

# MANAGEMENT OF BIOSAFETY AT UNIVERSITY

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**Abstract:** This manual was developed by the Institutional Biosafety Committee (IBC) of Universiti Tun Hussein Onn Malaysia to provide information to protect workers and the surrounding environment and to comply with applicable standards and regulations. The planning and the implementation of biohazard controls to prevent laboratory-associated infections and to control the spread of contamination must be a part of every laboratory activity in which biohazardous agents are used. The handling of biohazardous agents requires various precautionary measures depending on the agent(s) involved. The purpose of this manual is to provide general guidelines for evaluation, containment, and control of biohazards, categorized as degrees of risk of infection. The implementation of this manual and procedures is the responsibility of the Principal Investigator and the person in charge of each laboratory. It is essential that they seek additional advice and training when needed to conduct research in a safe manner for employees, students, and the surrounding community. To assist in this regard, the Occupational Safety, Health and Environment Office services are available at the university.

**Keywords:** Biosafety, environment, community, procedures, infection



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# Preface

This manual was developed by the Institutional Biosafety Committee (IBC) of University Tun Hussein Onn Malaysia to provide information to protect workers and the surrounding environment and to comply with applicable standards and regulations.

The planning and the implementation of biohazard controls to prevent laboratory-associated infections and to control the spread of contamination must be a part of every laboratory activity in which biohazardous agents are used. The handling of biohazardous agents requires various precautionary measures depending on the agent(s) involved. The purpose of this manual is to provide general guidelines for evaluation, containment, and control of biohazards, categorized as degrees of risk of infection.

The implementation of this manual and procedures is the responsibility of the Principal Investigator and the person in charge of each laboratory. It is essential that they seek additional advice and training when needed to conduct research in a safe manner for employees, students, and the surrounding community. To assist in this regard, the Occupational Safety, Health and Environment Office services are available at the university.

## CHAPTER ONE

# Introduction

### 1.1 PURPOSE OF MANUAL

This manual is prepared to explain the vital biosafety components of working in a research laboratory at University Tun Hussein Onn Malaysia (UTHM). This is to ensure students and staff have adequate information on training, safe work practices, safety equipment and personal protective equipment to protect them and the surrounding community from possible hazards associated with biohazardous agents.

Additionally, this manual includes an introduction to biosafety in Section 1, risk assessment in Section 2, procedures required for biohazard control in Section 3, emergency preparedness and response in Section 4, and guidelines for containment of biohazards in **Section 5**. This is for Principle Investigators (PI) who are required to obtain approval through the Institutional Biosafety Committee (IBC), UTHM and the National Biosafety Board (NBB). Lastly, this manual includes the control of biohazard of animals in **Section 6**:

### 1.2 DEFINITION OF BIOHAZARDS

**The term** "biohazard" refers to any biological substance that is hazardous to humans, animals, or the environment. Numerous biohazards are comprised of valuable biological materials (VBM)

## CHAPTER TWO

# Biological Risk Assessment

Risk assessment is a process used to identify the degree of risk to laboratory workers, other personnel, and the environment. The degree of risk considers the virulence, pathogenicity, biological stability, and communicability of the organisms and the route of transmission. A biological risk assessment takes into account both the hazardous characteristics of the biological agents and the laboratory procedure hazards.

If the biological agents are GM, the risk assessment must take into account how the modification potentially changes the agents' hazardous characteristics such as virulence, pathogenicity, or susceptibility to treatments. This information can be found in Section 5: LMO / GMO Experimentation.

The laboratory manager or PI is responsible for ensuring that adequate and timely risk assessments are performed and for working closely with the Safety Committee and BSO to ensure that appropriate equipment and facilities are available to support the work being considered. Once performed, risk assessments should be reviewed routinely and revised when necessary, taking into consideration the acquisition of new data having a bearing on the degree of risk and other relevant new information from the scientific literature.

## CHAPTER THREE

# Procedures for Biohazard Control

### 3.1 FACILITY REQUIREMENTS

#### 3.1.1 Biosafety Level 1 Laboratory (BSL-1)

The facility requirements of BSL-1 is presented in detail as the basis for all biosafety laboratories. Each laboratory should adopt safety or operation manuals that identify known and potential hazards and determine practices and procedures to eliminate or minimise such risks.

