

Institutional Biosafety Committee

Terms of Reference

1. To administer all of the requirements of the Institutional Biosafety Committee as prescribed by the Biosafety Law on behalf of UPM.
2. To make recommendations to the University Health and Safety committee on actions and/or policies related to biosafety at the Universiti Putra Malaysia.
3. To provide a point of reference and referral on all matters related to biologically hazardous materials.
4. To advise on the legislative requirements (development and implementation) for the handling of biologically hazardous material of safe conditions and procedures in situations that involves potentially hazardous microorganisms, cells and products and the use of genetically modified organisms.
5. To approve protocols involving the use of potentially biohazardous agents including genetically modified organisms and animals potentially carrying infectious zoonotic agents and to confirm the appropriate containment level for the work; to verify that the appropriate facilities and procedures are in use and to ensure that appropriate procedures for the use, storage and disposal of the named agents are followed.
6. To monitor and promote compliance with the established policies and procedures as set out in the most current version of the Malaysia's Biosafety Act, and other government and University guidelines related to biosafety.
7. To develop and recommend policies and procedures to meet or exceed the requirements for each containment level as stated in most current version of the Biosafety Act and Regulations, or the most current version of other applicable standards for teaching and research.
8. The Biosafety Committee will receive applications for approval of research projects involving:
 - a) Any dealing with a genetically modified organism (GMO)
 - b) Any biohazardous material (including human fluids, human tissue specimen collection from patients and specimen testing.
 - c) Ensure that laboratory activities are planned and executed in such a way that every reasonable precaution is taken to protect the health and safety of each employee, the public, students, and environment, and to prevent damage to property

- d) Make recommendations to the Deputy Vice –Chancellor(Research) and the Dean relating to the granting of approvals to conduct, or participate in, research utilizing GMOs and biohazardous materials, to members of academic staff, to postgraduate research students and to other persons who wish to use facilities for the purpose of such research;
 - e) Make recommendations to the Deputy Vice –Chancellor (Research) and the Dean in relation to the terms upon which such approvals shall be held, provided that the Deputy Vice –Chancellor (Research) and the Dean shall be free to terminate ant such at any time;
 - f) Make recommendations to the Deputy Vice – Chancellor (Research) and the Dean relating to the safety precautions, either generally of for particular projects, which must be observed by those involved in research utilizing GMOs and biohazadous materials. Recommend approval of proposed projects, either absolutely or subject to conditions, provided that the Deputy Vice – Chancellor (Research) and the Dean shall be free to terminate any such approval at any time;
 - g) Co- operate closely, for the purpose of evolving effective safety standards, with The Ministry of Natural Resources, Malaysia (NRE), GMAC invested with the responsibility to monitor the use of GMOs and biohazadaous materials, with a view to making fully effective laid down from time to time by the above committees;
 - h) Establish appropriate auditing systems to ensure that safety guidelines laid down for particular research projects are adhered to in the conduct of research;
 - i) Establish a register of research projects where GMOs and biohazardous materials are being used; ensure that this register is kept up - to - date;
 - j) Participate in public discussions about the biosafety of research conducted at the Universiti Putra Malaysia;
 - k) Ensure that procedures are in place for dealing with accidents and incidents;
 - l) Ensure that procedures are in place for avoiding potential breaches of Biosafety Policy and procedures. The Committee may:
 - m) Appoint, from its membership, subcommittees or working parties to assist in its function. Membership of subcommitties may include persons from outside the membership as agreed by the committee.
9. To approve applications for greenhouse or filed trials of genetically modified organisms.
10. To review the procurement and use of all human source tissues, blood and body fluids for research and undergraduate teaching, and to recommend and monitor the appropriate safety precautions.

11. In collaboration with the University Biosafety Officer, to review, recommend and act as an expert resource for biosafety education and training programmes at Universiti Putra Malaysia.
12. To recommend to the University that appropriate institutional occupational health programmes be put in place as necessary to achieve the outcomes stated below.
13. To establish sub-committees to carry out specific tasks as mandated by the Universiti Putra Malaysia.
14. In relation to exempt dealings with GMOs, the IBC shall:
 - a) Assist individuals within University to correctly identify the proposed dealing with the GMO as an exempt dealing with GMO (in accordance with Malaysia's Biosafety Regulations).
 - b) In relation to notifiable low risk dealing (NLRDs) with GMOs the IBC shall:
 - i. assist proponents to correctly identify the conditions applying to NLRDs;
 - ii. assist the applicant to understand the conditions applying NLRDs;
 - iii. consider proposals prepared by applicants, in accordance with the legislation;
 - iv. notify the Regulator within 14 days of the IBC assessment of the proposal. The notification to the Regulator must include a copy of the information provided by the applicant and the results of the IBC's consideration (supporting information); and
 - v. notify the applicant, and the project supervisor, that the IBC has provided the required information to the Regulator.
15. In relation to dealings with GMOs requiring licensing by the Regulator the IBC shall:
 - a) Assist applicants to prepare applications for license, in accordance with the Regulator's application requirement;
 - b) Consider proposals prepared by proponents, in accordance with the legislation; and
 - c) Provide advice to the Regulator on applications for license (supporting information)
16. An appropriately qualified member of the IBC shall, on behalf of Universiti Putra Malaysia, perform the following functions in relation to containment facilities:
 - a) Inspect all of the organization's containment facilities, against the Regulator's requirements for containment, at least once per year;

- b) Inspect new PC2 facilities (for which certification from Regulator is sought).
17. As an Accredited University, the Universiti Putra Malaysia, must meet the conditions for accreditation. The accreditation of the University is subject to the following classes of conditions:
- a) Conditions relating to maintaining and IBC or maintaining access to an IBC;
 - b) Conditions relating to maintaining a register and documenting personnel;
 - c) Conditions relating to reporting to the Regulator;
 - d) Conditions relating to the development of internal operating procedures and appropriate staff training;
 - e) Conditions relating to potential conflicts of interest;
 - f) Conditions relating to the indemnifications of IBC members;
 - g) Conditions relating to the membership of an IBC;
 - h) Conditions relating to the functions of an IBC; and
 - i) Conditions relating to inspection of facilities.
18. Thus in addition, the IBC will assist the University to maintain its accreditation by undertaking the following activities as required by the requirements of the conditions listed a) – i) above;
- Ensure that registers of all exempt dealings, notifiable low risk dealings and licensed dealings undertaken by the university and/or in the university's certified facilities are maintained;
 - Ensure that register of all GMOs held in the university's certified facilities are maintained;
 - Maintain a register of certified facilities;
 - Ensure that records of personnel working in certified facilities and of personnel authorized to access certified facilities are maintained;
 - Ensure that registers of all staff and students who have undertaken training are maintained;
 - Prepare an annual report for submission to the National Biosafety Board;
 - Liaise with the National Biosafety Board regarding every aspect of accreditation, compliance and licensing;
 - Provide training for staff and students involved with gene technology research and teaching;
 - Provide advice to staff and students about the Act, Regulations and Guidelines;
 - Develop internal operating procedures in relation to the management of GMOs;

- Implement appropriate procedures for dealing with accidents and incidents with GMOs;
- Ensure appropriate mechanisms to address conflict of interest