UAB BIOSAFETY MANUAL

Fourth Edition, 2025

ENVIRONMENTAL HEALTH AND SAFETY

UAB
THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM

Table of Contents

1.0 POLICY

The University of Alabama at Birmingham

BIOSAFETY POLICY

Effective Date: July 1st, 2021
Last Reviewed: March 16th, 2023

INTRODUCTION

The purpose of this policy is to establish a framework for the University of Alabama at Birmingham Biosafety Program, intended to protect students, employees, volunteers, visitors, and the environment from the hazards associated with recombinant, biological, or potentially infectious agents or materials used and stored on campus. UAB's Biosafety Program is based on federal, state, and local regulatory codes.

SCOPE

This policy applies to all members of the UAB community, including students, employees, volunteers, and visitors and to all research and teaching activities in UAB facilities (owned and leased) where students, employees, and visitors may be exposed to potentially hazardous biological agents and materials. This policy also extends to any facility or activity subject to UAB's Biosafety Program by virtue of a formal agreement.

DEFINITIONS

For the purposes of this policy, the following definitions apply:

Biological Agents – Any biological organism, including viruses and invasive species, that pose a real or potential hazard to humans, animals, plants, or the environment.

Biological Materials – prions, biological toxins, blood, tissues, cells, bodily fluids, and recombinant nucleic acid molecules.

Biosafety Manual (BSM) – The Biosafety Manual is a written program, developed and implemented, to describe the procedures, work practices, equipment, and other control measures required to protect students, staff, and visitors from the hazards presented by biological agents used on campus.

Biological Safety Officer (BSO) – The BSO is a Department of Environmental Health and Safety (EHS) employee with expertise in biological hazards and biocontainment controls. The BSO provides guidance in the development and implementation of the provisions of the Biosafety Manual and oversees the UAB Biosafety Program.

The Responsible Official (RO) – The RO is an EHS employee that is designated with the authority and responsibility to act on behalf of UAB to ensure compliance with the Federal Select Agent regulations.

Select Agents (SA) – Biological agents identified by the Federal Select Agent Program to have potential to pose severe threat to public, animal, or plant health, or to animal or plant products.

UAB Select Agent Program – UAB policies, procedures, training, and containment controls for SA work, implemented to ensure compliance with the Federal Select Agent Program regulations.

POLICY STATEMENT

UAB is committed to maintaining a safe environment for all individuals participating in UAB-approved research activities and ensuring compliance with federal, state, and local regulatory codes. The standard operating procedures in the BSM outline the roles and responsibilities of administrators and individuals working in UAB laboratory facilities and demonstrate UAB's commitment to safety.

NONCOMPLIANCE

Violations of federal, state, and local regulations can lead to criminal and civil penalties for individuals and the institution. Confirmed violations of this policy or any of the associated elements described in the BSM are subject to commensurate consequences, up to and including termination, dismissal, or severance of other relationships with UAB.

IMPLEMENTATION

The Associate Vice President for Research Facilities and Infrastructure and the Chief Facilities Officer share responsibility for the implementation and maintenance of UAB campus safety programs to ensure UAB-approved activities remain compliant with federal, state, and local regulatory codes, as described in applicable UAB handbooks, policies, and safety manuals.

The Vice President for Research is responsible for appointing an Institutional Biosafety Committee (IBC), which is tasked with review of UAB policies and activities involving infectious and/or recombinant agents or materials, and stipulates containment conditions required for final approval and compliance with the NIH Guidelines

The Senior Vice President for Finance and Administration, through the Facilities Division and the Department of Environmental Health and Safety (EH&S), is responsible for administering the Institutional Biosafety Program. The BSO is a member of EH&S and, with support from EH&S staff, has the overall responsibility for developing, implementing, and maintaining a Biosafety Program at UAB that is compatible with all local and federal regulations. The RO, also a member of EH&S, supports the activities of the BSO and manages the UAB Select Agent Program.

2.0 UAB BIOSAFETY PROGRAM ADMINISTRATION

2.1 INTRODUCTION AND RATIONALE

UAB strives to promote a healthy and safe environment for the entire community (faculty, students, staff, and visitors), and all members of the UAB community must recognize their roles for ensuring personal safety and the safety of others. Although we will never be able to prevent all accidents and injuries, a robust culture of safety across the community will minimize the occurrence and severity of incidents. A robust safety culture begins with clearly defined roles and responsibilities among all stakeholders. The hierarchy of roles and responsibilities relating to Biosafety, from upper administration, to individuals working in the laboratory, is described below.

2.2 ROLES AND RESPONSIBILITIES

The Offices of the Vice President for Research (OVPR) and the Chief Facilities Officer share responsibility for the implementation and maintenance of UAB campus safety programs to ensure UAB-approved activities remain compliant with federal, state, and local regulatory codes, as described in applicable UAB handbooks, policies, and safety manuals.

The Executive Directors of UAB Hospital, in conjunction with Director of Hospital Planning and Management and the Manager of Policies and Standards Resources, are responsible for ensuring that hospital activities are conducted in conformity with Hospital Standard Policies and Procedures.

2.2.1 Office of the Vice President for Research

The Office of the Vice President for Research is responsible for:

- Promoting the importance of safety in all research activities
- Endorsing a broad-based research safety program that will protect UAB laboratory personnel, visitors, students, and the community from ill-health effects and injuries associated with the use of hazardous agents in use in UAB facilities
- Encouraging faculty engagement and service in Research Safety Committees to provide the expertise needed to protect UAB laboratory personnel, visitors, students, and the community from the ill-health effects and injuries associated with the use of hazardous agents during UAB-approved activities
- Supporting the administrative personnel and resources needed to maintain efficient operation of the ***Research Safety Committees*** at UAB

Research Safety Committees:

The University has established several safety committees tasked with the review of policies or proposals associated with the acquisition, use, handling, and final disposition of potentially hazardous materials. These committees consider available literature, regulations, guidelines, and UAB safety manuals to stipulate the appropriate precautions needed to mitigate risks associated with hazardous material work on campus.

Membership for all committees is composed of UAB researchers and/or faculty, administrators, Environmental Health & Safety (EH&S) staff, and other UAB and/or community stakeholders. Cross-membership with other institutional committees is emphasized to reduce paperwork for PIs and provide coordinated comprehensive review and reporting of research activities (e.g. Institutional Animal Care and Use Committee, Institutional Review Board, Hospital Infection Control).

Committees relating to Biosafety include:

- Institutional Biosafety Committee
- Radioactive and Radiation Safety Committee
- Hospital Safety Committee

2.2.2 Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) is one of the Research Safety Committees that reports to the OVPR. The IBC is responsible for assessing the risk(s) associated with non-exempt recombinant or synthetic nucleic acid (rsNA) molecules and infectious agents that can cause disease in healthy humans (Risk Group 2 or above). IBC membership is appointed by the OVPR, but the composition must meet the criteria prescribed in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ("The NIH Guidelines"). Members are generally appointed for two-year terms but frequently serve more than one term. Some members represent the health and environmental interests of the surrounding community and have no additional affiliation with UAB. Other members provide expertise in one or more areas, including infectious agents, biological safety, containment principles, human gene transfer, animal handling, public health, law, and UAB policy. Each member is responsible for naming an alternate to act on their behalf in their absence.

Investigators who wish to perform activities under the purview of the IBC must register their project with Research Safety and Security using a RSC-EHS Project Registration Form. A detailed description of the proposed work (equivalent to the methodology section of the grant), or the associated grant itself, must be submitted with the registration. Principal Investigators who propose work involving Human Gene Transfer must submit the above documentation, as well as a copy of the Investigator's Brochure, a complete copy of the Study Protocol, a copy of the NIH Recombinant Advisory Committee (RAC) determination letter, and any additional safety documentation provided by the sponsor. This includes a site-specific safety plan describing the local practices and safeguards in place to protect faculty, staff, students, or visitors from potential exposure to the investigational products. All Serious Adverse Event (SAE) reports must be submitted to NIH OBA as well as the IBC. Further, any modifications or any documentation submitted to or from the Sponsor regarding the project must also be provided for review.

It is important for faculty and staff members to understand that the IBC only meets monthly and certain information in Committee files may be subjected to public scrutiny under a disclosure provision of current NIH guidelines. Upon request, minutes of IBC meetings pertaining to recombinant DNA/RNA activities and documents or reports submitted or received from federal

funding agencies are required to be made public. These may include documents such as project registration documents, research related accidents, and facilities inspection reports.

The IBC is responsible for:

- Reviewing campus activities involving rsNA material and RG-2 or higher biological agents to assess the biological risk(s) and stipulating approval conditions, including the containment levels and the associated controls needed to mitigate the risks.
- Reviewing policies and procedures associated with the Biosafety Program to make endorsement recommendations to the University Safety Committee.
- Working with the EH&S Biosafety Program, which has institutional responsibility and enforcement authority in matters of workplace safety, to ensure activities at UAB involving any biological agent are compliant with the NIH Guidelines and other regulatory agencies.
- Reviewing the Biosafety Officer's (BSO) reports on research-related violations, accidents, or illnesses to determine whether official reporting to the NIH Office of Science Policy is warranted.

2.2.3 Chief Facilities Officer

The Chief Facilities Officer is responsible for:

- Promoting the importance of safety in all activities
- Endorsing a broad-based research safety program that will protect UAB laboratory personnel, visitors, students, and the community from ill-health effects and injuries associated with the use of hazardous agents in use in UAB facilities.
- Providing administrative, financial, and operational support to EH&S to ensure the day-to-day operations at UAB remain safe and according to local, state, and federal regulations.
- Ensuring EH&S staff numbers and expertise are sufficient to maintain safe and compliant operations at UAB.

