GUIDELINES FOR UCSI UNIVERSITY INSTITUTIONAL BIOSAFETY COMMITTEE

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1. INTRODUCTION

1.1 PURPOSE

The purpose of this guideline is to provide guidance to organisation that conducts research or activities involving living modified organisms (LMO)/recombinant DNA (rDNA) and other relevant scopes mentioned under section 1.2 on the setting up of an Institutional Biosafety Committee (IBC) in compliance with the Malaysian Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010 and other related government regulations and policies to safeguard human health and the environment.

The UCSI University Biosafety Guidelines describe the methods, means, procedures and policies that govern the conduct of work by employees and/or facilities that presents possible biohazard risks to employees, visitors, the general public or the environment. These Guidelines also delineate roles and responsibilities for Principal Investigators (PI), Researchers, Laboratory Personnel, the UCSI University's Biosafety Officer (BSO), the Institutional Biosafety Committee (IBC) and certain Administrative Officials.

1.2 SCOPE

The UCSI University Biosafety Guideline applies to setting up of the IBCs, clinical/diagnostic, research, and teaching activities when obtaining, using, storing, transferring, or destroying any of the following:

- Recombinant or Synthetic Nucleic Acids
- Human, animal and plant pathogens *including toxins of biological origin*
- Bloodborne pathogens and other potentially infectious materials, as defined in http://www.biosafety.gov.my/en-my/Corporate-Info/Documents/exemption%20first%20schedule%20(english).pdf.
- Selected agents, including designated biologically-derived toxins, as defined by Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010 and other related government regulations and policies.
- Transgenic animals and plants
- Field Collection or Sampling of Wild Animals, when there is risk of exposure to zoonotic diseases.

Activities that are not subject to IBC review: Clinical/diagnostic, research, and teaching activities that:

- are properly conducted at biosafety containment level 1 (BSL-1); and
- do not involve human, animal, or plant pathogens; and/or
- involve only the *in vitro* use of nucleic acids (e.g., PCR. miRNA, siRNA, sequencing) and does not involve the cloning and propagation of recombinant or synthetic nucleic acid molecules in cells; and
- the nucleic acid molecules are not able to produce infectious forms of a biological select agent or encode for the functional form of a select agent toxin.

1.3 DEFINITIONS

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

Biosafety refers to the containment principles, technologies and practices, protection, control and accountability that are implemented to prevent the loss, theft, misuse, diversion of, unauthorized access, intentional or unintentional exposure or release of biological agents and toxins as covered in Section 1.2.

Principal Investigator (PI) refers to any person with primary authority over the work conducted, whether the work is related to research, clinical/diagnostics or teaching. The PI is accountable to the IBC and must comply with the appropriate research guidelines and all applicable laws and guidelines related to biosafety.

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.

Institutional Biosafety Committee (IBC) refers to a formal expert committee of an organisation undertaking modern biotechnology work, which involves the use of any LMO/rDNA and other materials and relevant scopes in compliance with the Malaysian Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010 and other related government regulations and policies to safeguard human health and the environment. However, the scope of the IBC may be extended as deemed necessary by the respective organisation. The IBC should be chaired by the President/Vice Chancellor or his designate (a suitable senior officer) of UCSI University.

Biological Safety Officer (BSO) refers to the designated officer who assists in ensuring compliance to the Biosafety Act 2007 and the Biosafety (Approval and Notification) Regulations 2010 at an organisation.

Health Safety & Environment (HSE) Committee 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, HSE committee may also protect co-workers, customers, suppliers, nearby committees and other members of the public impacted by the workplace.

Work activities is any activity involving conducting experiments on or with, testing, sampling or analysing any biological material or sample from a human, animal or plant that falls into one of categories outlined.

Rapid Response Team (RRT) is a subcommittee of the IBC, is appointed by UCSI University President/Vice Chancellor 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, pathogens and other potentially infectious materials, within 24 hours of occurrence and to immediately engage the different components of the organisation, including the IBC and OHSC.

Incident is defined as unintended release, breach of containment, spill or occupational exposure to LMO/rDNA, pathogens and other potentially infectious materials governed by the Biosafety Act 2007 and the Biosafety (Approval and Notification) Regulations 2010.