The facility requirements for BSL-1 laboratory are:

- a. It is not separated from the general traffic patterns in the building.
- b. It is designed with open benches which can be cleaned easily.
- c. Bench tops should be impervious to water and resistant to acids, alkali, organic solvents, and moderate heat.
- d. Laboratory furniture should be sturdy. Open spaces between and under benches, cabinets, and equipment should be accessible for cleaning.
- e. Ample space must be provided for the safe conduct of laboratory work and for cleaning and maintenance.

## CHAPTER FOUR

# Emergency Preparedness and Response Plan

**An emergency response plan (ERP) is** a series of documents for dealing with laboratory incidents and accidents which is a necessity in any facility that works with or stores biological hazards. The head of the centres should implement the ERP and establish a response team (ERT) in case of a biological emergency.

### 4.1 BIOHAZARDOUS SPILLAGE

Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived.

Biohazardous spillages come in two types:

- a. Unintended release of potentially infectious material which has been handled or generated within a laboratory (e.g.: liquid cultures of micro-organisms).
- b. Human or animal bodily fluids or materials such as blood, urine, vomit or faeces either accidentally or maliciously.

A proper response to such incidents ensures the safety of employees and students while reducing the environmental contamination concerns. The responses include assuring the spillage kits are available for use and verifying that all personnel understand and are able to implement the requirements of the spill response procedures shown in the latter part of this section.



## CHAPTER FIVE

# LMO/GMO Experimentation

In UTHM, IBC UTHM acknowledges that modern biotechnology can cause harm to human health and the environment (risk assessment). These risks can be managed or mitigated to a minimal level (risk management/ mitigation). The following is the checklist that principle investigators (PIs) need to follow if they are working with modern biotechnology research:

- a. Be aware that your work may have risks.
- b. Identify the potential risks.
- c. Do a risk assessment – are the risks acceptable?
- d. Do risk management/mitigation.
- e. Is the risk reduced to an acceptable level?
- f. Prepare Emergency Response Plans in case something bad happens.

### 5.1 BIOSAFETY CHECKLIST

- a. Before carrying out the research, PI needs to identify the types of organisms that they are going to use; non-exempted GMO/LMO or exempted GMO/LMO or LO.
- b. PI is responsible for ensuring that adequate and timely risk assessments are performed and working closely with IBC UTHM to ensure that appropriate equipment and facilities are available to support the work.

## CHAPTER SIX

# Controls for Biohazards in Laboratory Animals

## 6.1 UTHM ANIMAL RESEARCH ETHICAL GUIDELINES & LAWS IN MALAYSIA

The use of living or dead animals in experiments and research or any related works must fully adhere to moral and ethical obligations as outlined in the animal ethics research guideline issued by the research management centre (Guidelines for animal and plant research ethics Universiti Tun Hussein Onn Malaysia 2018). The Principal Investigator and all personnel involved must be aware of the biosecurity threats posed when working with animals regardless of the researchers themselves, colleagues, students or community. In addition, the principal researcher must also comply with other laws governing animals in Malaysia from time to time such as:

### a. **Animal Act 1953**

An act to amend and consolidate the laws for preventing the introduction into, and the spreading within, Peninsular Malaysia of diseases of animals; for the control of the movement of animals into, within and from Peninsular Malaysia; for the control of the slaughter of animals; for the prevention of cruelty to animals; for measures pertaining to the general welfare, conservation and improvement of animals in Peninsular Malaysia; and for purposes connected therewith.

