INTERNATIONAL MEDICAL UNIVERSITY
MALAYSIA

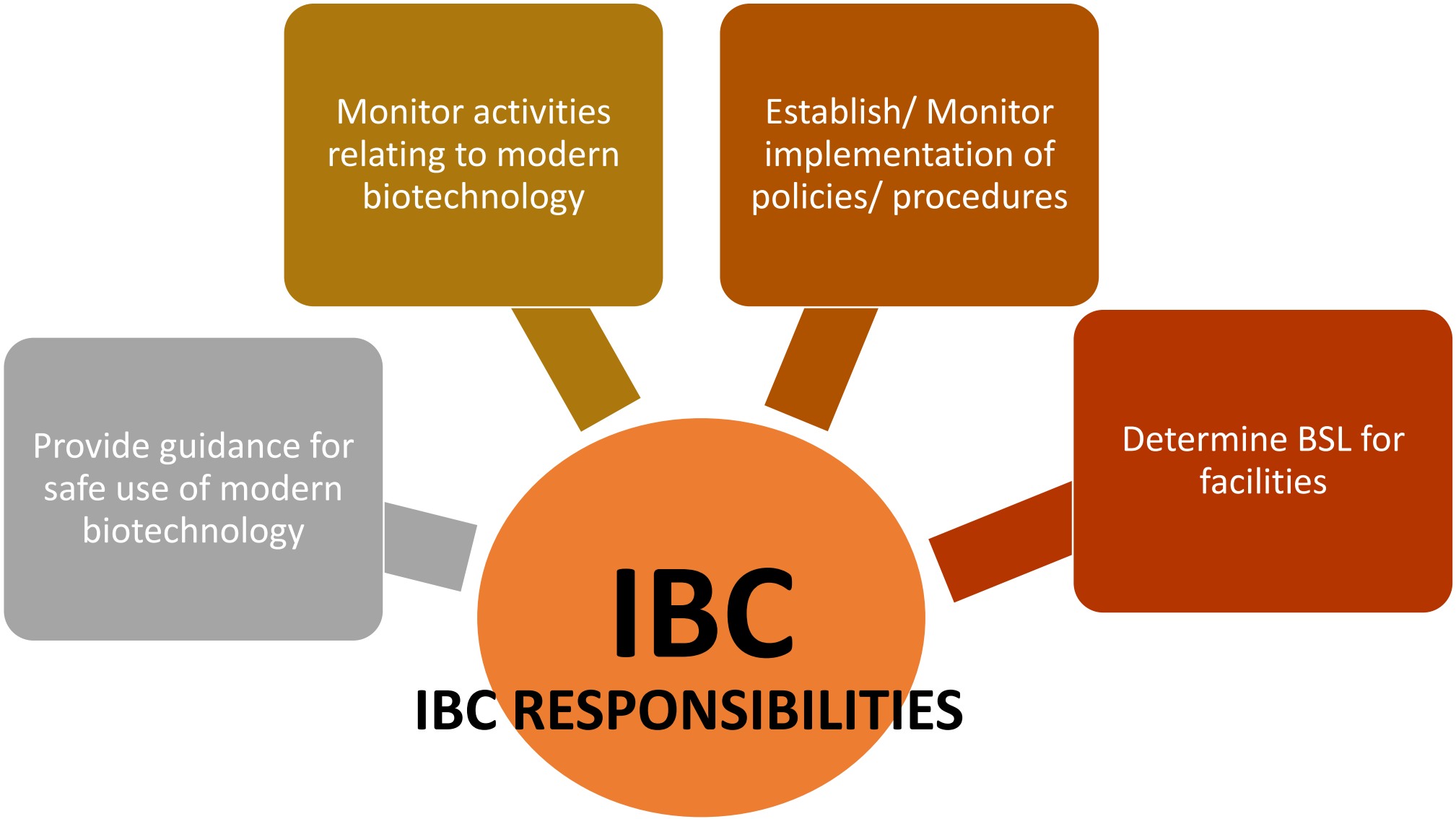
INSITUTIONAL BIOSAFETY COMMITTEE (IBC) UNDER BIOSAFETY ACT 2007 TRAINING MATERIAL

OUTLINE

1	• Introduction to IBCs
2	• Responsibilities of IBC
3	• Responsibilities of IBC Chair
4	• Responsibilities of BSO
5	• Scope of IBC Review
6	• Compliance Oversight and Corrective Action

Introduction

- The IMU Biosafety Committee (IBC) is formed to comply to the Biosafety Act 2007 [Act 678] and Part II of the Biosafety (Approval and Notification) Regulations 2010. IBC is responsible to oversee all activities involving the handling, manipulating, working, using, storing and disposing of infectious and potentially infectious agents/materials and biological toxins in all forms and sizes of laboratories and containment zones in IMU.
- Regulated under the Section 5(1) of Biosafety Regulations 2010
- All modern biotechnology activities which involves the use of any Living Modified Organism or recombinant DNA molecule (LMO/rDNA) materials must be conducted in accordance to the lab biosafety standards and best practices to ensure safety of personnel, campus community and environment. The IBC is registered with the National Biosafety Board (NBB).