Environmental Health and Safety: Under the leadership of the Executive Director of EH&S, the EH&S Department facilitates the day-to-day operation of the individual safety programs, including:

- Asbestos Abatement
- Biosafety
- Campus Safety
- Chemical Safety
- Construction Safety
- Controlled Substances
- Environmental Management
- Hospital and Clinic Safety

- Radiological Health and Safety
- Research Safety

The Biosafety Program:

The Biosafety Program at UAB provides the following services:

- Provides advice to faculty and staff on Biosafety matters
- Reviews Project Registrations, including Recombinant DNA/RNA Registration
- Provides agent-specific risk assessments and recommendations to the IBC
- Provides guidance on practices and procedures for laboratory use of recombinant DNA/RNA (rDNA/RNA) and infectious materials
- Provides consultation on the purchase of biological safety cabinets (BSC), and other laboratory ventilation equipment
- Reviews plans for new labs and renovations and provides recommendations on lab ventilation and lab design
- Provides biological safety education and training aids and develops educational and training programs
- Provides consultation for shipping, receiving, transport, and work with infectious agents
- Assists in the UAB Medical Waste Management Plan training, coordinating, and implementing
- Coordinates and runs the UAB Select Agent Program
- Provides consultation for clean-up and decontamination of biohazardous accidents or spills
- Performs periodic audits of laboratory facilities
- Performs environmental assessments involving hazardous biological material
- Assists PIs and staff in performing laboratory and project specific risk assessments
- Collaborates with other EH&S staff to further promote a University–wide safety environment

2.2.4 Biosafety Officer (BSO)

The Executive Director of EH&S appoints the Biosafety Officer (BSO). The BSO oversees the Biosafety Program and ensures day-to-day compliance with policies, guidelines, and regulations set forth by University Administration, the IBC, and/or regulatory and granting agencies. The BSO's specific duties are stipulated in the NIH Guidelines to include, but not limited to:

- ***NIH Section IV-B-3-c-(1):*** Periodic inspections to ensure that laboratory standards are rigorously followed.
- ***NIH Section IV-B-3-c-(2):*** Reporting to the Institutional Biosafety Committee and the institution any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which the Biological Safety Officer becomes aware

unless the Biological Safety Officer determines that a report has already been filed by the Principal Investigator.

- ***NIH Section IV-B-3-c-(3):*** Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecule research.
- ***NIH Section IV-B-3-c-(4):*** Providing advice on laboratory security.
- ***NIH Section IV-B-3-c-(5):*** Providing technical advice to Principal Investigators and the Institutional Biosafety Committee on research safety procedures.
- At UAB the BSO also stipulates containment conditions for activities involving biological material or organisms that are beyond the purview of the IBC, including exempt recombinant DNA/RNA projects and coursework, and work involving the use of material of human origin.

2.2.5 Dean/Department Chairs/Directors

Deans, Department Chairs, and Directors are responsible for:

- Taking appropriate measures to assure that university/department/division activities comply with all relevant research safety policies, laws, regulations, and guidelines.
- Ensuring that staff have had instruction in laboratory safety and security procedures appropriate for their assignments.
- Ensuring that students have had instruction in laboratory safety and security procedures, including teaching laboratories or field situations, where biohazardous agents are used or encountered.
- Identifying technically qualified laboratory safety coordinators for the unit and providing adequate training and time to carry out the assigned responsibilities.
- Ensuring that emergency response plans are in place for their areas and facilities of responsibility.
- Providing EH&S with the name of the designated laboratory safety coordinator for their respective units.

2.2.6 Principal Investigators / Laboratory Director

The Principal Investigator (PI) / Laboratory Director (LD) is directly and primarily responsible for full compliance with the policies and procedures described in the Biosafety Manual. This responsibility extends to all aspects of Biosafety involving all individuals who enter or work in the PI's/LD's laboratory or collaborate in carrying out the PI's research. Although the PI/LD may choose to delegate aspects of the safety program in his/her laboratory to other laboratory personnel or faculty, this does not absolve the PI/LD from the ultimate responsibility.

Responsibilities include, but are not limited to:

- Assessment of the risks associated with the agents used and selection of appropriate safeguards.

- Preparation of a written safety plan.
- Registration of potentially infectious agents with the EH&S.
- Modification of an activity covered by an IBC approved protocol must also be approved by the IBC before taking place.
- Training and supervision of staff and students in safe practices and incident responses.
- Reporting of accidents; exposures, clinical illnesses and sero-conversions of laboratory personnel to UAB EH&S.
- Understanding roles and responsibilities, as they pertain to safety, signing and submitting a PI assurance statement.

2.2.7 Laboratory Staff

Laboratory staff members (faculty members, students, interns, visiting scholars or volunteers) are the most critical element in maintaining a safe working environment. Each person must consider their own safety and that of their co-workers. The laboratory staff's responsibilities include, but are not limited to the following:

- Attentively follow lab-specific biosafety and security practices and procedures.
- Understand all protocols and organisms used in the laboratory.
- Know all emergency procedures established by the Principal Investigator or laboratory director.
- Complete training and assure documentation of that training.
- Follow all appropriate laboratory practices as outlined in the Biosafety Manual and all additional practices outlined in the protocol and lab specific safety plan.
- Report to the PI, lab director, or lab supervisor all problems, violations in procedure, exposure events or spills as soon as they occur.
- Report to the Biosafety Officer any significant violations in biosafety policy, practices or procedures. No adverse action shall be taken against any person for reporting real or perceived problems or violations of procedures.

2.3 LIABILITY CONSIDERATIONS & INCIDENTS OF NON-COMPLIANCE

2.3.1 Liability Considerations

All faculty members and investigators should be aware of the potential for personal liability in performance of research and teaching involving biohazardous agents. The general rule of law that every individual is liable to others for negligent acts or omissions that cause injury to other persons is applicable to you and the work done under your direction. The rule applies whether a faculty member is working with a biohazard or pursuing other routine duties of teaching, research, and administration. **The increased potential for personal injury in a laboratory where individuals are working with biohazardous agents is known or should have been known.**

To avoid injury and liability for injury, an investigator should exercise **due care** in research activities. What **due care** is, of course, will vary with the facts of a research situation. In everyday life activities, such as driving an automobile, the question to be asked in determining liability is whether a person acted as a reasonable person would have acted. In a laboratory setting, then, the question is whether the person **in charge** of research has behaved in a way that others with appropriate training and experience would have behaved. (One notable exception to the "reasonable man" standard is the principle of strict liability. Some activities have been judged to be so inherently dangerous that liability for injury attaches even in absence of negligence. Research with some biohazardous agents may fall into such a category of activities.) Whenever there is widely accepted procedure for handling materials or laboratory situations, that procedure usually will be the standard against which activities are measured. **Departures from written policies of an institution are also indications of a failure to exercise due care.**

As injuries are most likely to involve employees, the most important responsibilities of a principal investigator are **providing adequate instructions and supervision** to personnel handling biohazardous agents. The actual degree of instruction and supervision necessary in each case will depend upon the project and the degree of education and sophistication of the persons involved.

The University of Alabama at Birmingham is an agent of the State of Alabama and administers a program of benefits for on-the-job injury. To promote efficient handling of claims or potential claims and to limit personal liability to the extent possible, all accidents or health problems related to work in a laboratory should be reported as an On-the-Job-Injury & Illness program according to instructions provided on the Human Resources Website.

2.3.2 Incidents of Non-compliance

Compliance with UAB, local, state, and federal safety regulations is required not only because of the need to conform to external regulations, but also to avoid endangering personnel, property, or the environment.

Incidents of non-compliance with campus Biosafety regulations or standards are usually discovered in the course of routine site visits by EH&S personnel, review of published studies, or project review by the IBC. In most cases, these can readily be resolved through consultation by the PI or laboratory director with the BSO. When more serious incidents arise, the BSO will report the incident to the IBC. The IBC will consult with the BSO and the responsible investigator and/or laboratory director to recommend corrective actions, which may include the following:

- The Institutional Biosafety Committee (IBC) is authorized by the President through the Vice President for Research to limit or suspend any research that is not in compliance with UAB Biosafety policies and procedures.
- The Biosafety Officer, upon concurrence by the chair of the IBC or, in his/her absence, by at least three other technically qualified members of the IBC, may stop any work with microbial agents that creates a potential hazard to personnel, involves experiments prohibited by the institution, or violates regulations or policies. The entire Committee will then review the problem and forward written recommendations to the Vice President for Research for final action.

- The Principal Investigator/Laboratory Director (PI/LD) and the IBC must concur on all matters relating to containment requirements, safe practices and handling procedures for biohazardous agents. The PI should submit a formal appeal to the IBC Chair stating noted differences along with data supporting his/her position. It may also be advantageous for the PI to meet with the IBC to assist in resolution of differences.
- In the event of failure to concur, the recommendations of the IBC shall prevail until such time as concurrence can be reached or they are modified or rescinded by appellate decision of University officials. The IBC may refer questions relating to recombinant DNA/RNA studies to the NIH Office of Biotechnology Activities for final opinion.
- When measures taken by the PI/LD are not sufficient to correct repeated noncompliance items and the PI/LD has not demonstrated any measure of intent to correct the reoccurring deficiencies, the Chair of the IBC may solicit assistance from the PI's Chair or Dean in resolving the noncompliance issues including recommending that the research be limited or suspended.
- A PI/LD who has laboratory activities limited will lose the privilege to perform certain work with the agent for a designated time period to be determined by the IBC.
- A PI/LD who has laboratory activities revoked will lose privileges to work with hazardous agents until adequate assurance is provided to the IBC that noncompliance items have been resolved.
- Should the efforts of the IBC fail to gain compliance from the PI/LD, the Office of the Vice President for Research and/or the Office of the President will be contacted to assist in resolution of the situation.
- The enforcement of safety measures instituted within a laboratory will ultimately rest with the PI/LD. Documented results of laboratory monitoring by EH&S will assist in determining the success of the program.
- The IBC will provide reports to the Office of the Vice President for Research and/or the Office of the President to be forwarded to regulatory or funding agencies as appropriate.

3.0 PRINCIPLES OF BIOSAFETY

3.1 INTRODUCTION AND SCOPE

Much of the information and material in the UAB Biosafety Manual is paraphrased from, or links directly to, the 6th edition of *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). This is to ensure that the UAB research community is aware of and compliant with BMBL guidelines, but more importantly, to convey the best practices for the safe conduct of research in biological labs, the conceptual intent behind the BMBL publication. The BMBL remains the most comprehensive source of information on the principles of biosafety, including how to conduct biological risk assessments, and the practices and containment controls necessary to mitigate biological risks. The UAB Biosafety Manual is primarily intended to highlight the best practices and regulatory requirements for work with recombinant and/or infectious agents, and to describe the local resources and facilities available for their implementation. Faculty and staff are strongly encouraged to refer to the linked sections of the BMBL6, the NIH Guidelines, or other references for a more thorough understanding of the associated safety principles and requirements applicable to their work.

