

INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA

PROCEDURE OF IIUM BIOSAFETY POLICY (PIBP)

PROCEDURE IN PROJECT NOTIFICATION

1.1 Notification process

- a. For research or experiments, the Principal Investigator (PI) has to submit Preliminary Assessment Form (refer to IIUM Biosafety and Biosecurity Guidelines) to the Institutional Biosafety and Biosecurity Committee (IBBC).
- b. The Preliminary Assessment Form is reviewed and the IBBC shall recommended the PI to fill Notification Form (refer to IIUM Biosafety and Biosecurity Guidelines) for genetically modification activities (both exempted and non-exempted activities)
- c. For non-exempted activities, the PI has to submit the completed Notification Form to the IBBC accompanied with:
 - Laboratory Self-Inspection Form Biosafety Level 1/2 Checklist, whichever applicable
 - Personnel Biosecurity Registration Form
 - Records of personnel training related to laboratory biosafety
- d. The Notification Form for non-exempted activities is reviewed by the IBBC and submitted to the respective department under the Ministry in prescribed manner. No lab work can be conducted without recommendation/order from relevant national authority.
- e. The Notification Form for exempted activities will be kept by the IBBC for record purpose and lab work can be conducted immediately once received notification from the IBBC.

1.2 Extension of Approved 'Notification' and Notice of Termination

- a. PI is required to submit the Project Extension & Notice of Termination form (refer to IIUM Biosafety and Biosecurity Guidelines) for extension application at least three (3) months before the expiry date.
- b. 'Notification' extension applications will be reviewed by the IBBC before it is approved.
- c. PI is required to submit the Project Extension & Notice of Termination form to IBBC if they wish to terminate their project before the stipulated duration of time.

1.3 Post-Approval Monitoring

- a. The IBBC may visit laboratories and facilities where IBBC approved activities are conducted to ensure biosafety and biosecurity compliance according to the international, national and institutional policies, regulations and guidelines. The visit will be communicated to the PI.

- b. Any non-compliance will result in immediate suspension of approval. The BSO or officials performing the visit will prepare a report of the findings to be submitted to both the IBBC and the PI concerned.

PROCEDURE IN PROJECT APPROVAL

- a. For field trial and commercialization, PI has to submit the completed Approval Form (refer to IIUM Biosafety and Biosecurity Guidelines) to the IBBC accompanied with:
 - Personnel Biosecurity Registration form
 - Records of personnel training related to Biosafety
 - Other information as may be specified by the national approving authority
- b. The Approval Form is reviewed by the IBBC and submitted to the respective department under the Ministry in prescribed manner together with the prescribed fees (refer to IIUM Biosafety and Biosecurity Guidelines). No field trial and commercialization are allowed without recommendation/order from relevant national authority.

PROCEDURE IN INCIDENT REPORTING

- a. When there is an incident related to biological materials and conduct, the PIs has to report the incident to IBBC by filling in the Incident Reporting Form (refer to IIUM Biosafety and Biosecurity Guidelines).
- b. When there is any occupational exposure to LMO/rDNA materials, infectious and potentially infectious agent and biological toxins, the PIs has to report the incident to IBBC by filling in the Occupational Disease/Exposure Investigation Form (refer to IIUM Biosafety and Biosecurity Guidelines).
- c. Further discussion and action pertaining to the incident and occupational exposure should be captured in the minutes of the IBBC meeting.
- d. The detailed report of the incident may need to be submitted to the university and relevant Ministry if necessary.

FLOWCHART ON PROJECT APPROVAL

FLOWCHART ON PROJECT NOTIFICATION