Monitor activities relating to modern biotechnology
Establish/ Monitor implementation of policies/ procedures
Provide guidance for safe use of modern biotechnology
Determine BSL for facilities
IBC
IBC RESPONSIBILITIES

IBC RESPONSIBILITIES

1. ***Provide guidance for safe use of Modern Biotechnology***
   - Guidance – biosafety policies/issues, safety of lab
   - Assist in development of procedures
   - Notify Principal Investigator (PI) of results of IBC's review, approval or rejection of application
   - Advise PI on exempted activities
   - Establish an institutional system to ensure compliance to requirements of the Biosafety Act

2. ***Monitoring activities relating to Modern Biotechnology***
   - Assess and monitor facilities, procedures, practices, training and expertise of personnel
   - Ensure information/documents provided in application form are complete
   - Recommend approval for activities that conform to Biosafety Act 2007 and Regulation 2010 & periodically review these projects

IBC RESPONSIBILITIES

2. ***Monitoring activities relating to Modern Biotechnology (Cont'd)***

- Assess field experiments – RA, RM & ERP -sufficient
- Adopt and implement ERP – accidental spills, personnel contamination, resulting from LMO research
- Review and report to Head/NBB of non-compliance and significant research related accidents/illnesses,
- Recommend action to be taken for non-compliance

3. ***Determine Biosafety Levels (BSL)***

- Set or modify containment level (BSL) for activity

IBC CHAIR RESPONSIBILITIES

Head of organization as IBC chair is required to:

- **Be aware** of all requirements for Biosafety Act compliance
- Provide leadership and support at management level
- Determine that facilities are appropriate and safe for the research proposed
- As necessary, appoint ad-hoc sub comm. for exemption activities
- As necessary, appoint Rapid Response Team (RRT) to review hazardous incidents within 24 hrs of occurrence and immediately engage relevant parties

IBC CHAIR RESPONSIBILITIES

- Ensure laboratory personnel receive appropriate training prior to the initiation of research projects,
- Support the work/decisions of IBC in its charge to protect the organization and staff, reduce liability for the organization, and be good stewards of public trust in the products of biotechnology
- Provide written notification of IBC decisions to PI
- Ensure activity does not start before getting acknowledgement letter from Director General of Biosafety

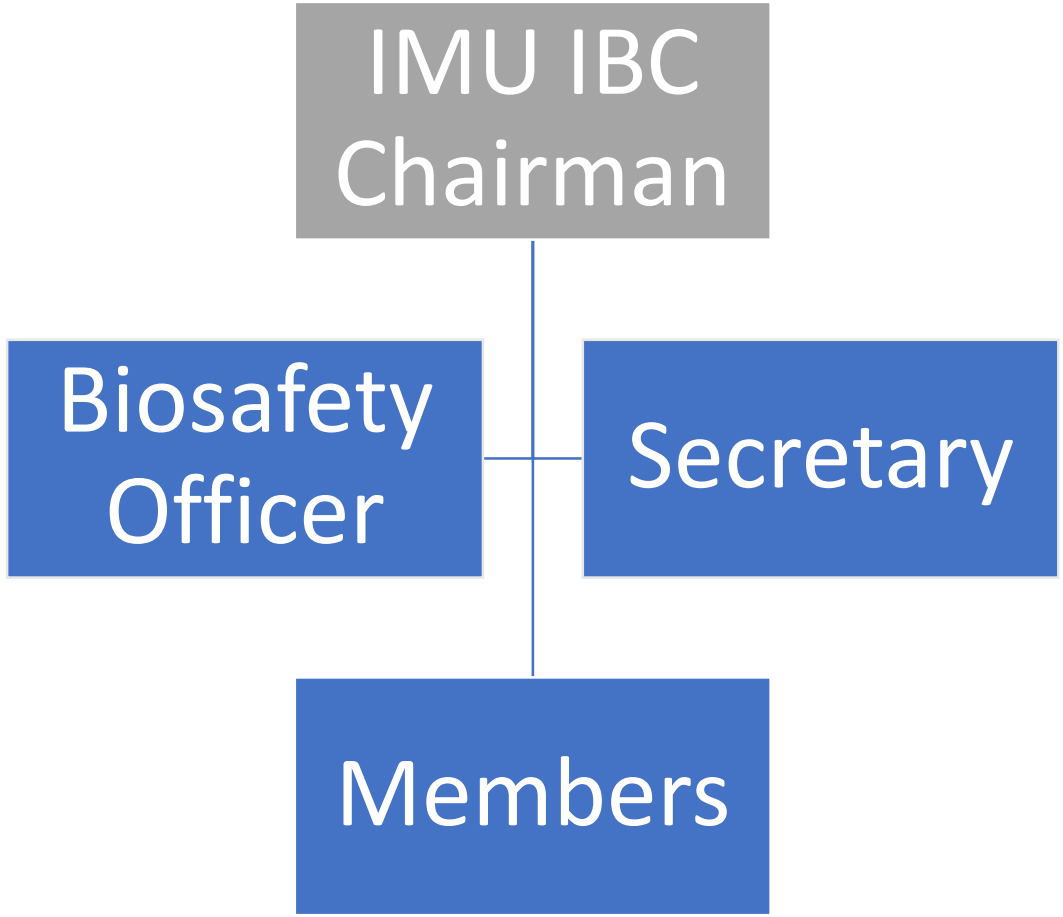
Biological Safety Officer (BSO) Responsibilities

