



University of Hawai'i - System

Biosafety Training Program Policy and Guidelines

Purpose

The University of Hawai'i (UH) is committed to providing a safe and healthy work environment for those who work in research and academic laboratory settings. In the last few years the use of Biological materials in these settings has increased greatly with the advent of newer technologies, more sophisticated techniques and increased funding opportunities. With these newer innovations comes the need to better train and prepare these researchers and laboratory staff to be able to have the tools and understanding so as to provide a safe working environment in which to conduct biological research at the UH. This policy is to set forth a series of guidelines on the training requirements for any UH laboratory conducting research utilizing biological materials.

It covers a wide range of specialized trainings which might be required for conducting research in the biomedical and biological laboratories some based on Federal, State and other oversight guidelines which have specific requirements for training individuals who plan on working and conducting research with specific biological commodities.

Authority and Responsibilities

A. Biosafety Program is responsible for:

1. Providing the appropriate level of basic training through the Biosafety program (BP) to ensure that all personnel are provided basic safety training in the use of Biologicals when working within any of the University of Hawai'i's (UH) laboratories. Basic training provided include but are not limited to:
 - General Biosafety training
 - Bloodborne Pathogens and Safe Sharps Use
 - Shipping and Receiving Biological materials
 - Select Agent training
 - Biological Safety Cabinet Use
 - Biological Awareness training
 - Bloodborne Pathogens Awareness
 - Institutional Biosafety Committee member trainings
 - AVS staff basic biosafety trainings
 - BSL3 or high containment lab trainings

Both Initial and Refresher trainings are conducted and available through the Biosafety training programs.

At minimum an individual must receive *General Biosafety training* within 10 working days upon commencement of work in ANY UH laboratory that uses biological materials.

2. The Biosafety compliance program will monitor laboratories using Biologicals to ensure that there is an active and current training program in place for lab personnel with regard to the specific activities being conducted in the lab. Although the magnitude and variety of research activities being conducted in UH biological laboratories make it difficult for the Biosafety program to monitor each lab and their research specific types of lab training needed. Verification that an active training program is in place which focuses on a lab's specific training needs will be in done in conjunction with Biosafety program regular laboratory audits through documentation provided by each lab. Principal investigators are responsible for their staff and students and visitors with regards to this laboratory specific training and documentation.
3. Non-compliance of training requirements will be evaluated by Biosafety and the IBC. The IBC will prescribe administrative actions appropriate for the level of non-compliance and the AWBP will conduct follow up evaluations of remedial actions to ensure compliance.

B. Principal Investigator (PI) Responsibilities

1. The Principal Investor (PI) shall be responsible for ensuring that all staff, students and visitors working in their lab have the appropriate level of training in order to provide a safe working environment and to stay in compliance with Federal and State regulatory and institutional policy guidelines. Basic Biosafety training shall be completed and documented within 10 working days of commencement of any active work in the laboratory
2. A PI and/or Director of any UH laboratory that is not actively working in the lab but is listed on any research protocol (IBC, IACUC, IRB) is still required to have Biosafety and/or Bloodborne Pathogens training and to keep that training current with UH guidelines.
3. Are responsible for making sure all staff, students and visitors are compliant with regards to current and updated training needed for the lab to use biological materials.
4. Are responsible for ensuring that there is an active "lab specific" training program in place for their lab. This program will address all specific training in relation to the general research direction of the laboratory. These "lab specific" trainings will be documented and maintained in the laboratory Biosafety Manual. Verification of "lab specific" training will be done during normal inspections and audits of the lab by Biosafety program. Lab specific trainings should be reviewed and updated at least annually in order to remain compliant with current programs.
5. If working in an "Open Bay" style laboratory any PI working with Bloodborne pathogens is required to inform and notify those researchers in adjacent bays to the presence of BBPs and determine through a risk assessment based on the PI's research activities the need for these neighboring PI to undergo BBP training.

UH Training Programs - Descriptions

General Biological Safety Training

UH researchers, laboratory staff and students working with biological commodities are required to complete a Initial **in-classroom** training. Refresher training is then required every three (3) years thereafter and can be completed on-line.

General training covers UH policies regarding biological safety, principles of safe lab practices, appropriate storage, transport and disposal, and decontamination of biological substances used in research. Using Risk assessment...defined by CDC, BMBL 5TH Ed., "...as the process used to identify the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in a person's exposure to an agent, the likelihood that such exposure will cause a LAI (Laboratory Acquired Infection), and the probable consequences of such an infection. The information identified by risk assessment will provide a guide for the selection of appropriate biosafety levels and microbiological practices, safety equipment, and facility safeguards that can prevent LAIs."