A **Living Modified Organism (LMO)** is any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (Biosafety Act 2007).

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

Institution is defined as any institution, company, organization, association, body or person that uses or intends to use LMO, rDNA, pathogens and other potentially infectious materials for Scientific Purposes and is registered to do so.

Experimenter/Researchers is defined as any person (students, research officers, research assistants, lab technologists etc) who uses LMO, rDNA, pathogens and other potentially infectious materials for scientific purposes.

1.4 COMPLIANCE WITH THE MALAYSIAN BIOSAFETY ACT 2007

Any organisation, which undertakes modern biotechnology research and development, shall establish an Institutional Biosafety Committee (IBC) to ensure that any LMO/rDNA, pathogens and other potentially infectious research, conducted at or sponsored by the organisation, irrespective of the source of funding, shall comply with the Malaysian Biosafety Act 2007 and the Biosafety (Approval and Notification) Regulations 2010, 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 National Biosafety Board.

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.

2.0 UCSI INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

2.1 IBC RESPONSIBILITIES

IBC is established under the Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010. The responsibilities of the IBC include, but are not limited to the following:

1. Provide guidance to PI on biosafety policies and issues in the use of LMO/rDNA, pathogens and other potentially infectious agents research as mentioned in Section 1.2, including safety of laboratory personnel and other members of the organisation.
2. Recommend approval for research projects that involve the use of LMO/rDNA, pathogens and other potentially infectious agents as mentioned in Section 1.2, that are found to conform to Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010 and periodically reviewing these research projects.
3. Assess and monitor the research facilities, procedures, practices, training and expertise of personnel involved in LMO/rDNA, pathogens and other potentially infectious agents as mentioned in Section 1.2.
4. 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 National Biosafety Board (NBB).
5. Assess and set containment levels for research projects and any activities that involve the use of LMO/rDNA, pathogens and other potentially infectious agents as mentioned in Section 1.2, and modify containment levels as necessary.
6. Assess field experiments to ensure that the proposed risk assessment, risk management and emergency response plan are sufficient.
7. Adopt and implement emergency response plan covering accidental spills and personnel contamination, resulting from research projects and any activities that involve LMO/rDNA, pathogens and other potentially infectious agents as mentioned in Section 1.2.
8. Review and report to the UCSI University President/Vice-Chancellor 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.

2.2 IBC MEMBERSHIP

The IBC is registered with the NBB for the purpose of LMO/rDNA, pathogens and other potentially infectious agents as mentioned in Section 1.2. The IBC is comprised of members who are appointed by UCSI University President/Vice-Chancellor. Members should represent the organisation and may include representatives from the community at large. Members will collectively have experience and expertise in research or activities related to LMO/rDNA, pathogens and other potentially infectious agents as stated in Section 1.2, and the capability to assess the safety of the related research activities, and identify any potential risk to human, animal and plant health or the environment posed by such research or activities.

The IBC should have the following minimum composition:

1. Chair
2. BSO
3. Committee members

It is also recommended that IBC include:

1. Experts in Biosafety and containment
2. Persons knowledgeable in institutional policies and applicable laws
3. Individuals reflecting community attitudes
4. At least one representative from the laboratory staff

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

- Appointment
  The President/Vice Chancellor of UCSI University 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, pathogens and other potentially infectious agents as stated in Section 1.2. The chair of the IBC will serve a 2 year term and may be re-appointed.

- 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. The appointed person should be by the Chair's authority – anyone in IBC can be appointed as acting chair.

2.4 BIOLOGICAL SAFETY OFFICER (BSO)

- Appointment
  The BSO should be appointed by the President/Vice Chancellor of UCSI University. 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. The appointment will serve a 2 year term and may be re-appointed.

- 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

- Appointment
  IBC members are appointed by the President/Vice-Chancellor of UCSI University and will serve a 2 year term and may be re-appointed. There is no limit to the number of terms a member may serve as an IBC member. The IBC Membership shall consist of at least six (6) members.

Qualifications of Members

The IBC 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.

- Responsibilities
  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 evaluated every 2 years, by the IBC Chair and the President/Vice Chancellor of UCSI University, based on participation.

- Changes of the IBC Membership
  IBC members may be removed or replaced by the President/Vice Chancellor of UCSI University. 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.