- Appointed by Head of organization
- Member of IBC (voting member) and must be affiliated with the organization
- Recommended to be permanent
- Contact person for NBB & other regulatory agencies

BSO Responsibilities (CONT'D)

- Assists in assuring compliance to BA
- Submits all applications (notification/ approval) and annual report of IBC on behalf of organization
- Periodically inspects laboratories
- Reports significant problems/non compliance/ research-related accidents or illnesses to IBC
- Provides guidance in development of Emergency Response Plan (ERP)-handling LMO/investigating incident
- Makes recommendations to IBC on the BSL for activities
- Works with Rapid Response Team (RRT) to provide technical advice on research safety and laboratory security procedures to PI, laboratory personnel and IBC

IMU-IBC Organization



IMU IBC Member

No.	Name	Unit/Department	Position
1	Prof Datuk Dr Lokman Hakim Sulaiman	Institute for Research, Development and Innovation (IRDI)	Chairman
2	Dr Kenny Voon Gah Leong	Pathology	Biosafety Officer
3	Prof Patricia Lim Kim Chooi	Pathology	Member
4	Dr Amalraj Fabian Davamani	Human Biology, Cells and Molecules	Member
5	Dr Nur Alia Johari	Institute for Research, Development and Innovation (IRDI)	Member
6	Mr Muhammad Faisal bin Selamat	Safety Officer	Member
7	Ms Malathi Murgaiyah	Research Laboratory	Member
8	Ms Liew Siew Wah	Multi-Disciplinary Lab	Member
9	Ms Norbazlin Md Marham	Research Laboratory	Secretary

Researcher's Roles & Responsibilities

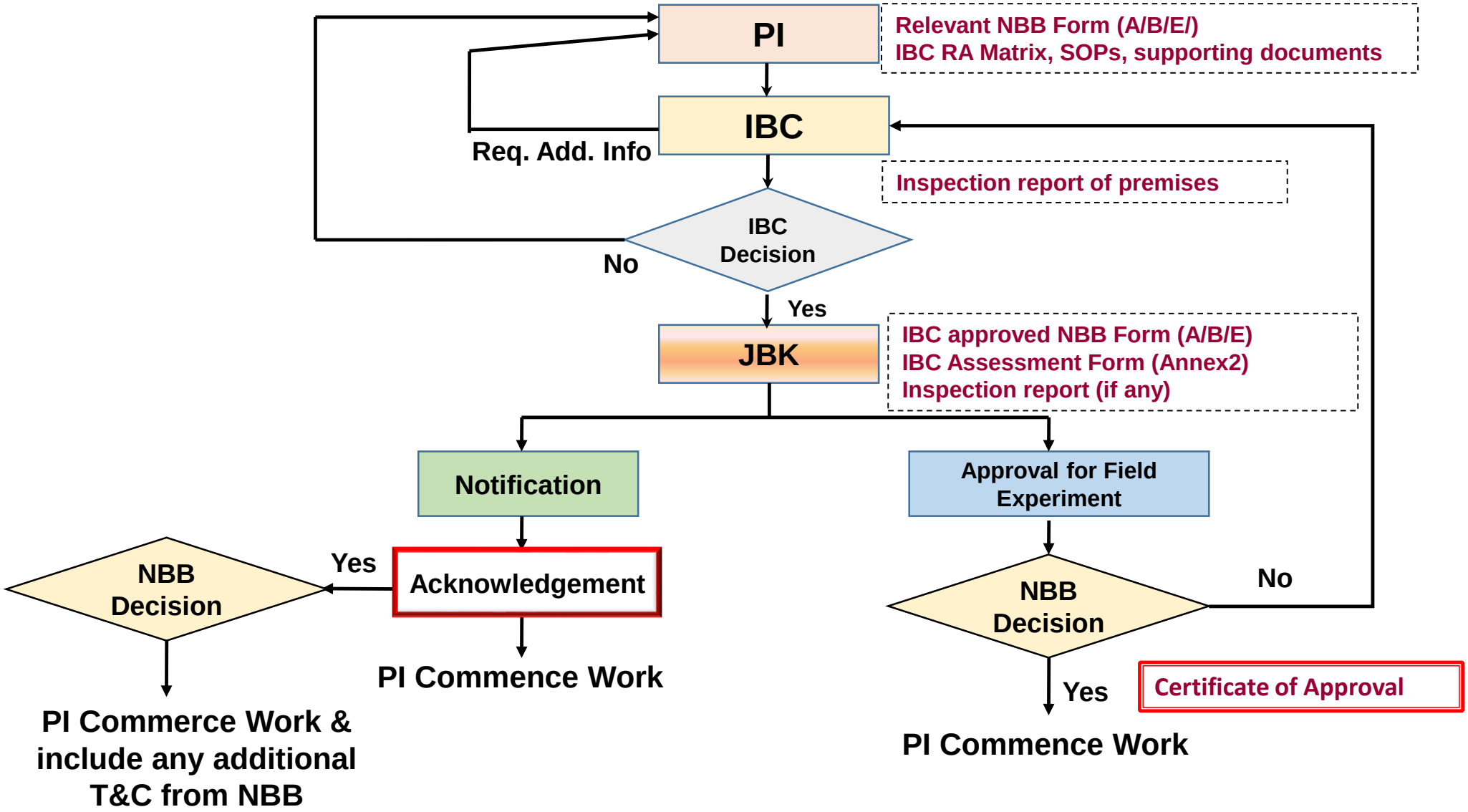
Principal investigators (PI) are responsible for:

- Understanding that any research activities involving LMOs, or storage of LMOs, undertaken within a facility, installation or other physical structure such as it prevents contact and impact of the LMOs on the external environment must be contained.
- Submitting an IBC application using the **IBC/AP/13/ANNEX 2** to secure required approval from the IBC and NBB, NRE for all research involving recombinant DNA or SNA before beginning the project.
- Amending the approved IBC application prior to implementing changes to the research.
- Fulfilling any additional PI responsibilities as detailed in the Biosafety Act (http://www.biosafety.nre.gov.my/act_regulations/biosafety-act2007.pdf) and Biosafety Guidelines for Contained Use Activity of Living Modified Organism (LMO)
- Ensuring that all laboratory personnel have received the required training for the work they will perform and that their type of work and their suitability is approved by the supervisor. Such training include:
- The use of proper microbiological practices and laboratory techniques at the approved biosafety level

SCOPE OF IBC REVIEW

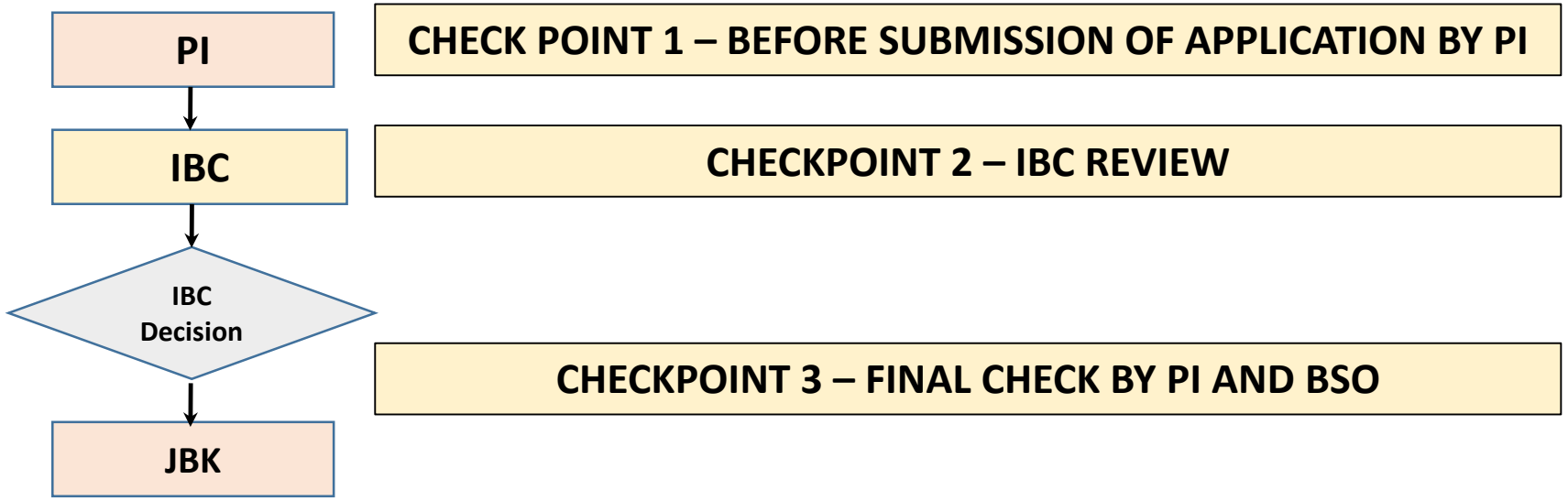
1. LMO activity - Notifications/Approval
2. Modifications to Approved Projects
3. Project Extension Review of Approved Projects & Notice of Termination
4. Exemptions
5. Incidents and Personnel Exposure
6. Biosafety Manuals
7. Laboratory Inspections

