



## **Biological Safety Program**

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## 1.0 Overview

The Brigham Young University Biological Safety Program includes the following elements:

- Designation of an Institutional Biological Safety Committee (IBC) to maintain overall control of the program.
- Designation of a Biological Safety Officer (BSO) with the authority to oversee program elements.
- Development of an effective training program.
- Development of an effective monitoring system.

## 2.0 Policy

All Brigham Young University employees and students working with biosafety level 2, biosafety level 3 or recombinant DNA agents will comply with the conditions and procedures stipulated in the Biological Safety Program.

## 3.0 Requirements and Standards

42 CFR 73  
NIH Guidelines for Research Involving Recombinant DNA Molecules  
Biosafety in Microbiological and Biomedical Laboratories

## 4.0 Purpose

The Biological Safety Program is designed to minimize the risk of illness caused by a laboratory acquired infection or the inadvertent release of a biological agent.

## 5.0 Scope

The Program applies to all Brigham Young University research and classroom instruction involving the use of biological safety level 2 or 3 agents or for work involving recombinant DNA molecules. In this program these materials are termed 'covered agents'.

## 6.0 Procedures

**6.1 Biosafety Committee Notification and Approval:** The Principal Investigator (PI) or classroom instructor proposing work with a covered agent (BSL-2, BSL-3 or recombinant DNA) will submit the appropriate IBC form to the Office of Research and Creative Activities (ORCA) and receive IBC approval before initiating work with that agent. For classes using numerous different agents, a generic form with a list of agents may be submitted.

**6.2 Risk Assessment:** The BSO will perform a risk assessment for each organism or agent submitted to the IBC. The risk assessment will include the following elements:

- Median infectious dose
- Normal transmission mode
- Previous history of laboratory acquired infections
- Quantity, concentration and form of proposed use
- Aerosol generating procedures proposed
- Potential for recombination events resulting in more virulent or replication competent organisms
- Special populations at risk (such as pregnant women, immune-compromised people)

- Consequences or severity of infections
  - Morbidity and mortality
  - Risk of aerosol transmission
  - Risk of spread to the community and consequences of such an event
  - Availability of treatment or prophylaxis

**6.3 IBC Stipulations:** The IBC will review the BSO risk assessment and the PI submission. Based on that information the IBC will stipulate the following:

- Vaccine requirements
- Medical surveillance
- Emergency response preparation
- Special containment procedures or facilities
- Special limitations

**6.4 Shipment and Receipt:** For BSL-3 agents the PI will notify the BSO of the date of an expected shipment of the organism at least one day prior to the anticipated arrival date. All shipments of risk group 2 or 3 infectious agents from BYU to another facility must be approved, and inspected by the BSO.

**6.5 Biosafety Manual:** A biosafety manual will be available in every covered laboratory. The manual will be based on principles contained in the publication Biosafety in Microbiological and Biomedical Laboratories (BMBL). The manual will include the following elements:

- Access restrictions
- Personal protective equipment
- Decontamination protocols and frequency
- Standard procedures (as listed in the BMBL)
- Emergency procedures
- Training
- Medical surveillance (if required by the IBC)
- Vaccinations (if required by the IBC)

**6.6 Posting and Labeling Procedures:** Each laboratory using BSL-2 or BSL-3 agents will post the following at the entrance to the area in which those agents are used:

- The universal biohazard symbol
- A list of agents used in the controlled space
- Restrictions or special qualifications required for entry
- The name of the PI controlling the space

**6.7 Disposal:** All infectious waste containing BSL-2 agents will be securely packaged and submitted to the Environmental Management Department. All BSL-3 waste will be securely packaged, autoclaved and submitted to Environmental Management.

## 7.0 Responsibilities

### 7.1 Biological Safety Officer

- Trains students at the request of the PI
- Inspects each covered laboratory at least once per year
- Completes agent risk assessment
- Serves on the IBC

- Assists PI's in creating the biosafety manual
- Offers information on program elements and federal regulations to the faculty

## **7.2 Institutional Biosafety Committee**

- Reviews and approves or rejects requests to use covered agents (BSL-2, BSL-3, or recombinant DNA)
  - If an IBC member has a conflict of interest (personal or financial) concerning a submitted application, they shall disclose the nature of the conflict to the IBC. The IBC member may be asked to leave the room during final discussion and voting on the application.
- May revoke the approval to use covered agents
- Stipulates special requirements for research based on the risk assessment
- Reviews the annual facility inspections conducted by the BSO, at the first IBC meeting held each calendar year, when possible.
- Reviews and updates Biological Safety Program and IBC charter

## **7.3 Principal Investigator**

- Notifies ORCA (using application form) prior to initiating work with covered agents
- Prepares a laboratory specific biosafety manual
- Responsible for training people working in the laboratory
- Sets restrictions and qualifications for work in the laboratory
- Maintains training records

## **7.4 Office of Research and Creative Activities**

- Provides IBC administrator
- Notifies BSO and IBC of applications for use of covered material
- Maintains IBC minutes
  - Upon request, minutes related to recombinant DNA are available to the public. However, proprietary or private information may be redacted; for example, trade secrets, confidential commercial information, home phone numbers and addresses, and information that may compromise BYU or national security.
- Maintains NIH IBC Registration

## **8.0 Training**

### **8.1 Training:** All people working with biological agents will be trained in the following:

- Signs and symptoms associated with agents used in the laboratory
- Normal transmission routes for agents used
- Required PPE
- Required vaccinations
- Specific limitations for vulnerable groups
- Biological safety and the biosafety manual
- Specific laboratory procedures

## **9.0 Monitoring**

### **9.1 Inspections:** Inspections are completed by the BSO for each covered laboratory once each year. Inspection results are submitted to the IBC for review.