		UTHM/OSHE/UP.002
<b>BORANG LAPORAN KEMALANGAN, KEJADIAN BERBAHAYA, PENYAKIT PEKERJAAN DAN KERACUNAN PEKERJAAN</b>		
<b>1. BUTIRAN KEJADIAN</b>		
i. Tarikh : _____	v. Jenis Kejadian :	<input type="checkbox"/> Kemalangan
ii. Masa : _____		<input type="checkbox"/> Kejadian Berbahaya
iii. Lokasi : _____		<input type="checkbox"/> Penyakit Pekerjaan
iv. PTJ : _____		<input type="checkbox"/> Keracunan Pekerjaan
<b>2. BUTIRAN MANGSA</b> <i>(Sila gunakan lampiran sekiranya mangsa lebih dari seorang)</i>		
i. Nama : _____	ii. Umur : _____	
iii. No. K.P/ No.Pasport : _____	iv. Jantina : _____	
v. Status : <input type="checkbox"/> Staf <input type="checkbox"/> Pelajar <input type="checkbox"/> Pekerja Kontrak <input type="checkbox"/> Orang Awam		
<b>3. KECEDEeraan DAN RAWATAN</b>		
i. Nama Klinik/Hospital : _____		
ii. Jenis Rawatan Yang Diberikan : _____		
iii. Bahagian Anggota Yang Tercedera : _____		
iv. Cuti Sakit : _____ hari ( Tarikh _____ )		
<b>4. PERINCIAN KEJADIAN</b>		
<i>(Sila jelaskan secara terperinci keadaan sebelum, semasa dan selepas Kemalangan/ Kejadian Berbahaya/ Penyakit Pekerjaan/ Keracunan Pekerjaan ini berlaku. Gunakan lampiran sekiranya ruangan yang disediakan tidak mencukupi.)</i>		
<b>5. KEROSAKAN HARTA BENDA</b>		
<i>(Sila nyatakan harta benda dan anggaran kos yang terlibat)</i>		
<b>6. CADANGAN PENAMBAHBAIKAN</b>		
<i>(Sila nyatakan cadangan penambahbaikan yang diambil bagi mengelakkan kejadian daripada berulang.)</i>		

**NOTIFICATION FOR ACTIVITIES INVOLVING LIVING ORGANISM (LO) AND LIVING MODIFIED ORGANISM (LMO) IN THE UNIVERSITY**

<b>A. Preliminary Information</b>		
1. Faculty:		
2. Name of applicant (Principal Investigator):		
3. Position: Telephone (office): Telephone (mobile): E-mail :		
<b>B. LO/ LMO Information</b>		
<b>LO/LMO</b>	<b>Containment Level (Level 1 , 2 , 3, 4 )</b>	<b>Risk Group (RG 1, 2, 3, 4)</b>



**STANDARD OPERATING PROCEDURE  
JAWATANKUASA BIOKESELAMATAN UNIVERSITI (IBC)  
(NAME OF THIS STANDARD OPERATING PROCEDURE)**

Standard Operating Procedure No.	
Revision No:	
Original Date of Issue:	
Revision Date:	
Revised by:	
Approved by:	

Procedure:

- List the tasks step by step to provide instruction on how to perform this procedure.
- 
- 

Related Forms and documentation:

- List the forms pertaining to this procedure.
- 

Records:

- List the records that will be kept as a result of this procedure.