IBC REVIEW 1 - LMO activity – Notifications & Approval

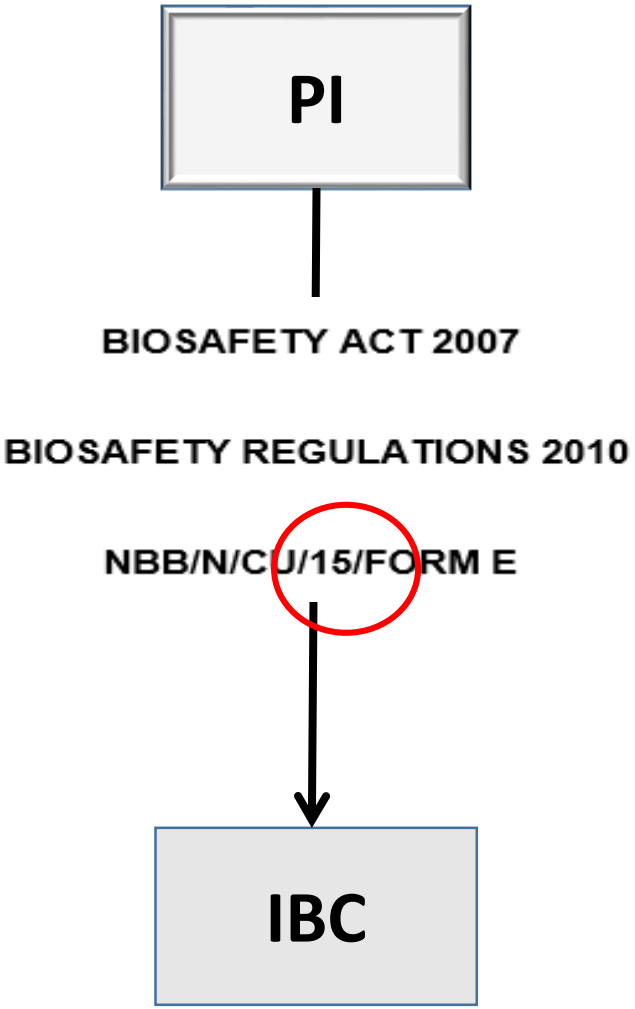


IBC REVIEW 1 - LMO activity – Notifications & Approval (cont'd)

3 IMPORTANT checkpoints ensure the notification/approval forms are complete



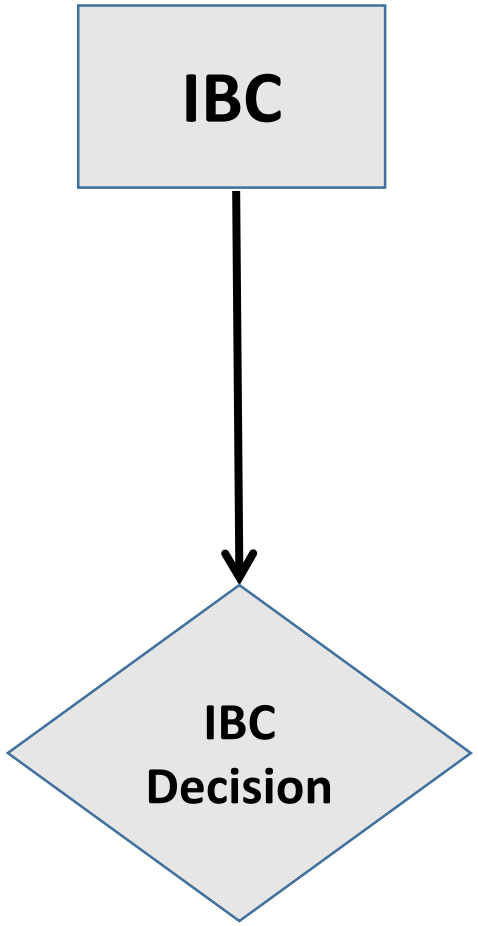
IBC REVIEW 1 - LMO activity – Notifications & Approval (cont'd)



CHECKPOINT 1 – BEFORE SUBMISSION OF APPLICATIONS BY PI

1. Ensure correct form and number of copies are submitted
2. Ensure all the correct supporting documents are included
3. IBC to record application of submission, case number, documentation of assessment in IBC minutes
4. Provide requested information by IBC promptly