3.2 BIOLOGICAL RISK ASSESSMENTS

Risk analysis is aimed at identifying hazards, determining the probability that a hazard will result in an adverse event, and understanding the consequences of such an event. Biological risk analyses primarily seek to determine the risks associated with work involving invasive or infectious agents, potentially infectious agents, or samples that could harbor such agents. As per the 6th edition of BMBL, the risk assessment is outlined in a six-step approach (See Figure 3.1) that provides structure to the risk management process and reinforces an ongoing positive culture of biosafety by following PLAN, DO, CHECK, ACT principle.

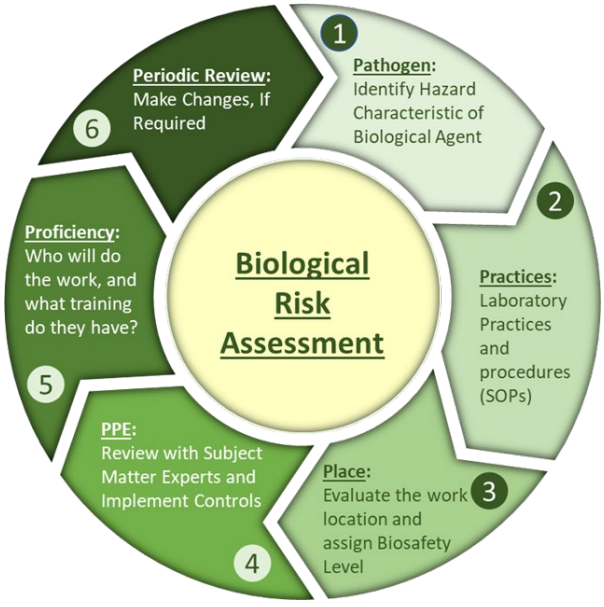


Figure 3.1. Steps in Biological Risk Assessment

This includes 1) Evaluating the intrinsic hazardous properties of a particular agent, 2) Hazards associated with the procedures conducted with that agent and determining the consequences of a release or exposure with respect to the individual, the community, and/or the environment, 3) Determine the appropriate biosafety level required to handle biological pathogen, 4) review with subject matter experts, biosafety professionals, and IBC committee before implementing the controls to mitigate the risks, 5) The effectiveness of the controls implemented should also be reviewed periodically by evaluating of proficiencies and safe laboratory practices of laboratory personnel and 6) Revisit regularly, verify risk management strategies and make changes if necessary. The entire process constitutes a biological risk assessment or risk management process. The responsibilities for performing these risk assessments are shared among principal investigators, EH&S Biosafety, and the UAB Institutional Biosafety Committee (IBC).

Two UAB resources have been developed to facilitate the biological risk assessment process: The first is an on-line training module, titled Basic Biosafety Training (Course ID: E-5VNQVM), available in the UAB Campus Learning System. This is a prerequisite for all faculty and staff intending to work with infectious agents in UAB research labs. The second resource is the Agent-Specific Safety and Data Plan (ASDP) (**Appendix 3.1**). This is a biological risk assessment template that can be used to identify and communicate the potential intrinsic/extrinsic risks associated with the specific agents in an investigator's lab, the necessary precautions needed to mitigate those risks, and the appropriate responses to an exposure or release. This form also serves to document the training and understanding of individuals that may be at risk, as required by the NIH guidelines. ASDPs pre-populated with agent-specific properties, appropriate controls, and incident response procedures may be available. Please contact EH&S for more information on existing ASDPs, or for help filling out these forms for the agents in your lab.

3.3 BIOLOGICAL RISK GROUPS

A number of infectious agents have been assigned to specific Risk Groups (RG). The RG designation is primarily based on the intrinsic characteristics of the agent, including host range, route of transmission, infectious dose, the severity of the disease in humans, and whether treatments are available. Other characteristics of biological agents, such as environmental stability, geographical distribution, and whether or not it has been genetically modified contribute to the overall risk analysis. See the "*Hazardous Characteristics of an Agent"* section of the Biological Risk Assessment chapter in the 5th edition of BMBL and American Biological Safety Association ABSA https://my.absa.org/Riskgroups for an in depth discussion on the intrinsic properties of agents. Agents are assigned to RG 1 through 4, with RG1 being the least hazardous and RG4 being the most hazardous (Table 3.1). The NIH Guidelines (Appendix B) specify RG assignments for a large number of microbial agents. At UAB, any work with RG2 (or higher) agents requires project registration with EH&S and approval by the IBC prior to initiation.

Table 3.1. Biological Risk Group Classification

PROPERTY	RISK GROUP 1	RISK GROUP 2	RISK GROUP 3	RISK GROUP 4
Route of transmission	N/A	Ingestion, percutaneous injury, or mucous membrane exposure	RG2 + inhalation	RG3
Infectious Dose	N/A	varies, generally high	varies, generally lower	as few as 1
Severity of Disease	no disease to healthy adults	low-moderate	moderate-high; higher mortality and morbidity	high; highest mortality rate
Available Treatments	N/A	may be available or controlled by host immunity	may not be available	generally, not available, unless experimental
Risk to Community	low	low	moderate	high, high public perception of risk
To be safe…	**Don't drink it!** avoid food and drinks in the laboratory, wash hands before exiting	**Don't touch it!** wear gloves, decontaminate surfaces, cover wounds, work in biosafety cabinet, wear eye protection	**Don't breathe it!** Wear respiratory protection, perform all work inside biosafety cabinet or other containment device	**Don't do it!** RG4 agents require significant containment and are not allowed at UAB
Example Agents	• *Bacillus subtilis* • Adeno- associated virus - all serotypes • *E. coli* strains lacking virulence or colonization factors	• *Helicobacter pylori* • *Staphylococcus aureus* • Adenoviruses SARS-associated coronavirus	• *Mycobacterium tuberculosis* • Chikungunya virus	• Ebola virus • Marburg virus • Herpes B virus

3.4 PROCEDURAL RISK FACTORS

In addition to the inherent hazards of a particular agent, exposure hazards posed by the procedures involved must also be considered during a biological risk assessment. Reports of laboratory-associated infections (LAIs) highlight the predominant routes of transmission in laboratories. These include parenteral exposures from contaminated sharps and animal bites/scratches, spill- and splash-based exposure to skin and mucous membranes, ingestion from mouth pipetting or poor hand washing practices, and inhalational exposure to infectious aerosols. An agent's route of transmission in nature may or may not be informative in regard to potential routes of transmission in the laboratory. For example, it's reasonable to expect that a mosquito-borne virus can be transmitted by a contaminated needlestick in the lab. However, contrary to natural modes of infection, many mosquito-borne viruses can also be contracted in the lab after inhalation of infectious aerosols inadvertently generated by sample processing.

Infectious aerosols and droplets are of particular concern, since they are obscure and may be produced by any laboratory procedure that imparts energy to a sample, including pipetting, vortexing, sonicating, and centrifugation without safety cups. The small particle size of infectious aerosols translates to a reduced infectious load per particle, but these particles are efficiently disseminated and pose an infection risk to anyone in the vicinity. In contrast, larger droplets quickly settle from the air, but contain higher loads of infectious agent. These droplets efficiently contaminate work surfaces and gloves, increasing the risks of mucous membrane or ingestion-based exposures.

Laboratory directors and principal investigators are ultimately responsible for the work that is conducted in their labs. In addition to assessing an employee's knowledge of agent and procedural hazards, laboratory directors and principal investigators should also assure workers demonstrate the diligence and proficiency required for infectious agent work, as carelessness can negate any protective safeguards in place. For example, a careless and rushed worker is likely to substantially increase the creation of infectious aerosols. Training, experience, knowledge of the agent and procedure hazards, good habits, caution, attentiveness, and concern for the health of coworkers are all prerequisites for work with infectious agents.

3.5 BIOLOGICAL CONTAINMENT CONTROLS

The essential objective of biosafety programs is to achieve containment of potentially harmful biological agents. "Containment" encompasses the methods, facilities, and equipment for the safe handling and storage of infectious materials, all aimed at preventing human exposures or release of these agents into the environment. Moreover, containment controls are stratified according to their effectiveness, with elimination of the hazard the most effective and the use of PPE the least effective control (See Figure 3.2).

- **Elimination/Substitution:** The most effective means for eliminating risk is to get rid of the hazard. Often a gene can be characterized apart from the infectious agents. If complete omission of the agent from the studies is not feasible, another option to consider is the use of attenuated strains or surrogates rated at a lower risk group.
- **Administrative controls:** Administrative controls are the policies and procedures that are put in place to help mitigate risk, including requirements for training, access control, and SOPs. Handwashing and sharps policies, and required enrollment in Employee Health Programs are other examples of administrative controls.
- **Workplace Practices:** Strict adherence to standard microbiological practices and techniques is the most critical element of containment. The laboratory director or supervisor is responsible for ensuring that personnel are both aware of potential hazards and proficient in the practices and techniques required to safely work with these agents. A laboratory-specific biosafety manual must be drafted and adopted (BSL-2 and ABSL-2) that specifies the hazards in the lab, designates the appropriate practices and procedures for risk mitigation, and describes incident response procedures in the event of an exposure. Appropriate training on these practices and procedures should be documented for everyone imperiled by these hazards.

- **Engineering Controls and Personal Protective Equipment (PPE):**
  - **Primary barriers:** Engineering controls are devices or equipment designed as primary barriers to mitigate exposure risk. Biosafety cabinets (BSC) and centrifuge safety cups are classical examples, both of which are designed to provide protection from infectious aerosols and droplets. PPE is typically used in conjunction with engineering controls, but it can also serve as a primary barrier in cases where it may be impractical to work inside a BSC. The laboratory-specific biosafety manual should define the safety equipment needed for specific procedures or agents, including the PPE required. See **Appendix 3.2 for a detailed description of common primary containment devices.**
  - **Secondary barriers:** The design and proper function of the facilities where infectious agent work will be conducted serve as secondary barriers for protecting personnel, the public, and the environment. The facility requirements vary, based on the procedures and transmission routes of the specific agents handled. Directional airflow, the number of air changes per hour, HEPA-filtered exhaust, and the presence of airlocks, and/or anterooms are all examples of secondary barriers.

Please refer to Appendix 3.2.b for information about Laboratory Autoclaves Safety and Sustainability Guidelines.