References



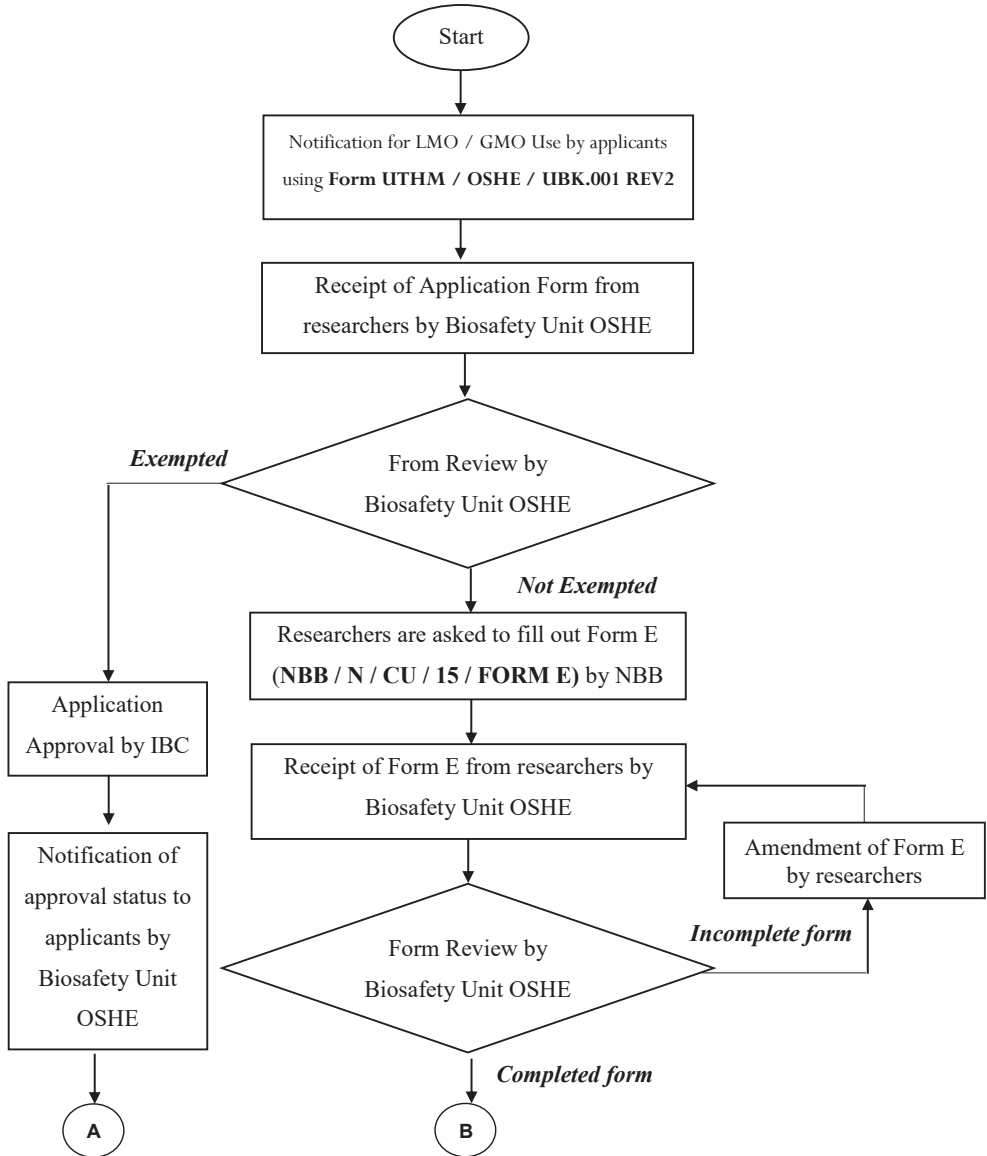
**LABORATORY BIOSAFETY CHECKLIST  
 FOR BIOSAFETY LEVEL 1 AND 2**

<b>A. Premise Information</b>	
1.0	Premise :
2.0	Principal Investigator :
3.0	Inspector :