This training is geared for first time users of biological materials in a UH research laboratory and includes...

- Introduction to the UH Biosafety Program
- Biological Safety Levels (BSL)
- Personal Protective Equipment (PPE)
- Using the Biological Safety Cabinet
- Decontamination and Disinfection
- Dealing with Biological Spills
- Biological Waste Management
- Risk Assessment
- Record Keeping and Documentation
- PI responsibilities
- General overview of a Biological Safety Manual

Refresher trainings are required every three (3) years and provide the latest and up to date information on changes in biological safety requirements.

Understanding and comprehension of presented materials is evaluated via a quiz at the end of each training session.

Bloodborne Pathogens Standard and Safe Sharps Use Training

This is a required course designed for all University of Hawai'i research staff that may come into contact with human fluids and other biological materials including cell lines derived from human materials. It is also required of any research staff that use vertebrate animals in the course of their work.

This training covers:

- Copy of the OSHA Bloodborne Pathogens Standard

- Epi and symptoms of selected BBP,
- HIV, HBV and HCV in the research lab
- Modes of transmission
- HepB vaccination and exposure control methods
- Site-specific exposure control plan
- Use of engineering, work practices and PPE
- Proper sharps handling and containment
- Proper waste management
- Hazard recognition and Risk assessment
- Question and answer session

Bloodborne pathogens training is required when there is an occupational exposure to blood or other potentially infectious materials OSHA 1910.1030(a).

Training is required if you work with or handle:

- Human blood products
- Human body fluids (including but not limited to, blood, semen, synovial fluid, amniotic fluid, CSF, pleural fluid, peritoneal fluid, pericardial fluid)
- Unfixed human tissue and organs
- Human cell lines, even if certified free of bloodborne pathogens
- Human organs or tissues
- Tissues or body fluids
- Hepatitis B virus or other bloodborne pathogens
- Enter or work in areas where other individuals work with any of the above materials where risk of exposure may occur.
- Vertebrate animals, their tissues or blood. This requirement has been added by the UH for researchers who utilize animals or animal products in their research.

NOTE: Non-lab personnel. For Non-laboratory Faculty, Staff and Students; Bloodborne Pathogens training is provided by UH Environmental Health and Safety Office (EHSO) Occupational Health and Safety Program.

Initial Bloodborne Pathogens training is required by OSHA to be held in a face to face interactive classroom session. Refresher training is required annually and can be on on-line.

Understanding and comprehension of presented materials is evaluated via a quiz at the end of each training session.

Transportation of Infectious and Biological Substances Training

This is a required course designed for University of Hawai'i personnel who intend to transport and/or plan on receiving any Biological substances, **Category A** infectious substances including Select Agents and Toxins.

This training has two sections:

1) Transport of Biological and Infectious Substance Transport Awareness.

Personnel who complete “Transport Awareness” training will be able to understand and be able to:

- Prepare biological materials for shipment
- Marking and Labeling of packages
- Prepare shipping documentation
- Accept/receive packages (Importation)
- Supervise the transport of packages

Initial training is required and refresher training every two (2) years after that. Training includes State of Hawai‘i Department of Agriculture (HDOA) Importation regulations overview, shipper’s responsibilities and provides necessary guidelines and references to ensure compliance with dangerous goods transportation.

Both Initial and refresher “Transport Awareness” training can be completed online. Refresher training is required every two (2) years.

2) Category A Infectious Substances Shipper, (includes Select Agents and Toxins)

Transfer of any Infectious Materials classified by the International Civil Aviation Organization (ICAO) and International Air Transport Association (IATA) as a **Category A**, Infectious Substance including select agents and toxins requires, first completion of “Transport Awareness” training **PLUS** attendance of an *in-classroom* training session. Refresher training is required to be completed every two (2) years.

After completing these training programs, participants will be able to:

- Differentiate between a Category A, B or exempt substances
- Identify how to properly pack biological or infectious substances for transport
- Identify required markings/labeling on packages submitted for shipment
- List what must be on shipping papers (DGD) and when one is required.
- Explain the requirements for importing biological commodities into the State of Hawai‘i.
- Understand the different requirements and documentations as required by IATA, DOT, DOC, CDC, USDA- APHIS, and CFR regulations.

Recertification is required every two (2) years.

Understanding and comprehension of presented materials is evaluated via a quiz at the end of each training session.

Select Agent and Toxins

Initial and Annual training on current Select agent regulations, biosafety principles and practices, biosecurity, bio-containment and any other applicable Biosafety Compliance Program trainings are required for all researchers and staff enrolled in a University of Hawai‘i Select Agent Program. All applicable training must be completed prior to being granted access to Select agents and/or toxins. Retraining is mandated and required annually.