- Use of Consultant
  IBC may request competent consultants (local or foreign) for advice and information, as and when required but such consultants should not have voting rights. These consultants may be a 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

- Regular Meeting
  The IBC should meet at least once a year to review and approve projects and to conduct project extension review of approved projects.
- Emergency Meeting
  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, pathogens and other potentially infectious agents as stated in Section 1.2, at the organisation.

- 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.

- Quorum
  At least 60% 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, pathogens and other potentially infectious agents as stated in Section 1.2, 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.

- 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 project review process may be removed from the committee.

- Minutes of the Meeting
  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 facilities required to conduct activities related to LMO/rDNA, pathogens and other potentially infectious agents as stated in Section 1.2.
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, pathogens and other potentially infectious agents as stated in Section 1.2.

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

Conflict of Interest

Any IBC member who have declared a conflict of interest shall not participate in the review and approval of the respective Notice of Intent.

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

2.7 IBC RECORDS Keeping

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

The IBC should retain the following records for at least seven 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 PERSONS RESPONSIBLE FOR COMPLIANCE

- Head (Vice Chancellor, President)
  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.

  Head 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, pathogens and other potentially infectious agents as stated in Section 1.2.
  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, pathogens and other potentially infectious agents as stated in Section 1.2.
  f) Determine the facilities are appropriate and safe for the research proposed if the research involves LMO/rDNA materials, pathogens and other potentially infectious agents as stated Section 1.2.

- Biological Safety Officer (BSO)
  The BSO should perform the following functions:
  a) Periodically inspect all laboratories where research works related to the use of LMO/rDNA, pathogens and other potentially infectious as stated in Section 1.2, 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, pathogens and other potentially infectious agents in Section 1.2.
  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, pathogens and other potentially infectious agents as stated Section 1.2. 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.

- 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. Refer to Section 3.2 for more information.

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

2.9 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, pathogens and other potentially infectious agents as stated in Section 1.2.
(b) Cessation of the approval for use of the LMO/rDNA materials, pathogens and other potentially infectious agents as stated in Section 1.2.
(c) Confiscation of the LMO/rDNA materials, pathogens and other potentially infectious agents as stated in Section 1.2.
(d) Destruction of the LMO/rDNA materials, pathogens and other potentially infectious agents as stated in Section 1.2.
(e) Any other action necessary to protect the public and/or the organisation, including suspending the relevant research activity.
(f) Reporting to the NBB.

3.0 SPECIFIC RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS

3.1 SELECTION OF APPROPRIATE BIOSAFETY LEVEL

The PI seeking approval for a project or any activity which involves the use of LMO/rDNA materials, pathogens and other potentially infectious agents as stated in Section 1.2, must make an initial risk assessment of the said materials/agents. The primary focus of a risk assessment is to prevent or reduce the risk of laboratory associated infections or intentional or unintentional release of LMO/rDNA materials, pathogens and other potentially infectious agents as stated in Section 1.2 into the environment. The assessment of risk is based on the organism's Risk Group and other risk factors and should be utilised 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, pathogens and other potentially infectious agents as stated in Section 1.2 (Appendix A). The IBC will make the final decision on the level of risk and appropriate biological and physical containment levels for the said materials/agents subject to its review and approval. The BSO may make recommendations to the IBC on 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 PRINCIPAL INVESTIGATOR

The PI involved in export, import, contained use and field experiment of LMO/rDNA materials, pathogens and other potentially infectious agents as stated in Section 1.2, 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, pathogens and other potentially infectious agents as stated in Section 1.2, 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.

(f) comply with all legislative requirements when conducting research involving LMO/rDNA materials, pathogens and other potentially infectious agents as stated in Section 1.2. 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:

(a) review the applicable guidelines and regulations and familiarise 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 (SOPs) 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, attendance of lab safety briefing).

(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 occupational health requirements including ensuring laboratory personnel know of the reasons and provisions for precautionary medical practices implemented and ensure that they are offered appropriate immunisations or tests for the LMO/rDNA materials handled or potentially present in the laboratory. Cost should be beared by the Principal Investigator.