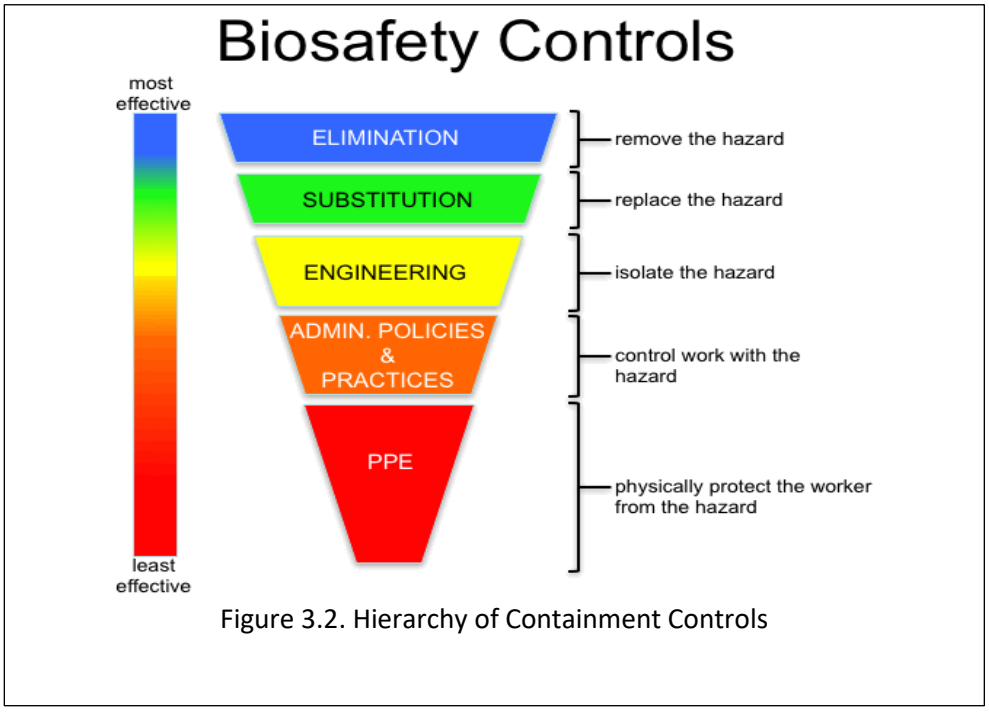


Figure 3.2. Hierarchy of Containment Controls

3.6 ASSIGNMENT OF BIOSAFETY LEVELS

Assigning a biosafety level to a project is one of the last steps of the risk assessment. Four biosafety levels (BSLs) have been designated to specify the combined containment controls (laboratory practices and techniques, safety equipment, and facilities) appropriate for the operations performed, potential routes of infectious agent transmission (ROT), and overall laboratory function (defined below). Like RGs, these are ranked 1 through 4, with BSL-1 having

the least stringent requirements, and BSL-4 the most stringent. Whereas RG describes the risk of an agent, as defined its association with, and the resulting severity of human disease, the biosafety level describes the conditions (containment controls) under which work with the agent can be safely conducted.

3.7 REVIEW AND REVISIT REGULARLY

The "last step" in a risk assessment is ongoing. This is because it involves continuous review of the containment controls assigned, specifically in regard to their efficacy in preventing exposure to-or releases of infectious agents. Technological advances may have resulted in engineering controls that are more practical to the laboratory applications involved. Alternatively, new knowledge, gleaned from LAIs, literature, or practical/hands-on experience, may warrant refinements to the controls assigned.

3.8 BIOSAFETY LEVEL CRITERIA

Biosafety Levels (BSLs) define the minimal containment controls appropriate for work with different infectious agent categories (Table 3.2), primarily distinguished by the activities in the lab and the potential routes of transmission and pathogenicity of the infectious agents involved. The requirements are additive, with each BSL building upon the previous level-thereby creating layer upon layer of practices (Table 3.2) and barriers (Table 3.3) that serve to mitigate the increasing risks associated with the agents/procedures.

3.8.1 Biosafety Level-1

As the lowest of the four, biosafety level 1 applies to laboratories for work with low-risk microbes that pose little to no threat of infection in healthy adults. Nonpathogenic strains of *E. coli* are typically worked with at BSL-1.
Laboratories operating under BSL-1 containment typically consist of research on benches without the use of special contaminant equipment (e.g. BSCs). These labs are not required to be isolated from surrounding facilities but do require the following:

Standard Microbiological Practices:

- The laboratory supervisor enforces the institutional policies that control safety in and access to the laboratory.
- The laboratory supervisor ensures that laboratory personnel receive appropriate training regarding their duties, potential hazards, manipulations of infectious agents, necessary precautions to minimize exposures, and hazard/exposure evaluation procedures (e.g., physical hazards, splashes, aerosolization) and that appropriate records are maintained.
- Personnel receive annual updates and additional training when equipment, procedures, or policies change. All persons entering the facility are advised of the potential hazards, are instructed on the appropriate safeguards, and read and follow instructions on practices and procedures. An institutional policy regarding visitor training, occupational health requirements, and safety communication is considered.
- Personal health status may affect an individual's susceptibility to infection and ability to receive available immunizations or prophylactic interventions. Therefore, all personnel, and

particularly those of reproductive age and/or those having conditions that may predispose them to increased risk for infection (e.g., organ transplant, medical immunosuppressive agents), are provided information regarding immune competence and susceptibility to infectious agents. Individuals having such conditions are encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

- A safety manual specific to the facility is prepared or adopted in consultation with the facility director and appropriate safety professionals. The safety manual is available, accessible, and periodically reviewed and updated, as necessary.
    - The safety manual contains sufficient information to describe the biosafety and containment procedures for the organisms and biological materials in use, appropriate agent-specific decontamination methods, and the work performed.
    - The safety manual contains or references protocols for emergency situations, including exposures, medical emergencies, facility malfunctions, and other potential emergencies. Training in emergency response procedures is provided to emergency response personnel and other responsible staff according to institutional policies.
- A sign is posted at the entrance to the laboratory when infectious materials are present. Posted information includes: the laboratory's Biosafety Level, the supervisor's or other responsible personnel's name and telephone number, PPE requirements, general occupational health requirements (e.g., immunizations, respiratory protection), and required procedures for entering and exiting the laboratory. Agent information is posted in accordance with the institutional policy.
- Long hair is restrained so that it cannot contact hands, specimens, containers, or equipment.
- Gloves are worn to protect hands from exposure to hazardous materials.

  Glove selection is based on an appropriate risk assessment.

  Gloves are not worn outside the laboratory.

  Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.

  Do not wash or reuse disposable gloves and dispose of used gloves with other contaminated laboratory waste.
- Gloves and other PPE are removed in a manner that minimizes personal contamination and transfer of infectious materials outside of the areas where infectious materials and/or animals are housed or manipulated.
- Persons wash their hands after working with potentially hazardous materials and before leaving the laboratory.
- Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption are not permitted in laboratory areas. Food is stored outside the laboratory area.
- Mouth pipetting is prohibited. Mechanical pipetting devices are used.

- Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware are developed, implemented, and followed; policies are consistent with applicable state, federal, and local requirements. Whenever practical, laboratory supervisors adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions are always taken with sharp items. These include:
    - Plasticware is substituted for glassware whenever possible.
    - Use of needles and syringes or other sharp instruments is limited in the laboratory and is restricted to situations where there is no alternative (e.g., parenteral injection, blood collection, or aspiration of fluids from laboratory animals or diaphragm bottles). Active or passive needle-based safety devices are to be used whenever possible.
        - Uncapping of needles is performed in such a manner to reduce the potential for recoil causing an accidental needlestick.
        - Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
        - If absolutely necessary to remove a needle from a syringe (e.g., to prevent lysing blood cells) or recap a needle (e.g., loading syringes in one room and injecting animals in another), a hands-free device or comparable safety procedure must be used (e.g., a needle remover on a sharps container, the use of forceps to hold the cap when recapping a needle).
        - Used, disposable needles and syringes are carefully placed in puncture-resistant containers used for sharps disposal immediately after use. The sharps disposal container is located as close to the point of use as possible.
    - Non-disposable sharps are placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
    - Broken glassware is not handled directly. Instead, it is removed using a brush and dustpan, tongs, or forceps.
- Perform all procedures to minimize the creation of splashes and/or aerosols.
- Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant. Spills involving infectious materials are contained, decontaminated, and cleaned up by staff who are properly trained and equipped to work with infectious material. A spill procedure is developed and posted within the laboratory.
- Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method, consistent with applicable institutional, local, and state requirements. Depending on where the decontamination will be performed, the following methods are used prior to transport:
    - Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leak-proof container and secured for transport. For infectious materials, the

outer surface of the container is disinfected prior to moving materials and the transport container has a universal biohazard label.

  - Materials to be removed from the facility for decontamination are packed in accordance with applicable local, state, and federal regulations.

- An effective integrated pest management program is implemented.
- Animals and plants not associated with the work being performed are not permitted in the laboratory.

No **special practices** are required to work at biosafety level 1 laboratories.

Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. The individual is responsible for informing the UAB Employee Health Program when medical conditions arise that may impact their susceptibility to infection, ability to receive immunizations or other medical interventions. They can do this by contacting the UAB Employee Health Program, now part of Employee Health to schedule a consult to determine what measures need to be taken to assure that they are adequately protected in the laboratory environment.

Table 3.2. Agents and Practices Appropriate for BSL1-4

BSL	Work with Agents…	Practices
1	• Not known to consistently cause disease in healthy adults	• Standard microbiological practices • Sharps policies must be implemented • Lab supervisors must ensure staff are properly trained regarding their duties and the necessary precautions to prevent exposures
2	• Associated with human disease • Percutaneous, ingestion, and mucous membrane exposure routes	**BSL-1 practices plus:** • Limited access • Biohazard warning signs • Lab-specific biosafety manual prepared and adopted as policy; defines agent-specific handling, waste/decontamination, medical surveillance, and exposure response procedures
3	• That are indigenous or exotic that may cause serious or potentially lethal disease through the inhalation route of exposure	**BSL-2 practices plus:** • Controlled access • Decon of all waste • Decon of all lab clothing before laundering
4	• That are dangerous/exotic and pose high risk of aerosol transmission, infections that are frequently fatal, with limited prophylaxis/treatment available • Unknowns with properties similar to RG4 agents	**BSL-3 practices plus:** • Clothing change before entry • Shower out • Decon of all material before departing facility

3.8.2 Biosafety Level-2

This biosafety level applies to work with agents associated with human diseases that pose a moderate health hazard. Examples of agents typically worked with in a BSL-2 include HIV and *Staphylococcus aureus.*

BSL-2 laboratories require the same standard microbial practices as BSL-1 labs, with enhanced measures due to the potential risk of human disease. Personnel working in BSL-2 labs are expected to take greater care to prevent exposures through percutaneous injury, ingestion, or mucous membranes.