4.0	Date / Time :
5.0	Laboratory Biosafety Level: <b>1 / 2</b>

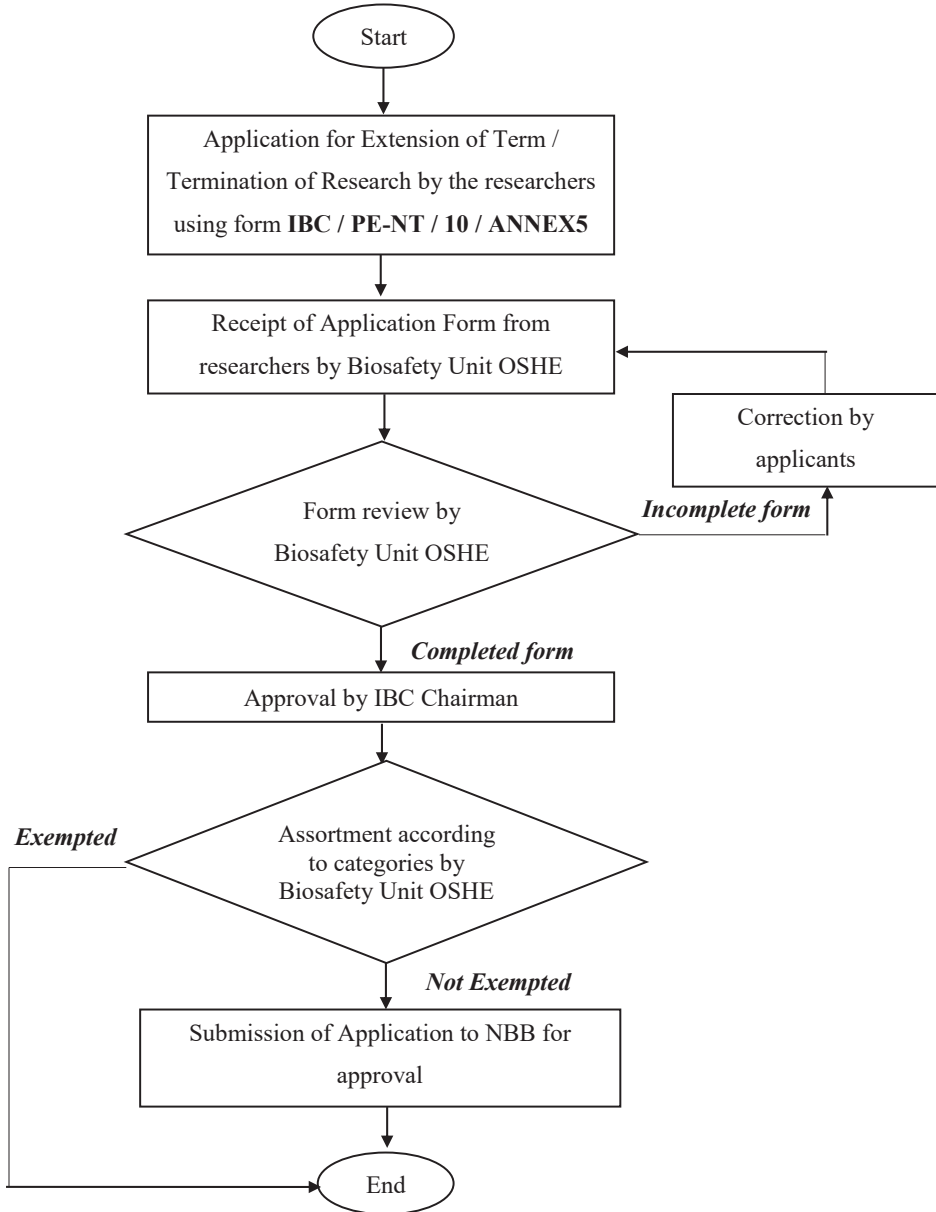
Check (√) in the appropriate box that most accurately describes the laboratory in which the work will be performed.