(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, Pathogens and Other Potentially Infectious Agents as Stated in Section 1.2

While performing research on LMO/rDNA materials, pathogens and other potentially infectious agents as stated in Section 1.2, the PI should:

(a) limit or restrict access to the laboratory when work with the pathogens and other potentially infectious agents as stated in Section 1.2.
(b) provide personal protective equipment (PPE) required for work with the specific LMO/rDNA materials, pathogens and other potentially infectious agents as stated in Section 1.2.
(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) rectify work errors and conditions that may result in the unintended release of LMO/rDNA materials, pathogens and other potentially infectious agents as stated in Section 1.2.
(f) Ensure the integrity of the biological and physical containment/biosafety level.
(g) Ensure the LMO/rDNA materials, pathogens and other potentially infectious agents, are stored appropriately and kept secure at all times.
(h) Have emergency response plan posted in the designated laboratory.

4.0 REVIEW PERFORM BY INSTITUTIONAL BIOSAFETY COMMITTEE

4.1 REVIEW OF LMO/rDNA ACTIVITY

The PI conducting any research or activity that involves LMO/rDNA, pathogens and other potentially infectious agents as stated in Section 1.2 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 (UCSI/IBC/FORM B) and a brief proposal would be required – emphasising on methods and steps used, in compliance to the biosafety and biosecurity act. The IBC should review and monitor the proposed activity involving the said materials/agents. Once approved by the IBC, the BSO should submit the application to the NBB.

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.

IBC members will review all NOI submissions in an IBC meeting with a quorum of at least sixty percent (60%) of its members present. The NOI will only be approved when the majority of the IBC members decided that the intended activities, personnel and biosafety and biosecurity requirements are deemed meeting the IBC requirements.

For activity involving contained use, 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.

The IBC review the feasibility of the proposed activity that involves the LMO/rDNA, pathogens and other potentially infectious agents as stated in Section 1.2 based on Malaysian Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010 and other related government regulations and policies, including the institutional procedures and guidelines.

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. The IBC may require the PI to provide data/record pertaining to scientific experiments involving the biohazard samples to justify the risk as well as the adverse event reporting for the purpose of monitoring the proposed research involving the LMO/rDNA, pathogens and other potentially infectious agents as stated in Section 1.2.

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 appropriate training. PI who believes that the work falls into any of the exemptions should nevertheless notify their IBC of the proposed project. If needed, an ad-hoc subcommittee can be formed to 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. Decision of IBC can be one of the following:

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 IBC.

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

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

Withhold approval: The NOI is withheld if it has not adequately addressed the applicable principles of biosafety and biosecurity. The decision outcome of the IBC 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.

4.4 APPROVAL PERIOD

IBC approval of LMO/rDNA materials and activities are valid for two years, unless otherwise stated. Application of extension is allowed, but subject to approval of 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 (UCSI/IBC/ANNEX 2). 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

(UCSI/IBC/ANNEX 3). 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 form (UCSI/IBC/FORM C) 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, pathogens and other potentially infectious agents as stated in Section 1.2, must complete and submit the IBC Project Extension Review/ Notice of Termination (UCSI/IBC/FORM D) 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.

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

4.7.2 Notice of Termination

The PI must complete an IBC Continuation Review/ Notice of Termination Form (UCSI/IBC/FORM D) and file it with the IBC Chair when a research project involving registered LMO/rDNA materials, pathogens and other potentially infectious agents as stated in Section 1.2, 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.

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

4.8 POST-APPROVAL MONITORING

The IBC may visit laboratories and facilities where IBC 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 IBC and the PI concerned.

5.0 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 or any activity with LMO/rDNA materials, pathogens and other potentially infectious agents. 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.

6.0 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 on their assessment of the risk group and BSL. The PI should begin with the IBC approved standard emergency response plan and insert appropriate information related to 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).

7.0 Health, Safety and Environment Committee (HSE Committee)

The organisation should provide occupational health and safety services coordinated by the organisation's HSE Committee 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 (UCSI/IBC/ANNEX 3) to make a formal report within 24 hours to the OHSC, IBC and NBB if there is any occupational exposure to LMO/rDNA materials.

8.0 LABORATORY INSPECTIONS AND BIOSAFETY MANUALS

8.1 LABORATORY INSPECTIONS

The IBC will inspect laboratories using checklists. Any issues arising 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.