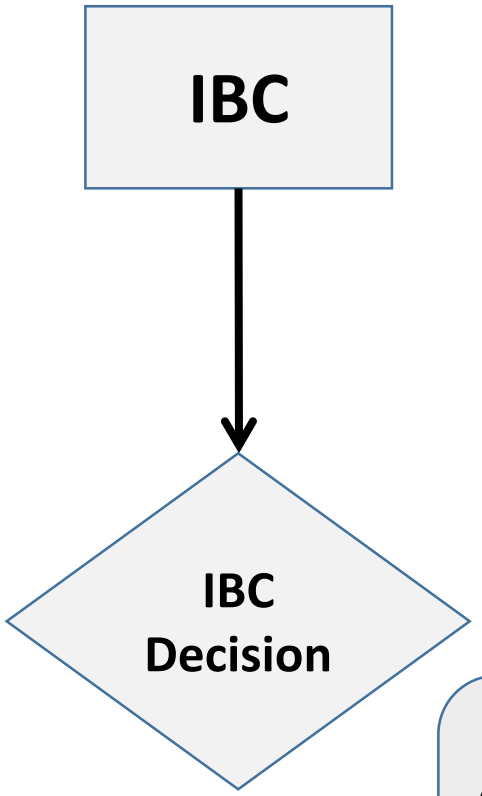
IBC REVIEW 1 - LMO activity – Notifications & Approval (cont'd



CHECKPOINT 2 – IBC REVIEW

1. Agent characteristics
2. Project Objective, methodology, types of manipulations planned
3. Qualification of personnel
   a) Categories of people authorized to handle project – Students? Technicians? Researchers?
   b) Experience & expertise
   c) Training and instruction
   d) Health
   e) Others

IBC REVIEW 1 - LMO activity – Notifications & Approval (cont'd)



4. Confirm validity and completeness of information provided by PI
5. Endorse time period proposed by PI to complete the activity
6. If it is inter-agency collaborative research, ensure that the partner IBC has endorsed use of their facilities
7. Ensure that RA, RM and ERP of activity is sufficient
8. Ensure that facility is suitable for activity

MATCH

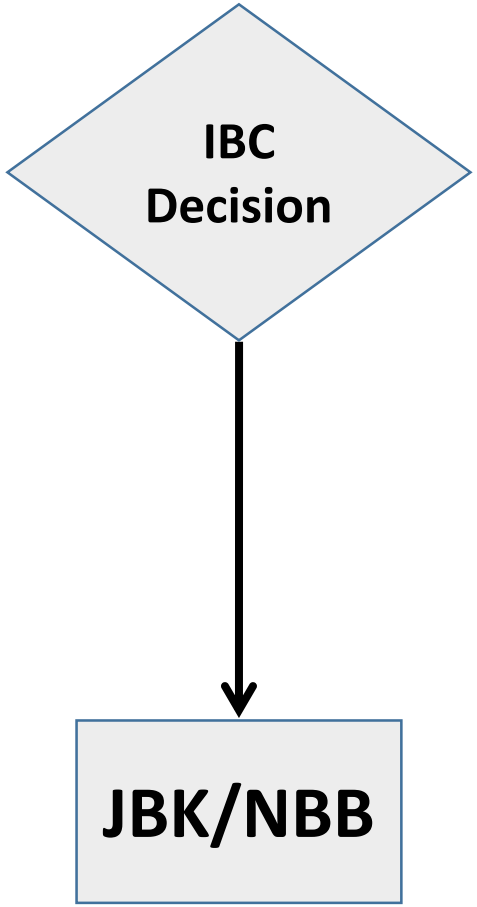
RA OF LMO ACTIVITY

Agent characteristics (e.g. virulence, pathogenicity, environmental stability), Project Objective, Methodology, Types of manipulations planned, Sources of the inserted DNA sequences (e.g. species), Nature of inserted DNA seq, hosts and vectors to be used, Qualification of personnel

PREMISES

Containment conditions to be implemented including RM and ERP as specified, SOPs, premise features and work practices

IBC REVIEW 1 - LMO activity – Notifications & Approval (cont'd)



CHECKPOINT 3 – FINAL CHECK BY PI AND BSO BEFORE SUBMISSION TO JBK

1. Provide IBC Assessment Report - IBC/AP/10/Annex2
2. Ensure form is in final version & complete
3. IBC Chair and Head to provide statutory declaration in Form and insert official stamp
4. Provide any premises inspection reports if necessary
4. Monitor progress of submission and any required response from JBK/GMAC/NBB to the PI

IBC REVIEW 1 - LMO activity – Notifications & Approval (cont'd)

CHECKPOINT 3 – FINAL CHECK BY PI AND BSO BEFORE SUBMISSION TO JBK (CONT'D)

USE THE CHECKLIST

1	• 1 original Form A/B/E
2	• 6 identical copies of the form
3	• Supporting documents
4	• CD with Form and supporting documents
5	• IBC Assessment Report
6	• Proof of payment

After submission, JBK will provide Acknowledgement letter and issue reference number

Important note on SOPs submitted

STANDARD OPERATING PROCEDURE

Treatment of equipment after use in GM related activities

Standard Operating Procedure No.	HGT 08
Revision No:	
Original Date of Issue:	06 May 2014
Revision Date:	
Revised by:	
Approved by:	IBC of ABC Company

Background:

Premise 1: Molecular biology laboratory, Biotechnology Unit
Premise 2: Tissue culture laboratory, Biotechnology Unit
Activities described in SOP HGT 01-05 leave behind used and potentially contaminated equipment (laminar flow hood, orbital shaker, spectrophotometer, etc.). Besides periodical maintenance service, the referred equipment is cleaned to ensure decontamination after each use.