In addition to biosafety level 1 requirements, the following **special practices** are required to work at biosafety level 2 laboratories:

- Access to a BSL-2 lab is far more restrictive. Outside personnel, or those with an increased risk of contamination, are often restricted from entering when work is being conducted.
- Laboratory personnel are provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory.
- Appropriate personal protective equipment (PPE) must be worn, including lab coats and gloves. Eye protection and face shields can also be worn, as needed.
- Properly maintained BSCs or other physical containment devices are used when possible. All procedures that can cause infection from aerosols or splashes are performed within a biological safety cabinet (BSC).
- Laboratory equipment is decontaminated routinely; after spills, splashes, or other potential contamination; and before repair, maintenance, or removal from the laboratory.
- The laboratory has self-closing, lockable doors.
- A sink and eyewash station should be readily available.
- Biohazard warning signs on the doors.
- A method for decontaminating all laboratory waste is available (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).
- Incidents that may result in exposure to infectious materials are immediately evaluated per institutional policies. All such incidents are reported to the laboratory supervisor and any other personnel designated by the institution. Appropriate records are maintained.
- A laboratory-specific biosafety manual must be drafted and adopted – See Appendix 3.3.a for the UAB Lab-Specific Biosafety Plan Template for BSL-2.

Table 3.3. BSL1-4 Primary and Secondary Barriers

BSL	Primary Barriers and Safety Equipment	Facilities (Secondary Barriers)
1	• No primary barriers typically required • Protective clothing recommended • Protective eyewear and appropriate gloves, when hazardous work conducted	• Lab doors for access control • Non-porous, benches and furniture (easily decontaminated) • Sink for handwashing
2	**BSL-1 plus:** • BSCs or other physical containment devises for all work that can generate infectious aerosols or droplets • PPE: Lab coat, gloves, face and eye protection, as needed	**BSL-1 plus:** • Autoclave available • Self-closing doors with locks • Airflow should not recirculate to public areas • Eye Wash station readily available
3	**BSL-2 plus:** • BSCs or other physical containment devices used for all open manipulation of agents • PPE: protective lab clothing, gloves, face, eye, and respiratory protection, as needed	**BSL-2 plus:** • Physical separation between access corridors • Self-closing, double-door access • Inward airflow directionality (clean to dirty), no reversal during failure • Lab entry through airlock or anteroom • Hands-free sink • All seams, floors, walls, & ceilings sealed
4	**BSL-3 plus:** • All procedures in Class III BSCs or Class I/II combined with full-body, positively pressured suit	**BSL-3 plus:** • Class III BSC or Suit Lab setups • Separate building or isolated zone • pass through autoclave • emergency power for all containment operations (HVAC, alarms, BSCs, entry/exit, etc.) • Dedicated HVAC, vacuum, & decon systems

3.8.3 Biosafety Level-3

In addition to the requirements at biosafety levels 1 & 2, a BSL-3 laboratory includes work on microbes that are either indigenous or exotic, and can typically cause serious or potentially lethal disease through inhalation. Examples of microbes worked with in a BSL-3 lab include, West Nile virus, Chikungunya virus, and *Mycobacterium tuberculosis* that causes tuberculosis. Work with Select Agents must be performed in a BSL-3 lab, Select agent work require registration with appropriate government agencies and oversight for receipt, storage, use, and disposal. Medical surveillance programs for BSL-3 personnel may require immunization against the microbes they work with, if available.

In addition to biosafety level 1 and 2 requirements, the following **special practices** are required to work at biosafety level 3 laboratories:

- All persons entering the laboratory are advised of the potential hazards and meet specific entry/exit requirements in accordance with institutional policies.
- All persons who enter operational laboratory areas are provided information on signs and symptoms of disease.

- The laboratory supervisor is responsible for ensuring that laboratory personnel demonstrate proficiency in standard microbiological practices and techniques for working with agents requiring BSL-3 containment.
- A system is established for reporting and documenting near misses, laboratory accidents, exposures, unanticipated absences due to potential laboratory-associated infection, and for the medical surveillance of potential laboratory-associated illnesses.
- Biological materials must be placed in a durable, leak-proof sealed primary container and then enclosed in a non-breakable, sealed secondary container prior to removal from the BSL-3 facility by authorized personnel.
- Standard personal protective equipment must be worn, which may include respirators, solid-front wraparound gowns, scrub suits or coveralls.
- Sustained directional airflow to draw air into the laboratory from clean areas towards potentially contaminated areas (Exhaust air cannot be re-circulated).
- A self-closing set of locking doors with access away from general building corridors.
- Decontamination of the entire laboratory is considered when there has been gross contamination of the space, significant changes in laboratory usage, major renovations, or maintenance shutdowns. Selection of the appropriate materials and methods used to decontaminate the laboratory is based on a risk assessment. Decontamination processes are verified on a routine basis.
- Access to BSL-3 containment is restricted and controlled at all times.

SEBLAB (BSL-3 High Containment Laboratory at UAB):
Southeastern Biosafety Laboratory Alabama Birmingham (SEBLAB) at UAB is one of the 12 Regional Biocontainment Laboratories (RBLs) in USA funded by National Institute of Allergy and Infectious Disease (NIAID), National Institutes of Health (NIH). BSL-3 high containment *In vitro* and *In vivo* laboratory suites at SEBLAB provides UAB investigators unique opportunity to conduct their research work with high-risk pathogens in the area of virology, bacterial pathogenesis, immunology, and vaccine development etc., Investigators interested in working at SEBLAB are required to register their project with IBC and complete comprehensive training program tailored to BSL-3 containment. Contact biosafety representative at biosafety@uab.edu to get started with SEBLAB access process. For more information about SEBLAB please click the link below:
Southeastern Biosafety Lab Alabama Birmingham | UAB

3.8.4 Biosafety Level-4

BSL-4 labs are rare and there are no BSL-4 facilities at UAB. However, some do exist in a small number of places in the US and around the world. At the highest level of biological containment, BSL-4 labs are for work with highly dangerous and exotic microbes. Infection by an agent designated for BSL-4 containment are likely untreatable and fatal. Ebola and Marburg viruses are examples of agents requiring BSL-4 containment.

In addition to requirements listed for biosafety level 1 through biosafety level 3, following **special practices** are required to work at biosafety level 4 laboratories:

- Additional training/security requirements may be required prior to gaining independent access to BSL-4 laboratories.
- Personnel are required to change clothing before entering, shower upon exiting.
- All waste is decontaminated by a verified method prior to removal from the laboratory.
- Personnel must wear appropriate personal protective equipment from prior BSL levels, as well as a full body, air-supplied, positive pressure suit.
- All procedures involving the manipulation of infectious materials are conducted within a Class III BSC.
- A logbook, or other means of documenting the date and time of all persons entering and leaving the laboratory, is maintained.
- An inventory system for agents stored within the laboratory is in place.
- Daily inspections of essential containment and life support systems are completed and documented before laboratory work is initiated to ensure that the laboratory is operating according to established parameters.

A BSL-4 laboratory is extremely isolated-often located in a separate building or in an isolated and restricted zone of the building. The laboratory also features a dedicated supply and exhaust air, as well as vacuum lines and decontamination systems.

3.9 VERTEBRATE ANIMAL BSL (ABSL) AND CRITERIA FOR VIVARIUM FACILITIES

Essential containment control measures have also been ascribed for vivarium facilities where infectious organism research is conducted. In general, the biosafety level for working with infectious agents *in vivo* and *in vitro* are comparable. However, animals experimentally infected, or those harboring zoonotic agents, present unique hazards not present in standard microbiological laboratories.

Table 3.4. ABSL1-4 Practice, Primary, and Secondary Barriers

ABSL	Practices	Primary Barriers and Safety Equipment	Facilities (Secondary Barriers)
1	**ABSL-1 practice:** • Standard animal care and management practices, including appropriate medical surveillance programs • "Sharps" precautions should be implemented	**ABSL-1 equipment:** As required for normal care of each species • PPE: laboratory coats and gloves; eye, face protection, as needed	**ABSL-1 facility:** Standard animal facility: • No recirculation of exhaust air • Directional airflow recommended • Hand washing sink is available
2	**ABSL-1 practice plus:** • Limited access • Biohazard warning signs • Biosafety manual • Decontamination of all infectious wastes and animal cages prior to washing	**ABSL-1 equipment plus:** • Containment equipment appropriate for animal special • PPE: Laboratory coats, gloves, face, eye and respiratory protection, as needed	**ABSL-1 facility plus:** • Autoclave available • Hand washing sink available • Mechanical cage washer recommended • Negative airflow into animal and procedure rooms recommended
3	**ABSL-2 practice plus:** • Controlled access • Decontamination of clothing before laundering • Cages decontaminated before bedding is removed • Disinfectant foot bath as needed	**ABSL-2 equipment plus:** • Containment equipment for housing animals and cage dumping activities • Class I, II or III BSCs available for manipulative procedures (inoculation, necropsy) that may create infectious aerosols • PPE: Respiratory protection	**ABSL-2 facility plus:** • Physical separation from access corridors • Self-closing, double-door access • Sealed penetrations • Sealed windows • Autoclave available in facility • Ante-room or airlock entry • Negative airflow into animal/procedure rooms • sink near exit of animal or procedure room
4	**ABSL-3 practices plus:** • Entrance through change room where personal clothing is removed and laboratory clothing is put on; shower on exiting • All wastes are decontaminated before removal from the facility	**ABSL-3 equipment plus:** • Maximum containment equipment (i.e., Class III BSC or partial containment equipment in combination with full body, air-supplied positive-pressure suit) used for all activities	**ABSL-3 facility plus:** • Separate building or isolated zone • Dedicated supply and exhaust, vacuum, and decontamination systems • Other requirements outlined in the text

Animals that serve as effective models for infectious disease are typically permissive to infection, which suggests they have the potential to harbor increased concentrations of the agent to which they were initially exposed. These animals may create infectious aerosols through coughing, sneezing, or by disrupting bedding particles that contain shed organisms. They also pose an increased risk for percutaneous exposures, through bites or scratches. **Thus, infectious organisms typically considered commensal or pervasive in nature may pose increased risk in the setting of an animal disease model.** The practices, primary and secondary barriers, and PPE defined for each ABSL (1-4) are summarized in Table 3.4.