9.0 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.

10.0 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.

11.0 STORAGE AND 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.

12.0 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).

13.0 PACKAGING AND TRANSPORTATION OF LMO/rDNA MATERIALS

All regulated biological materialas and LMO/rDNA materials must 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). Standard operation procedure for packaging and transfer is stated in the Biosafety Manual. Principal Investigator is the person in charge of packaging with a Material Transfer Agreement (MTA) (UCSI/IBC/ANNEX 4), approved by a licensed officer.

14.0 INSTITUTIONAL BIOSAFETY COMMITTEE RELATED FORMS

No.	Form	Code
1	Submission Checklist	-
2	Preliminary Assessment Form	UCSI/IBC/FORM A
3	Notice of Intent (NOI) Form	UCSI/IBC/FORM B
4	Amendments of Approved NOI Form	UCSI/IBC/FORM C
5	Project Extension and Notice of Termination	UCSI/IBC/FORM D
6	Notification for Contained Use and Import for Contained Use Activities Involving Living Modified Organism (LMO) For Biosafety Levels 1, 2, 3 And 4	UCSI/IBC/FORM E (NBB/N/CU/15/ FORM E)
7	Biological Risk Assessment Form	UCSI/IBC/ANNEX 1
8	Incident Reporting Form	UCSI/IBC/ANNEX 2
9	Occupational Disease / Exposure Investigation Form	UCSI/IBC/ANNEX 3
10	Material Transfer Agreement	UCSI/IBC/ANNEX 4
11	Biosafety Level 1 Self-Assessment	UCSI/IBC/ANNEX 5

15.0 REFERENCES

Malaysia Biosafety Clearing House: http://www.biosafety.nre.gov.my/

User's Guide to the Biosafety Act and Regulations http://ibc.um.edu.my/images/ibc/Download/Biosafety%20User%20Guide.pdf

The Biosafety Act 2007
http://www.nre.gov.my/Malay/Pusat-Media/Penerbitan/Dispelling%20the%20Myths.pdf

Biosafety Guidelines for Contained Use Activity of Living Modified Organism
http://www.vertic.org/media/National%20Legislation/Malaysia/MY_containment%20guidelines.pdf

Guidelines On The Handling And Management Of Clinical Wastes In Malaysia
http://www.doe.gov.my/webportal/wp-content/uploads/2010/07/anagement_Of_Clinical_Wastes_In_Malaysia__2__0.pdf

Environmental Quality (Scheduled Wastes) (Amendment) 2007, P.U. (A) 158
http://cp.doe.gov.my/cpvc/wp-content/uploads/2011/04/Regulations/Environmental%20Quality%20(Scheduled%20Wastes)%20(Amendment).pdf

Environmental Impact Assessment (EIA): Procedure and Requirements In Malaysia.
http://eia.doe.gov.my/portal/wp-content/uploads/2013/06/EIA-Procedure-and-Requirements-in-Malaysia.pdf

Guidelines for Institutional Biosafety Committee: Use of Living Modified Organisms and related Materials http://ibc.um.edu.my/images/ibc/IBC%20GUIDELINES.pdf

APPENDIX A: Summary of Biosafety Levels Recommended for Infectious Agents

Biosafety Level	Practice Technique	Safety Equipment	Facilities
1	Standard Microbiological Practices	None: Primary containment provided by adherence to standard laboratory practices during open bench work.	Basic
2	Level 1 practices PLUS: laboratory coats; decontamination of all infectious wastes; limited access; protective gloves and biohazard warning signs as indicated.	Partial containment equipment (e.g., Class I or II Biosafety Cabinets) used to conduct mechanical and manipulative procedures that have high aerosol potential that may increase the risk of exposure to personnel.	Basic
3	Level 2 practices PLUS: special laboratory clothing; controlled access.	Partial containment equipment used for all manipulations of infectious materials.	Containment
4	Level 3 practices PLUS: entrance through a change room where street clothing is removed and laboratory clothing is put on; shower on exit; all wastes are decontaminated on exit from the facility.	Maximum containment equipment (e.g., Class III Biosafety Cabinet or partial containment equipment in combination with full-body, air supplied, positive-pressure personnel suit) used for all procedures and activities.	Maximum Containment