## 10.0 Appendices

### Appendix A Biosafety Inspection Form

**Biosafety General Inspection Form** (note this list includes all elements for BSL-3, some items not applicable to BSL-2)

Building/Room: \_\_\_\_\_ Inspection Date: \_\_\_\_\_

PI: \_\_\_\_\_ Telephone: \_\_\_\_\_

Inspector Name: \_\_\_\_\_ Telephone: \_\_\_\_\_

Standard Checked	Yes	No	N/A	Comments
Standard Practices				
1. Access limited when experiments in progress				
2. Persons wash hands after work w/cultures, after removing gloves, and before leaving lab				
3. Eating, drinking, storing food, etc. prohibited in laboratory				
4. Mouth pipetting prohibited;				
5. Sharps policies in place				
6. Splashes and aerosols are minimized				
7. Work surfaces disinfected 1x per day and after spills (disinfectant is effective)				
8. Regulated waste disposed properly				
9. Insect and rodent control program in place				
Special Practices				
1. Lab doors are kept closed when experiments in progress				
2. Access restricted to required personnel. No minors allowed in BSL-3 laboratories				
3. Policies so that access restricted to only persons advised of hazards and meeting entry requirement				
4. Laboratory sign includes biohazard symbol, agents, BSL, PPE, exit requirements, PI name and phone				
5. Personnel receive appropriate immunizations and tests for agents handled				
6. Baseline serum collected, as appropriate				
7. Biosafety manual adopted. Persons informed of special hazards.				
8. Director ensures personnel receive appropriate training and annual updates				
9. Director ensures personnel demonstrate proficiency in				

standard and specific microbiological procedures				
10. Sharps precautions: needles, slides pipettes, capillary tubes scalpels handled properly				
a. Sharps restricted to use when no alternative exists				
b. Needles are integral to syringe and not recapped, bent etc.				
c. Safe needle devices used where appropriate				
d. Broken glassware handled by mechanical means				
11. Open manipulation in BSC. No work on open vessels on open bench (depending on agent)				
12. Equipment and work surfaces disinfected regularly after work with agents and after spills				
a. Spills decontaminated and cleaned by appropriate professional or trained staff. Spill procedures posted				
b. Contaminated equipment decontaminated prior to removal from facility				
13. Specimen containers leak proof and covered during transport				
14. Contaminated waste decontaminated before disposal or reuse				
15. Spills and accidents reported to PI. Medical follow-up as appropriate				
16. Animals and plants not involved in work not permitted in laboratory				
C. Safety Equipment (Primary Barriers)				
1. Protective clothing is worn and not removed from lab. Reusable clothing decontaminated before laundering				
2. Gloves worn when working with agents, animals or potentially contaminated equipment				
3. Gloves changed frequently accompanied by hand washing. Gloves not reused				
4. All potentially aerosol producing manipulations of infected material conducted in Class II or III BSC				
5. If procedure can't be conducted in BSC, appropriate combination of PPE used				
6. Respiratory and face protection used in rooms with infected animals where indicated				
D. Laboratory Facilities (Secondary Barriers)				
1. Lab separated from building traffic. Self-closing doors for entry. Doors lockable. Clothes change room may be included				
2. Each lab room contains sink for hand washing				
3. Surfaces cleanable (walls floors ceiling) Seams and penetrations sealed. Floors monolithic and coved				
4. Bench tops impervious to water and resistant to				

chemicals				
5. Lab furniture is appropriate for loading and use. Spaces accessible for cleaning. No fabric-covered chairs.				
6. All windows closed and sealed (bsl-3 only)				
7. Wastes decontaminated, preferably within lab (BSL-3). If contaminated wastes leave lab they are sealed				
8. BSC's located away from doors, heavily traveled areas etc. , to maintain air flow				
9. Ducted exhaust system provides airflow in the direction of 'clean to dirty'. Exhaust not recirculated. (BSL-3)				
10. Class II BSC certified annually. If BSC discharged to outside must have system to prevent positive pressurization				
11. Aerosol producing equipment contained in devices that exhaust through HEPA filters				
12. Vacuum lines protected by disinfectant traps and HEPA filters or equivalent				
13. Eyewash readily available				
14. Illumination is adequate, avoiding glares and reflections impeding vision				
15. BSL-3 facility and operational procedures documented. Facility tested for verification prior to operation. Facilities re-verified, at least annually against these standards.				
16. Additional environmental protection considered as determined by risk assessment.				
17. Autoclave procedures verified				