GUIDELINE ON COMPLETING BIOLOGICAL RISK ASSESSMENT

PIs must conduct risk assessment (Biological Risk Assessment Form, UM/IBBC/ANNEX 1) in relation to the activity proposed to be carried out and putting in place the appropriate measures. The biological risk assessment should be communicate to the personnel involved to the hazards of working with infectious agents and to the need for developing proficiency in the use of selected safe practices and containment equipment.

To conduct the laboratory/work activity based risk assessment shall consist of the following elements:-

1) Prepare all information necessary for risk assessment (eg: Pathogen safety data sheet, process flow chart, operation manual, accident records, etc)
2) Identify the personnel involve in the project (risk assessment team(s)) and describe each respective roles or job duties
3) Open an electronic copy of **Biological Risk Assessment Form - UM/IBBC/ANNEX 1** and complete the details of at the top of worksheet.

EXAMPLE:

WORK INVENTORY FORM			
Complete address where work will be performed: (Specify the Bldg BLOCK & FLOOR)	*Eg: Research Laboratory 1* *Department of Medical Microbiology* *Faculty of Medicine* *University of Malaya*	**IBBC registration no:**	**Eg:** UMIBBC/NOI/D/XXXX/XXX-004/2017
		Name of PI:	Name of the lead scientist who takes direct responsibility for the technical and/or scientific direction of a project, the relevant course coordinator and service laboratory director
Project Name:	*Eg: Dengue Serology Testing*	**Conducted By:** **Date:**	Name of personnel who is responbonsible in conducting the risk assessment
Name of Biological Agent:	*Ex: Dengue Virus*	**Reviewed and Approved By:** **Date:**	Name of person who reviewed and approved the risk assessment. Date of approvel.

4) Register the work processes or experiments and a listing of work activities (from beginning to end point for each process) with information on hazardous materials used and the location where the activity is performed. Prioritize the most critical process and activities involved in the experiment.

EXAMPLE:

UM/IBBC/ANNEX 1
BIOLOGICAL RISK ASSESSMENT FORM

No	Work Process	Act No	Work Activities
1.	Receiving suspected blood sample and blood sample preparation for diagnostic testing	1.1	Receiving blood sample tubes (in secondary or outer container) sent from blood collection clinic , etc
		1.2	Register the samples
		1.3	Transferring blood sample tubes out from the external parcel/box/container for processing.

5) Hazard Identification
    a. Identify what hazards, in addition to biological, are associated with each work activity.
    b. Enter the hazard in column 2 (activities), second page of the Risk Assessment worksheet.

6) Risk Evaluation
    a. Upon identifying the hazard(s), state the possible corresponding outcome related to human (injury, death/ ill-health) contribute by the hazards, column 3.
    b. Consider any current/existing controls measures in related to the work activity, record this in column 5 **(Likelihood score – Existing Risk Control)**
    c. Refer to classification table for scoring severity (table 1) and scoring likelihood (table 2).
        - Assessing the severity rating that relates to how severe is the possible injury, death/ ill-health
        - Determine the likelihood occurrence arising from identified hazard(s) by considering the existing controls
    d. Record the value for the severity in column 4 and likelihood in column 6. Estimate the risk levels of the activity in related to the hazards identified. Risk level are deduced from risk scoring of severity and likelihood (severity x likelihood). Use the 5 X 5 risk matrix (table 3) below as a guide to assess the level.
    e. Determine the acceptable level of the risk acceptability of risk)

Table 1 : Scoring Severity

Score	Impact to human	Impact to community	Impact to environment
1 (Insignificant) Negligible	Not likely to cause harm or injury	Does not lead to disease in human or animal	No impact to environment
2 (Minor) Slight	Injury of ill-health requiring 1st aid treatment only. Discomfort is temporary and reversible	May infect lab worker but is not serious. Not community risk	No impact to environment
3 (Moderate)	Injury require medical treatment	May infect lab worker but not infectious or May spread but prophylaxis is available e.g: normal flu	May have impact that take weeks to reverse
4 (Major) High	Serious injury or long term life threatening occupational disease (e.g: cancer)	High risk of spreading to community but affective prophylaxis or treatment is available.	Great impact to environment and may take years to reverse
5 (Catastrophic) Very high	Fatality disease or injury	Readily infect lab worker and transmittable to human or animal. No effective treatment is available	Irreversible e.g:

Table 2: Scoring Likelihood

LEVEL	DESCRIPTON	LIKELIHOOD – DESCRIPTION
1	Remote (very unlikely)	Never happen in a lifetime due to robust existing control and no risk
2	Unlikely	May occur at some time
3	Possible	Possible or known to occur
4	Likely (Frequent)	Will probably occur in most circumstances or at constant interval
5	Most likely (very frequent)	Is expected to occur in most circumstances

Table 3: 5 X 5 Risk Matrix

LIKELIHOOD	SEVERITY(S)				
	1	2	3	4	5
5	5	10	15	20	25
4	4	8	12	16	20
3	3	6	9	12	15
2	2	4	6	8	10
1	1	2	3	4	5

EXAMPLE:

Laboratory:	**Laboratory 1, Diagnostic Virology Laboratory**	**Conducted By:** **Date:**	
Work Process:	**Receiving suspected blood sample and blood sample preparation for diagnostic testing**	**Reviewed and Approved By:** **Date:**	

Act No	Hazard/Threat Identification	Risk Evaluation					Risk Control & Mitigation						
		Severity Score		Likelihood Score		Risk Level Score (S x L)	Proposed Risk Controls	(S)	(L)	Final Risk Level Score (S x L)	Person-in-Charge	Due Date	Remarks
	Activities	Possible Injury/ ill-Health	(S)	Existing Risk Control (if any)	(L)								
1.1	Receiving blood sample tubes (in secondary or outer container) Register the samples	Exposure to contaminated tubes surface or container	4	PPE (lab coat) when receiving opening container	1	4							
1.2	Register the samples	Incorrect sample ID & Information	3	Bar Code Inventory system	1	3							
1.3	Transferring blood sample tubes out from the external parcel/box/container for processing. Collecting the blood from patients **Discovered** (a) Breakage of blood tube => sharp injury (percutaneous) => direct contact with blood sample	- Sharp injury and blood borne infection (Dengue or others	4	PPE (lab coat) when receiving opening container	3	12							

7) Determine if the risks are acceptable

   a. Based on the risk level, the risk assessor, team, working with management and other stakeholders, should determine if the assessed risk is acceptable to the facility, laboratory, individuals working in the facility, and the community (refer table 4 Acceptability of risk) .

   b. For a risk that is determined to be unacceptable, risk control must be put in place and to determine which mitigation measures are appropriate

   c. Control measures are derived from the hierarchy of control measures below:

      - Elimination
      - Substitution
      - Engineering controls
      - Administrative controls
      - Standard Operating Procedure (SOP)
      - Personal protective equipment (PPE)

   d. An effective and practicable risk controls must be implemented to reduce risk to **Reasonably Acceptable Level.**

Table 4: Acceptability of Risk

RISK	DESCRIPTION	RISK ACCEPTABILITY	RECOMMENDED ACTION
15 - 25	**HIGH RISK**	**Not Aceptable**	A **HIGH** risk requires immediate action to control the hazard as detailed in the hierarchy of control. Actions taken must be documented on the risk assessment form including date for completion. Work shall not start.
5 - 12	**MEDIUM RISK**	**Tolerable**	A **MEDIUM** risk requires a planned approach to control the hazard interim control measures may be imlemented while longer term measures are being establish and to ensure that the risk level is reduce to as low as ressonably practicable within a define period. It is acceptable to start the work activities and actions taken must be documented on the risk assessment form including date for completion.
1 - 4	**LOW RISK**	**Acceptable**	A risk identified as **LOW** may be considered as acceptable and further reduction may not be necessary. However, if the risk can be resolved quickly and efficiently, control measures should be implemented and recorded.

8) Estimate the reduction in severity (enter in column 9) and likelihood (enter in column 10) provided by the control(s). Determine the final risk level score (column 11).
9) Identify a person that will be responsible to implement the controls and enter the name at column 12 and estimate the due date of the controls to be implemented.
10) Completed work activity risk assessments must be reviewed and approved by PI and be reviewed
    a. once every two years, or;
    b. upon occurrence of accidents, near misses, dangerous acts, or;
    c. when there are changes in work processes, technologies or workplace condition / layout,
11) On completion of the form, the original form must be submitted to IBBC secretariat for the NOI submission. A copy of the complete document is placed in the file and should be clearly identifiable and accessible to the users.
12) The risk assessment should be fully and systematically documented and communicated to the laboratory personnel. Understanding any limitations that influenced a risk assessment is essential for transparency of the process that is important in decision making. The formal document and record should indicate any constraints, uncertainties, and assumptions and their impact on the risk assessment.

Refer to sample template for work activity risk assessment for laboratory handling biological materials