For detailed descriptions, refer to Section V—*Vertebrate Animal Biosafety Level Criteria for Vivarium Research Facilities* in the 6th edition of BMBL.

3.10 CONTAINMENT CRITERIA FOR PLANTS, PLANT PATHOGENS, AND VECTORS

Organisms that are not a direct threat to human health may still pose serious economic or ecological consequences if released into the environment (e.g., inadvertent release of a pathogen capable of harming livestock or agricultural crops). In these situations, containment efforts are primarily focused on preventing a release.

Table 3.5. Containment for Plants, Plant Pathogens, and Vectors

Plants	Microbes	Insects
• Use genetic engineering techniques that localize transgenes to non-propagative plant parts or confer plant sterility • Cover or remove flower and seed heads to prevent pollen and seed dispersal • Use male sterile strains • Harvest the plant material prior to the reproductive stage • Control flowering time so pollen shed does not occur during the receptive period of nearby cross-fertile plants • Ensure that cross-fertile plants are not growing within the known pollen dispersal range of the experimental plant	• Genetically disable the microbes to minimize survival and reproduction • Avoid creating aerosols when inoculating plants • Provide adequate distance between an infected plant and another susceptible host; especially if dissemination can occur through the air or by leaf contact • Grow experimental plants and microbes at a time of year when susceptible plants are not growing nearby • Eliminate vectors for insect-borne microbes • Choose microbes with an obligate association with the host plant • Treat runoff water to kill living organisms	• Choose or create non-flying, flight-impaired, or sterile strains • Conduct experiments at a time of year when escaped organisms will not survive • Choose organisms that do not have an obligate association with nearby plants • Treat or evaporate runoff water to eliminate viable larvae and eggs • Avoid use of small insects in greenhouse cages • Destroy all pollinating insects in cages after pollen transfer • See Arthropod containment levels, special practices, and facilities

3.10.1 Invertebrates

As for vertebrates, the biosafety level will be determined by the risk groups or assessed risk of the agents under investigation. Arthropods lacking human pathogens may still pose a risk to the environment if, by escaping, they complete a transmission cycle for a disease that they vector or they are a non-native/invasive species. Handling practices, safety equipment, and containment facilities should be discussed with EH&S before handling arthropods, particularly if the species is a potential vector or ecological risk. Recombinant projects require registration with EH&S and approval by IBC.

3.10.2 Plant Biosafety Level-1 (BL1-P)

Standard Practices:

- Access to a greenhouse (any structure with walls, roof, and floor used for growing plants) is restricted, at the discretion of the director, when experiments in progress.
- Prior to entry personnel are required to read and follow BL1-P greenhouse practices and procedures, written in accordance with those appropriate to the experimental species housed.
- A record shall be kept of experiments currently in progress in the greenhouse facility.
- Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside of the greenhouse facility.
- Programs are implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens), by methods appropriate to the organisms and in accordance with applicable state and Federal laws.
- Arthropods and other motile macro-organisms shall be housed in appropriate cages. If macro-organisms (e.g., flying arthropods or nematodes) are released within the greenhouse, precautions shall be taken to minimize escape from the greenhouse facility.

Facilities:

- The greenhouse floor may be composed of gravel or other porous material. At a minimum, impervious (e.g., concrete) walkways are recommended.
- Windows and other openings in the walls and roof of the greenhouse facility may be open for ventilation as needed for proper operation and do not require any special barrier to contain or exclude pollen, microorganisms, or small flying animals (e.g., arthropods and birds); however, screens are recommended.

3.10.3 Plant Biosafety Level 2 (BL2-P)

Standard Practices; BL1-P Plus:

- Greenhouse access is restricted to individuals directly involved in the experiments, at the discretion of the director.
- A greenhouse practices manual shall be prepared or adopted. This manual shall: (i) advise personnel of the potential consequences if such practices are not followed, and (ii) outline contingency plans to be implemented in the event of the unintentional release of organisms.

- Prior to entry, personnel are required to read and follow BL2-P greenhouse practices and procedures, written in accordance with those appropriate to the experimental species housed.
- A record shall be kept of experimental plants, microorganisms, or small animals brought in or removed from the greenhouse.
- A record shall be kept of experiments currently in progress in the greenhouse facility.
- The Principal Investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms to the Greenhouse Director, Institutional Biosafety Committee, NIH OSP and other appropriate authorities immediately (if applicable).
- Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside of the greenhouse facility.
- A program shall be implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens)
- A sign shall be posted indicating that a restricted experiment is in progress. The sign shall indicate the following: (i) the name of the responsible individual, (ii) the plants in use, and (iii) any special requirements for using the area.
- If organisms are used that have a recognized potential for causing serious detrimental impacts on managed or natural ecosystems, their presence shall be indicated on a sign posted on the greenhouse access doors.
- Facilities; BL1-P Plus:
- A greenhouse floor composed of an impervious material. Concrete is recommended, but gravel or other porous material under benches is acceptable unless propagules of experimental organisms are readily disseminated through soil. Soil beds are acceptable unless propagules of experimental organisms are readily disseminated through soil.
- Windows and other openings in the walls and roof of the greenhouse facility may be open for ventilation as needed for proper operation and do not require any special barrier to exclude pollen or microorganisms; however, screens are required to exclude small flying animals (e.g., arthropods and birds).
- An autoclave shall be available for the treatment of contaminated greenhouse materials.
- If intake fans are used, measures shall be taken to minimize the ingress of arthropods. Louvers or fans shall be constructed such that they can only be opened when the fan is in operation.

BL2-P greenhouse containment requirements may be satisfied by using a growth chamber or growth room within a building provided that the external physical structure limits access and escape of microorganisms and macroorganisms in a manner that satisfies the intent of the containment requirements.

3.10.4 Plant Biosafety Level-3 (BL3-P)

BL3-P (and higher) research requires specialized facilities and practices. Refer to the NIH Guidelines and contact EH&S Biosafety at biosafety@uab.edu for further information.

3.11 BIOSAFETY FOR TEACHING LABORATORIES

In 2012, the American Society for Microbiology (ASM) published a document titled, Guidelines for Biosafety in Teaching Laboratories. These guidelines recommend specific equipment, facilities, and practices for coursework requiring BSL-1 and BSL-2 containment laboratories. The ASM publication was influenced by the lack of safety guidelines for microbiology teaching laboratories and a multistate outbreak of Salmonella typhimurium originating in teaching and clinical laboratories in 2011. A major finding identified during an investigation of the outbreak and a similar one in 2014, was a lack of biosafety training and awareness for staff and students. UAB has many teaching labs at the introductory, intermediate, and advanced undergraduate levels, as well as graduate levels. The following sections of this manual will focus on biosafety for teaching laboratories at UAB. Please refer to Appendix 3.4 and 3.5 for the ASM publications regarding biosafety for teaching laboratories.

UAB has adopted the ASM Guidelines for Biosafety in Teaching Laboratories as policy. All coursework/activities conducted in UAB teaching laboratories must either adhere to these guidelines or be pre-approved by the IBC. It is important to note that not all teaching laboratories are designed or equipped to safely operate at BSL-2.

3.11.1 BSL-1 Requirements for Biosafety in Teaching Laboratories

BSL-1 includes microorganisms that are not known to cause human disease, and that can be handled safely on bench tops. The use of BSL-1 containment is most appropriate for teaching laboratories, especially introductory level students.

BSL-1 Laboratory Facility Requirements

- Non-porous flooring, bench tops, chairs, and stools
- Sink for hand-washing
- Eyewash station
- Lockable door to the laboratory
- Proper pest control practices
- *Recommended:* Separate storage area for personal belongings
- *Recommended:* Access to an autoclave

BSL-1 Stock Culture Requirements

- Stock cultures must be from approved and reputable sources.
- Sub-culturing microbes isolated from the environment, clinical samples, or other unknown locations is discouraged as BSL-2 (or higher) microbes may be isolated.

- Sub-culturing from the environment must be reviewed and approved by the UAB IBC.
- When possible, only well-characterized microbes should be used (e.g., identified with an ATCC number). Examples are provided in Table 3.6.
- The laboratory instructor must maintain safety documentation for all stock organisms, sources, and procedures for handling stock cultures.
- Microorganism stock cultures should be obtained/replaced on a regular basis to be certain of the source culture, to minimize spontaneous mutations, and to reduce contamination.

Culturing Unknowns:

It is recommended that testing of unknowns should be performed from a mixture of microorganisms that remain known to the instructor, or from individual "unknown" cultures de-identified by the instructor, instead of true unknowns obtained from the environment. If necessary, students are permitted to grow primary cultures of unknown organisms collected from soil, water, food materials, and the air. However, **IBC review and pre-approval must be obtained for:**

- Culturing unknown samples cultured from environments such as water fountains, door handles, community soil samples, wastewater treatment facilities, the students themselves, or any other source likely to be enriched for human pathogens.
- Culturing unknowns with media that preferentially selects for the growth of organisms listed at RG-2 or higher.
- Sub-culturing unknowns.

BSL-1 Training Practices:

- Faculty and teaching assistants must complete BIO303 Basic Biosafety, BIO301L Medical Waste Management for Laboratories.
- Instructors and/or teaching assistants must review basic biosafety and microbiological practice with students on the first day of lab. Training sessions must be documented with a sign-in sheet maintained by the instructor.
- Students and instructors are required to handle microorganisms safely and in conjunction with requirements outlined in the UAB Biosafety Manual, or as designated by the IBC.
- Inform students of safety precautions applicable to each exercise before the procedure is performed.

BSL-1 Laboratory Documentation

- Students must sign a safety agreement indicating that they have been informed about the safety requirements and the hazardous nature of the microbes and materials that they will handle throughout the semester. The laboratory instructor must maintain student signed agreements in the laboratory.
- Prepare, maintain, and post appropriate signs on lab doors (biohazard symbol).

- Instructors must provide a detailed list of microorganisms that will be handled in the laboratory by students. This list can be included in the syllabus, laboratory manual, or online at the course website.
- Emergency phone numbers and contact information must be posted in the laboratory.