After completing this training program, participants will have an understanding of:

- Who should register with the UH Select Agent (SA) program
- Understanding all applicable Select Agent Regulations
- What are the requirements to be to participate in the program?
- How to register with the UH Select Agent Program?
- UH Select Agent Training

Understanding and comprehension of presented materials is evaluated via a quiz at the end of each training session.

Note: Access to the UH Select Agent Program Lulima site is restricted to researchers and staff preparing for enrollment and who are currently enrolled in a UH Select Agent Program

Understanding and Using the Biological Safety Cabinet.

This training provides an understanding of the basics of how Biological Safety Cabinets (BSC) works and how they protect the person, the material / product and the environment in a research lab.

After completing this presentation, participants will:

- Understand the basics of how the Biological Safety Cabinet (BSC) works
- How the BSC protects the **person**, the **material / product** and the **environment**.
- Be able to describe the basic differences between the 3 Classes of BSCs
- How they differ from the Chemical Fume hood and the Laminar Flow Clean Bench.
- Describe basic procedures for working safely and effectively in a BSC.
- Maintenance requirements, certification and alarms
- Understand the basic procedures for dealing with spills in the BSC

Understanding and comprehension of presented materials is evaluated via a quiz at the end of each training session.

Biological Training Mandates, Regulations and Guidelines

From the “Biosafety in Microbiological and Biomedical Laboratories” (BMBL) (NIH) 5th ed.:

- **(All BSLs 1-4)** Laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures.
- **(All BSLs 1-4)** The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur.

From the **NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules**.
(Effective April 2019) (NIH Guidelines):

- **Section IV-B-1-a.** (General) Establish and implement policies that provide for the safe conduct of recombinant DNA research and that ensure compliance with the NIH Guidelines.
- **Section IV-B-1-h.** Ensure appropriate training for the Institutional Biosafety Committee Chair and members, Biological Safety Officer and other containment experts (when applicable), Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the NIH Guidelines. The Institutional Biosafety Committee Chair is responsible for ensuring that Institutional Biosafety Committee members are appropriately trained. The Principal Investigator is responsible for ensuring that laboratory staff are appropriately trained. The institution is responsible for ensuring that the Principal Investigator has sufficient training; however, this responsibility may be delegated to the Institutional Biosafety Committee.
- **Section IV-B-7-d-(2).** (Principal Investigator) Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents;

From **Bloodborne Pathogens 29 CFR 1910.1030 Occupational Safety and Health Administration (OSHA)**:

- **1910.1030(g)(2)(i)** The employer shall train each employee with occupational exposure in accordance with the requirements of this section. Such training must be provided at no cost to the employee and during working hours. The employer shall institute a training program and ensure employee participation in the program.
- **1910.1030(g)(2)(i)** The employer shall train each employee with occupational exposure to bloodborne pathogens (including human cell lines and tissues) initially upon employment and annually thereafter.

From the **Bloodborne Pathogens §12 205.1 Hawai'i Occupational Safety and Health (HiOSH)**

(2)(i) Employers shall ensure that all employees with occupational exposure participate in a training program that must be provided at no cost to the employee and during working hours.

(2)(ii) Training shall be provided as follows:

(A) At the time of initial assignment to tasks where occupational exposure may take place;

(B) At least annually thereafter

(2)(iv) Annual training for all employees shall be provided within one year of their previous training.

(2)(v) Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the

employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

From 42 CFR 73 Select Agents and Toxins:

- An entity must provide training at the time of an individual's initial assignment to an area where Select Agents and Toxins are present and annual refresher training thereafter.

From 49 CFR 172.704 Shipping hazardous biological materials:

- ...employees must receive general awareness and function specific training initially and every 3 years thereafter. (UH requires refresher training every two (2) years)

From OSHA - 29 USC 654 (General Duty Clause)

- Each employer --
 - shall furnish to each of his employees' employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;
 - shall comply with occupational safety and health standards promulgated under this Act.
- Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this Act which are applicable to his own actions and conduct.

Training Matrix

Staff \ Training	General Biosafety	Bloodborne Pathogens	Biosafety Awareness	Shipping and Receiving Biologicals	BSC	SAP
Principal Investigator	X	D		D	O	D
Researcher	X	D		D	O	D
Student	X	D	X		O	D
Visitor	D	D	X	D	O	D
Teaching Assistant (TA)	D	D	X	D	O	
Working in SAP	X	X		X	X	X

X=Required; D=Required but dependent on labs type of biological use; O=Optional; SAP=Select Agent Program