Purpose: To provide instruction on standard operating procedure of treating equipment after use in GM related activities, from premises 1 and 2.

Related Standards and Procedures:

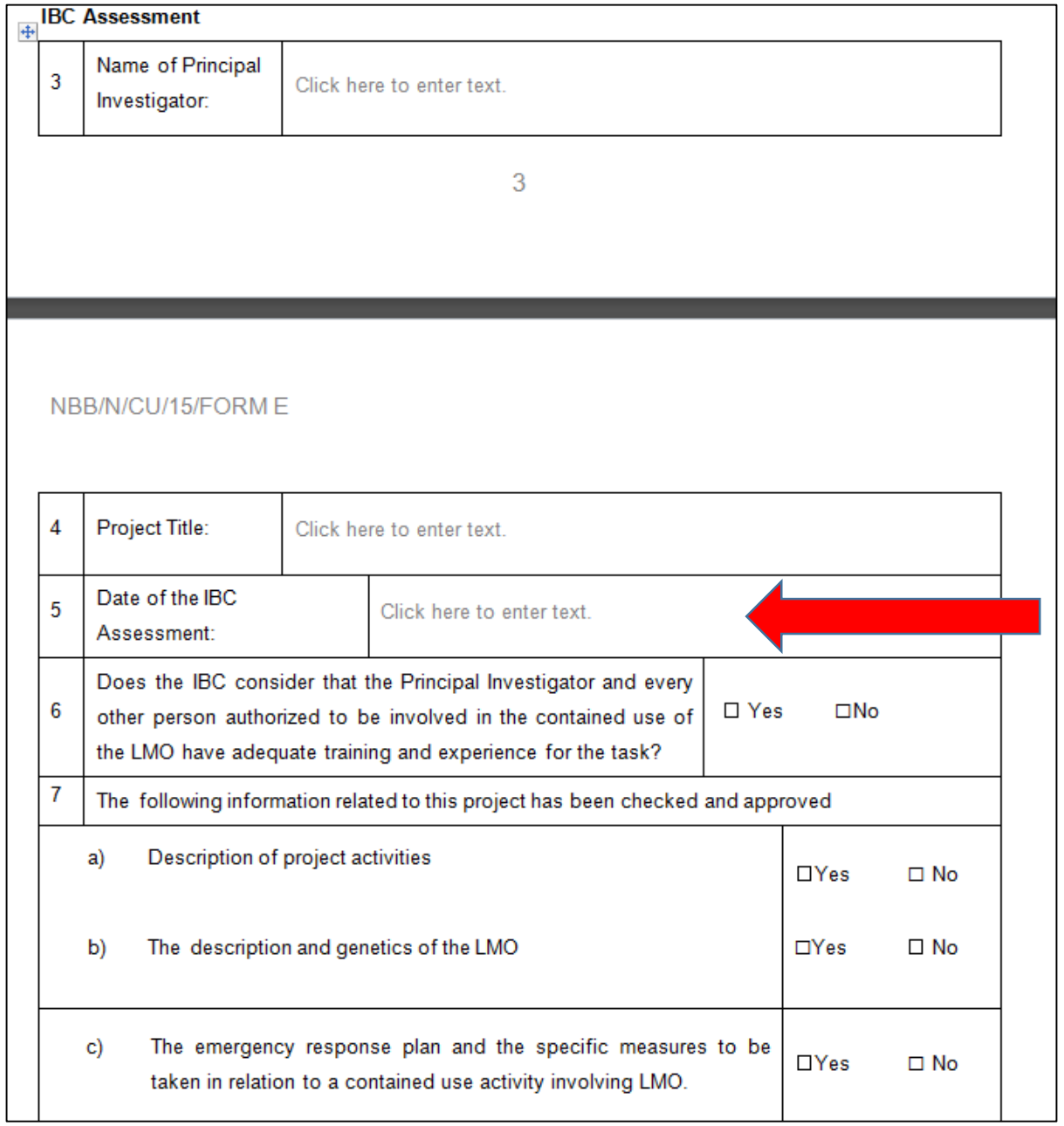
- Biosafety Guidelines of Contained Use Activity of Living Modified Organism, ISBN No. 978-967-10117-1-3

Procedure:

- Laminar flow hood:
  1. Wipe clean work surface of the laminar flow hood thoroughly with paper towel presoaked with 70 % v/v ethanol after completion of activities. 2. Leave the light and blower operating for 2 minutes to allow the work surface to dry completely. 3. Switch off the light and blower, and pull down the front screen to prevent contaminants from entering the hood.
- Temperature controlled orbital shaker:
  1. Wipe clean door, internal walls, and orbital platform after use with 70 % v/v ethanol. 2. Leave the door open for 2 minutes to allow the wet surface to dry completely. 3. Switch off the light and close the door to prevent contaminants from entering the orbital shaker.
- Spectrophotometer:

Form E_IBC Assessment

Important note on IBC ASSESSMENT



IBC Assessment

3	Name of Principal Investigator:	Click here to enter text.

3

NBB/N/CU/15/FORM E

4	Project Title:	Click here to enter text.
5	Date of the IBC Assessment:	Click here to enter text.
6	Does the IBC consider that the Principal Investigator and every other person authorized to be involved in the contained use of the LMO have adequate training and experience for the task?	☐ Yes ☐No
7	The following information related to this project has been checked and approved	
	a) Description of project activities	☐Yes ☐ No
	b) The description and genetics of the LMO	☐Yes ☐ No
	c) The emergency response plan and the specific measures to be taken in relation to a contained use activity involving LMO.	☐Yes ☐ No

Date of IBC assessment

IBC/AP/13/ANNEX 2

Important note on IBC ASSESSMENT

1.	Experience and expertise	:
2.	Training	:
3.	Health	:
4.	Other (please specify)	:

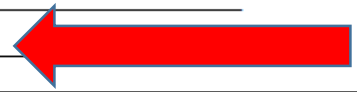
4. List of all personnel[1] involved in project

No.	Name	Designation
1.		
2.		
3.		
4.		
5.		

Signature (of IBC Chair) and Date

Name : _____

Date : _____



Date of IBC assessment

IBC REVIEW 2 - MODIFICATIONS TO APPROVED PROJECTS

- PI SHOULD NOT initiate or implement any significant change or modification to IBC approved projects without prior review and approval of the IBC and NBB
- Modification refers to changes in LMO materials, procedures, personnel, laboratory location or any change which may increase/change Risk Group of the project or its BSL

IBC REVIEW 3 - PROJECT EXTENSION REVIEW OF APPROVED PROJECTS & NOTICE OF TERMINATION

- PI should submit IBC Project Extension Review/ Notice of Termination Form (IBC/PE-NT/10/Annex 5) to extend time period of activity or report that activity has been completed/no longer active
- Form should be submitted at least one month prior to the next scheduled IBC meeting
- Notice of Termination should include description of when and how the LMO materials were disposed.

IBC REVIEW 3 - PROJECT EXTENSION REVIEW OF APPROVED PROJECTS & NOTICE OF TERMINATION

If project extension involves the following changes, a New Notification should be submitted:

- New PI,
- New Risk Group,
- BSL,
- Type/amount of LMO,
- Moving of LMO materials to another laboratory/facility

IBC REVIEW 4 - EXEMPTIONS

- IBCs should be notified of exempted projects using internal procedure
- An ad hoc sub committee can review projects to verify the status of exemption
- Techniques and contained use activities that are exempted are listed in First Schedule (Regulations 2010)
- Exempted activities should be carried out under conditions of standard microbiological lab practice
- Personnel should have appropriate training

IBC REVIEW 5 - INCIDENTS & PERSONNEL EXPOSURE

- IBC to ensure Accident/Incident are reported
- Review information provided through Incident Reporting Form (IBC/IR/10/Annex3) or/and Occupational Disease /Exposure Investigation Form (IBC/OD/10/Annex 4)
- Discussions and actions pertaining to incident should be documented in minutes of IBC meeting
- Accident/Incident should be reported to JBK through IBC annual report
- NBB may request for detailed report if necessary

IBC REVIEW 6 – BIOSAFETY MANUALS

- Collection of biosafety protocols and procedures (safety manuals) must be available in every laboratory
- IBC will review these document during inspection

IBC REVIEW 7 – LABORATORY INSPECTIONS

- IBC will conduct routine inspections and sometimes as part of assessment of proposed activity
- Inspection checklists are provided in JBK website
- Problems are reported to PI for remedial procedures. Inspection reports will be maintained on file by IBC
- Routine inspection may also be conducted by representatives/officers authorized by NBB

Compliance Oversight & Corrective Action

IBC may take the following actions:

- Suspension of the use of LMO materials
- Cessation of the approval for use of the LMO materials
- Confiscation of the LMO materials
- Destruction of the LMO materials
- Any other action necessary to protect the public and/or the organization, including suspending the relevant research activity
- Reporting to the NBB through JBK

Compliance Oversight & Corrective Action (cont'd)

PI has to take the following actions to prevent any non compliance:

- Comply with all legislative requirements when conducting research involving LMO materials
- Immediately report any significant problems with respect to the implementation of relevant laws, regulations and guidelines
- Notify IBC promptly of any significant research related accidents that have resulted or could result in human illness, in unanticipated plant or animal disease, or in the unintended release of an organism under study from an intended confinement
- Complete required training as specified

THANK YOU