<b>B. Biosafety Level 1</b>					
<b>1.0</b>	<b>Laboratory Facilities</b>	<i>Yes</i>	<i>No</i>	<i>NA</i>	<i>Details/ Comment</i>
1.1	Is a universal biohazard symbol for BSL 1 posted at the laboratory entrance? Does the sign include the name and phone number of the laboratory supervisor or other responsible personnel?				
1.2	Do the laboratories have a sink for hand washing?				

**Flowchart of Notification of LMO / GMO Use in Research**

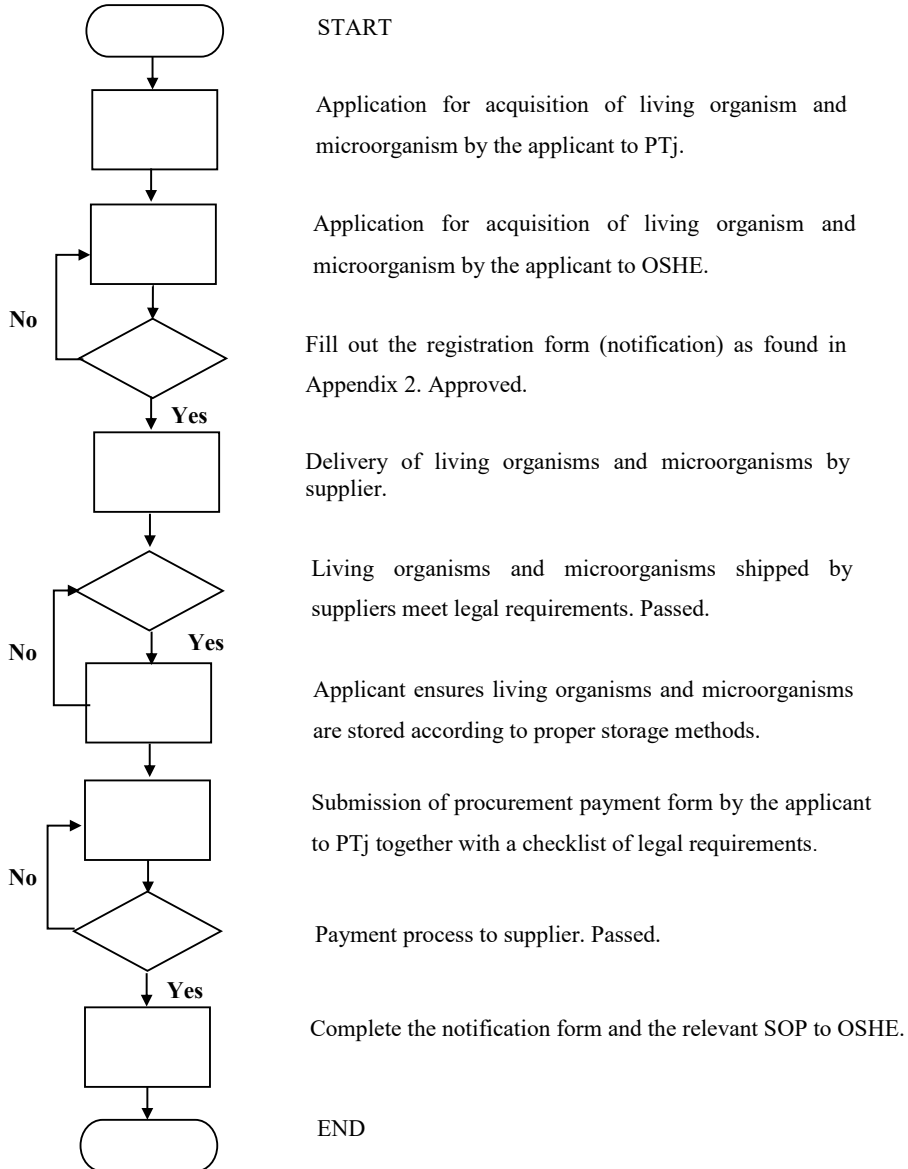


**Flow Chart of Research Extension and Research Termination**





### Flow Chart of Purchasing Microorganisms



## BIBLIOGRAPHY

- Biosafety Manual (2019). University of Washington, Seattle, USA.
- Biosafety Program (2019). The University of Tennessee, Knoxville, USA (<https://biosafety.utk.edu/biosafety-program/biosafety-manual/3-biosafety-practices-and-laboratory-biosafety-manual>)
- Laboratory Biosafety Manual (2004). – 3rd ed., World Health Organization.
- Laboratory Biosafety Manual (2019). – 4th ed., World Health Organization.
- Malaysian Occupational Safety and Health Profile (DOSH/01/2016/OSHPROFILE)
- Manjunath, M., Deepak, T. A., Krishna, S., & Bhanushree, R. (2008). Biohazards in dentistry. *Journal of Indian Academy of Oral Medicine and Radiology*, 20(4), 125.
- Pray, C. E., Ramaswami, B., Huang, J., Hu, R., & Bengali, P. (2006). Costs and enforcement of biosafety regulations in India and China.
- The Control of Substances Hazardous to Health Regulations 2002. *Legislation.gov.uk*. <http://www.legislation.gov.uk/ukSI/2002/2677/>
- The University of Tennessee Knoxville. (2018). Biohazardous Waste Categories. Biosafety Program. Retrieved on 24 December 2019, from <https://biosafety.utk.edu/biosafety-program/waste/>
- UC San Diego. (2015). How to Identify, Label, Package and Dispose of Biohazardous and Medical Waste. *Biohazardous & Medical Waste* Retrieved on 23 December 2019, from <https://blink.ucsd.edu/safety/research-lab/hazardous-waste/medical/index.html>

UC San Diego. (2019). Decontamination Methods for Laboratory Use. Biosafety. Retrieved on 23 December 2019, from <https://blink.ucsd.edu/safety/research-lab/biosafety/decontamination/index.html>

University of Washington. (2019). Biosafety Manual. Retrieved on 25 December 2019, from <https://www.ehs.washington.edu/resource/biosafety-manual-4>

University of Washington. Manual of Standard Operating Procedures User Registration and Safe Working Practices Cell Sorting in E-386A&B, E-377A. Retrieved on 2 Mac 2020, from [https://depts.washington.edu/flowlab/Cell%20Analysis%20Facility/Biosafety%20Cell%20Sorter%20SOP\\_SLU%20submitted%20051413.pdf](https://depts.washington.edu/flowlab/Cell%20Analysis%20Facility/Biosafety%20Cell%20Sorter%20SOP_SLU%20submitted%20051413.pdf)

User's Guide to the Biosafety Act and Regulations. Department Of Biosafety. Ministry of Natural Resources and Environment Malaysia. <http://www.biosafety.nre.gov.my>.

Biorisk Management.Laboratory Biosecurity Guidance. WHO. September 2006