3 and 4) form in the event my use of, or amount of LMO/rDNA materials changes, or if I have terminated my use /possession of LMO/rDNA and wish to begin modern biotechnology activity again.

[Empty signature box for Principal Investigator]

Signature of Principal Investigator

Name:

Date:

[Empty signature box for Biosafety Officer]

Signature of Biosafety Officer

Name:

Date:

[Empty signature box for IBC Chair]

Signature of IBC Chair

Name:

Date:

Send a copy to NBB,
Department of Biosafety,
Ministry of Natural Resources & Environment,
Level 1, Podium 2,
Precinct 4, 62574 Putrajaya.
Tel: 03-88861580 Fax: 03-88904935

IBC Use only

- Use /Possession Approved*
- Use/Possession Disapproved*
- Termination Approved*



Ministry of Natural Resources and Environment

Department of Biosafety
Level 1, Podium 2
Wisma Sumber Asli, Precinct 4
62574 Putrajaya, Malaysia

Tel : + 603 8886 1580
+ 603 8886 1579

Fax : + 603 8890 4935

www.biosafety.nre.gov.my

For more information or clarification, please send your
queries to biosafety@nre.gov.my