Table 3.6. Recommended Microbes and ATCC Numbers

Microbe	BSL	ATCC Number
Alcaligenes faecalis	**1**	8750
Aspergillus niger	**1**	16888
Bacillus globigii	**1**	49760
Bacillus megaterium	**1**	35075
Bacillus stearothermophilus	**1**	7953
Bacillus subtilis	**1**	23857
Citrobacter freundii	**1**	8090
Clostridium sporogenes	**1**	3584
Enterobacter aerogenes	**1**	13048
Enterococcus casseliflavus	**1**	700327
Enterobacter cloacae	**1**	13047
Enterococcus durans	**1**	19432
Escherichia coli B	**1**	11303
Escherichia coli K-12	**1**	10798
Geobacillus stearothermophilus	**1**	12980
Halobacterium salinarum	**1**	33170
Lactobacillus acidophilus	**1**	4356
Micrococcus luteus	**1**	4698
Neurospora crassa	**1**	10815
Penicillium chrysogenum	**1**	10106
Providencia alcalifaciens	**1**	9886
Pseudomonas fluorescens	**1**	13525
Rhanella aquatilis	**1**	15552
Rhizopus stolonifer	**1**	14037
Rhodococcus rhodochrous	**1**	13803
Saccharomyces cerevisiae	**1**	9763
Sarcina aurantiaca	**1**	146
Serratia liquefaciens	**1**	27592
Serratia marcescens Bizio	**1**	13880
Staphylococcus epidermidis	**1**	14990
Staphylococcus saprophyticus	**1**	15305

3.11.2 BSL-2 Requirements for Biosafety in Teaching Laboratories

BSL-2 laboratories are suitable for working with microbes posing a moderate risk to the individual and a low community risk for infection. There are many microorganisms handled at BSL-2 that primarily cause disease in humans via ingestion or inoculation. The guidelines for BSL-2 laboratories build upon those for BSL-1 facilities, and typically include additional engineering controls to protect students (e.g. biological safety cabinets, centrifuge safety cups, and safety needle devices).

BSL-2 Laboratory Facility Requirements

- Non-porous flooring, bench tops, chairs, and stools
- Sink for hand-washing
- Eyewash station
- Lockable door to the laboratory
- Proper pest control practices
- Separate storage area for personal belongings
- Access to a working and validated autoclave
- Biohazard signage where BSL-2 cultures are used and stored, on the door to the laboratory, and on any containers used for transport
- Strongly Recommended: Annually Certified Biological Safety Cabinet (required for any procedures which may create infectious aerosols)

BSL-2 Stock Culture Requirements

- Stock cultures must be from approved and reputable sources
- Sub-culturing microbes isolated from the environment, clinical samples, or other unknown locations is discouraged as BSL-2 (or higher) microbes may be isolated
- Sub-culturing unknowns must be reviewed and approved by the UAB IBC
- The laboratory instructor must maintain safety documentation for all stock organisms, sources, and procedures for handling stock cultures
- Store cultures in a secure (locked) location
- When possible, utilize RG-1 surrogates for common RG-2 pathogens

Substitution of specific RG-2 cultures

When choosing a test organism, many instructors want to choose organisms that are clinically relevant, i.e. pathogens. There are six microorganisms that are considered major threats for microbiological teaching laboratories, not because they cause the most devastating illnesses, but because they comprise the majority of antibiotic-resistant infections observed in health care settings. These are referred to as **ESKAPE** pathogens and include: ***E****nterococcus faecium,* ***S****taphylococcus aureus,* ***K****lebsiella pneumonia,* ***A****cinetobacter baumannii,* ***P****seudomonas aeruginosa,* ***E****nterobacter species.*

Recommended substitution organisms for ESKAPE pathogens	
ESKAPE pathogen	**Safe relative**
Enterococcus faecium	*Enterococcus raffinosus* or *Enterococcus casseliflavus*
Staphylococcus aureus	*Staphylococcus epidermidis*
Klebsiella pneumonia	*Escherichia coli*
Acinetobacter baumannii	*Acinetobacter baylyi*
Pseudomonas aeruginosa	*Pseudomonas putida*
Enterobacter species	*Enterobacter aerogenes*

3.12 REGISTRATION AND APPROVAL OF BIOLOGICAL AGENT WORK AT UAB

Hazard Registration with Environmental Health and Safety (EH&S):
All work involving hazardous materials (e.g., biological, chemical, radiological, nanoparticles) or processes (e.g., irradiation, lasers, excessive noise) must be registered with Environmental Health & Safety and the Research Safety Committees Office. Similarly, all work with materials and/or processes that are subject to local or federal regulations must be registered. Efforts are underway to update and consolidate the registration process into EHSA (Environmental Health and Safety Assistant), but IBC project registration is currently (as of June 2025) submitted by downloading RSC-EHS Project Registration Form at Office of Research website and sending to completed From to projects@uab.edu. Projects are distinguished by funding source. This means that each independently-funded project (internally or externally) must be registered and approved separately, regardless of whether the work was previously approved under a different funding source.

Internal EH&S Review:
Registrations are first reviewed internally by EH&S subject matter experts. Initial review will ensure laboratories are in compliance with the Laboratory Review Program, and laboratory personnel associated with the work are currently enrolled and compliant with the UAB Employee Health Program and up-to-date with applicable laboratory safety training offered through the UAB Faculty and Staff Learning System. Depending on the hazards and/or federal regulations, further review and approval by a specific UAB Safety Committee may then be required.

Biological Hazards that Require Registration:

Although specific exemptions may apply, projects that involve toxins, Risk Group 2 (RG-2) or higher organisms, recombinant or synthetic nucleic acid molecules, or biological agents that pose risk to agriculture (economic) or the environment, require a project registration with EH&S and may also require Institutional Biosafety Committee (IBC) approval before work can commence.

Projects requiring EH&S approval before initiation of work:

- Agricultural pathogens (Non-Select Agents)
- Invasive species
- Venomous or poisonous animals

Projects requiring EH&S and IBC approval before initiation of work:

- Human pathogens: All *in vitro* and *in vivo* studies involving human pathogens (associated with human disease), zoonotic agents that are considered RG-2 or higher, and any untested primary tissues, fluids, or materials that likely contain such agents. See Appendix B of The NIH Guidelines for the RG designation of most human pathogens.
- Experiments Covered Under The NIH Guidelines for Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)
- Work with Select Agents or Toxins

Projects requiring EH&S and IBC NOTICE simultaneous to initiation of work:

- Experiments Covered Under The NIH Guidelines: Section III-E

4.0 BLOODBORNE PATHOGENS

4.1 BLOODBORNE PATHOGENS POLICY STATEMENT

UAB laboratories which generate, process, store, or use material that contains or may contain human bloodborne pathogens are required to adhere to the OSHA Bloodborne Pathogens Standard. The required policies are described in this chapter:

- Conduct a laboratory specific risk assessment
- Develop a laboratory specific Exposure Control Plan
- Provide appropriate PPE for all laboratory members
- Ensure that all laboratory members who may be exposed to bloodborne pathogens have enrolled with UAB Employee Health
- Follow recommended incident reporting requirements and post exposure procedures
- Observe appropriate sharps and waste handling procedures
- Complete appropriate bloodborne pathogens training (lab specific and required courses in the UAB Campus Learning System)

4.2 OSHA'S BLOODBORNE PATHOGEN STANDARD

Exposures to blood and other body fluids occur across a wide variety of occupations. Laboratorians, health care workers, emergency responders, and public safety personnel can be exposed to blood or other potentially infectious material (OPIM) through needlestick, other sharps injuries, mucous membrane, and skin exposures. The Bloodborne Pathogens Standard contains four key elements:

1. Exposure Control Plan (ECP): An ECP is a site-specific risk assessment, conducted by a Principal Investigator (PI) or other Designee, designed to identify and reduce the risk of BBP exposures. It must be reviewed and updated at least annually by the PI or Designee, or earlier if significant changes in personnel or procedures occur.
2. Determination of Risk: An evaluation must be made to determine if an employee's duties place them at an increased risk for a BBP exposure. If an employee is identified to be at risk, the offering of the HBV vaccination and follow-up procedures, by the Employer are required.
3. Vaccinations and Post-Exposure Follow-Up Procedures: Employees who are at risk for BBP exposure must be offered HBV vaccinations within ten days of initial assignment. Confidential medical evaluation and follow-ups must also be available to employees that have experienced an exposure incident. Follow-Up Procedures include any needed BBP testing, preventive treatment, counseling, or other associated treatments.
4. Training: Employees whose job assignments place them at risk for BBP exposure must complete training within ten working days of initial appointment and annually after that.

Bloodborne pathogens include pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV).

OPIM may include human body fluids (semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, all body fluids in situations where it is difficult or impossible to differentiate between body fluids) unfixed tissue or organ (other than intact skin) from a human (living or dead), HIV-containing cell or tissue cultures, organ cultures, HIV- or HBV-containing culture medium or other solutions, blood, organs, or other tissues from experimental animals infected with HIV or HBV. It is important to note that because of the potential for human cell lines to harbor a bloodborne pathogen, OSHA includes primary human cell lines and explants in the bloodborne pathogens standard.

There are different levels of risk encountered when working with human cell lines.

- Cell lines, which are certified by their source as being bloodborne pathogen free and have been protected from subsequent contamination, may be excluded from the bloodborne pathogen standard. Work with these cell lines are not excluded from the superseding biosafety level at which the laboratory conducts work.
- The bloodborne pathogen standard DOES apply to cell lines that have not been certified to be bloodborne pathogen free from the source. These cell lines may be free from known contaminants, but are used/stored where contamination by bloodborne pathogens is possible. Work with these cell lines are not excluded from the superseding biosafety level at which the laboratory conducts work.
- Cell lines that are known to be contaminated with bloodborne pathogens must adhere to the bloodborne pathogens standard. At minimum, BSL-2 practices and procedures must be used in the laboratory. Please refer to the Guidelines for Human Xenograft Experiments at UAB for more information about administering human cell lines to animals.

The OSHA Standard includes specific guidelines for research personnel working in HBC, HCV and HIV laboratories. There also may be additional specialized facility requirements. Standard microbiological practices should always be followed.

- Controls for Laboratory Safety
- Infectious Diseases

Workers in HBV, HCV and HIV laboratories may require special training in addition to what is presented in this training program. Special work practices must be followed, and specific containment equipment used. Ask your supervisor about your lab's Agent Specific Data Safety Plan for more detailed information if you have questions.

OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) prescribes safeguards to protect workers against the health hazards caused by bloodborne pathogens. The standard places requirements on employers whose workers can be reasonably anticipated to contact blood or OPIM. Requirements include:

- Exposure Control Plan
- Standard precautions
- Engineering controls

- Work practice controls
- Personal protective equipment
- Appropriate housekeeping/waste management
- Hepatitis B vaccination
- Post-exposure follow-up
- Hazard communication
- Training
- Recordkeeping

4.3 EXPOSURE CONTROL PLAN (ECP)

The ECP must be designed to document procedures that minimize employee exposure to bloodborne pathogens. The required elements of an ECP are:

- The exposure determination which identifies jobs with occupational exposure, tasks and procedures where there is occupational exposure
- The procedures for evaluating the circumstances surrounding exposure incidents
- How provisions of the bloodborne pathogen standard are implemented (e.g. methods of compliance, HIV and HBV laboratory requirements, hepatitis B vaccination and post-exposure evaluation and follow-up, communication of hazards to employees, and recordkeeping.
- Methods of compliance include:
- Standard Precautions
- Engineering and work practice controls (e.g., safer medical devices, sharps disposal containers, hand washing, and PPE)
- Housekeeping
- Disposal of regulated waste
- Documentation should include:
- The annual review and/or implementation of effective safer medical devices designed to eliminate or minimize occupational exposure
- The ECP must be reviewed and updated at least annually, and whenever necessary to reflect new or modified tasks/procedures which affect occupational exposure. The annual review should also reflect additions or modification of employee positions with occupational exposure.
- **Please refer to Appendices 4.1.a, b, and c ECPs for different job functions on UAB's campus.**

4.4 PERSONAL PROTECTIVE EQUIPMENT (PPE)

Personal Protective Equipment (PPE) is specifically worn to prohibit human blood or OPIM from passing through to your clothing, skin, eyes, or mucous membranes.

Gloves

- Always wear gloves when handling human blood or OPIM and during clean up procedures or whenever there is a possibility of contamination on a work surface.
- Never use ripped or compromised gloves.
- Never reuse single use gloves!
- Use latex alternative gloves if a latex allergy exists. Contact your Supervisor if an alternative solution is needed.

Goggles, Surgical Mask, or Face Shields

These must be:

- Worn if there is a possibility of a splash hazard to the face
- Made of a material that does not absorb liquid

If you have questions about PPE, ask your supervisor or contact EH&S at biosafety@uab.edu

4.5 VACCINATIONS, INCIDENT RESPONSE, AND REPORTING

Vaccinations

The PI/Manager will ensure that all persons determined to be at risk for occupational exposure to human Bloodborne Pathogens are offered a Hepatitis B Vaccination within ten days of starting work. The PI or department must maintain documentation of HBV participation or declination. Medical records are confidential and are to be maintained by the UAB Employee Health Program or healthcare provider for at least 30 years post-employment. For further information on UAB Employee Health, refer to Chapter 7 of this document.

Incident Response

If you are exposed to human blood or OPIM:

- Wash affected areas with soap and water for 15 minutes
- Flush mucous membranes with water for 15 minutes
- Notify your supervisor
- Seek treatment immediately (timing may be critical for HIV-based prophylaxes)
- You are required to report any exposure or injury to a supervisor, PI, or manager. The supervisor, PI, or manager is responsible for reporting the incident to the Biosafety Officer (BSO) at UAB Environmental Health & Safety (EH&S) at biosafety@uab.edu. The BSO will investigate the circumstances surrounding the exposure and work to mitigate the risk of future exposures.

- A completed Initial Medical Evaluation Authorization Form, signed by a Supervisor, PI, or Manager, should accompany any employees seeking treatment.
- UAB Campus/Hospital Employees and students who have experienced a potential bloodborne pathogen exposure or injury should call the Employee Health Needle Stick Team at (205) 934-3411 for guidance and treatment.

Please refer to Appendix 4.3 for UAB Exposure Response Flowchart.

4.6 HANDLING AND DISPOSAL OF MATERIAL

Sharps

The term "sharps" refers to needles, syringes, scalpel blades, lancets, disposable medical instruments, broken glass, and similar devices or materials sent through the waste stream that have the potential to cut and/or puncture an individual or the transport liner in which it is placed. Sharps, whether contaminated or not, must be disposed of as medical waste. This MUST never be placed in the regular trash. Contact EH&S at biosafety@uab.edu if you need assistance disposing of medical waste in your area.

- Place all needles, syringes, and other sharps into rigid, red plastic sharps containers (biohazard label).
- Never remove needles from syringes.
- Do not cut, bend or recap needles.
- Secure the sharps container lid when it is full.
- Never overfill sharps containers and risk getting stuck.

This policy applies to **all** needles and syringes, whether (a) used or unused, (b) used together or separately, (c) used with human blood, or (d) used for any other purpose.

Laboratory Glassware

Uncontaminated glassware must never be placed directly into the regular trash can. This applies to glass items from medical, research, and teaching labs. This includes flasks, beakers, pipettes, tubing, glass slides, and cover slips, etc. Uncontaminated glassware must be placed in a rigid container that is puncture resistant (i.e., cardboard boxes, plastic, or metal drums). This rigid container must be labeled "Caution – Broken Glass." When the container becomes full, secure the top of the container with tape. The uncontaminated glassware waste that is contained in a rigid container may be disposed of in the regular trash.

Contaminated glassware which may be contaminated with infectious agents should be placed in approved sharps containers. The containers can then be treated as described in the **Appendix 4.2 UAB Campus Medical Waste Management Plan.**

4.7 REQUIRED TRAINING

Although many classes are available on the UAB Campus Learning System, the following courses are considered core essentials, particularly for those with the potential for exposure to bloodborne pathogens:

- **Basic Biosafety Training** (ID: E-5VNQVM) is required for anyone working with biological agents at UAB.
- **Bloodborne pathogen training** (ID: E-E04XR0) is required for all UAB employees with the potential for occupational exposure to bloodborne pathogens in their work environment, and it must be completed annually. Bloodborne pathogen training and annual refresher training is offered through UAB Campus Learning System.
- **Medical Waste Management for Labs** (ID: E-7VR7VE) is also required for anyone who:
    - Offers medical waste for transport from a UAB campus location
    - Generates medical waste
    - Handles medical waste
    - Signs the manifest
    - Packs the transport containers
    - Operates a transport vehicle or
    - Loads, unloads, or handles medical waste

5.0 UAB GUIDANCE FOR WORK WITH SELECT AGENTS and BIOLOGICAL TOXINS

5.1 THE FEDERAL SELECT AGENT PROGRAM

The **Federal Select Agent Program (FSAP)** is jointly managed by two United States federal agencies, The Division of Select Agents and Toxins (DSAT) part of The Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services (HHS) and the Animal and Plant Health Inspection Service (APHIS**)** of the United States Department of Agriculture (USDA). The Federal Select Agent Program oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to human, animal or plant health or to animal or plant products. Federal agencies oversight of biological select agents and toxins is established to decrease the risk of terrorism by constraining access to these agents and to decrease the risk of accidental release through enforcement of biosafety and biosecurity standards at the institution. As of January 14th, 2025, the Federal Select Agent Program regulates the possession, use, and transfer of 63 biological select agents and toxins. Because the list of select agents and toxins may be regularly updated, it is recommended to visit Federal Select Agent Program website for current information.

The FSAP effectively manages risk associated with possession and use of select agents and toxins by following steps:

- **Registration:** An organization needs authorization to possess, use, or transfer biological select agents and toxins.
- **Security:** An individual must first undergo an assessment of security risks conducted by the FBI's Criminal Justice Information Services Division.
- **Inspection:** On-site inspections, ensures that appropriate measures are established in each registered entity. This is to prevent unauthorized access, theft, loss, unintended exposure, or release of biological select agents and toxins.
- **Communication:** All entities are required to promptly report instances of theft, loss, or release of biological select agents and toxins that occur outside of intended containment. This could involve situations like exposure (such as a needlestick, spill, or animal bite), laboratory-acquired infections, or missing inventory. The FSAP follows up with each entity to confirm that appropriate corrective actions are taken to prevent recurrence of the incident.
- **Transfer:** Requests to transfer biological select agents and toxins between entities will be approved in advance. The FSAP must approve both the institution and the individual laboratory.

Responsible Official (RO), The RO has institutional responsibility for the biosafety, biosecurity, and regulatory compliance of select agents. FSAP regulations require that a RO be designated for each institution to monitor and oversee possession and use of select agents. **Biosafety Officer (BSO)** and the **Institutional Biosafety Committee (IBC)** will review and approve any proposed work related to select agents and toxins.

Investigators at UAB who want to possess and/or use select agents must contact the Responsible Official and Biosafety Officer (biosafety@uab.edu) for assistance with the registration process.

5.2 INTRODUCTION TO BIOLOGICAL TOXINS

Biological toxins are naturally produced substances that may be lethal in relatively small quantities. Examples of toxins of biological origin include Diphtheria Toxin, Tetrodotoxin, Pertussis Toxin, Botulinum Toxin, Snake Venom Toxins, Conotoxin, and Ricin. Toxins are not infectious, but their extreme toxicities warrant management like infectious agents in the workplace. Controls must be in place to ensure that lab staff and visitors are trained and protected from exposure. Potential exposures can occur through inhalation, mucous membrane contact, percutaneous injury or absorption, and ingestion. The main issues of concern in the laboratory are accidental exposures to toxins caused by contact with mucous membranes, transdermal absorption (depending on the diluents used), needlesticks, or inhalation of inadvertently aerosolized toxins.

All work with toxins of biological origin must be registered with EH&S and approved before the work begins. All toxins with a median lethal dose (LD50) of equal or less than 100 μg per kg body weight in vertebrates must be approved by the UAB IBC prior to the start of the research. The PI must ensure training on toxin-specific hazards and standard operating procedures (SOP) is conducted and documented for all at risk laboratory personnel. The training must include, but is not limited to, appropriate workplace practices, personal protective equipment, the health and physical hazards of the toxin, signs and symptoms associated with exposure, and emergency response procedures. Any deficiencies in training material or documentation of training may delay project approval.

5.3 SELECT TOXINS

Biological toxins that pose an elevated risk to human, plant, and/or animal health and safety fall under regulations stipulated by the U.S. Patriot and the Public Health Security and Bioterrorism Preparedness Response Acts. These acts jointly tasked the Departments of Health and Human Services (DHHS) and Agriculture (USDA) with establishing the Department of Select Agents and Toxins (DSAT), which specifies the list of toxins that require federal oversight and enforces the regulations for their possession, use, and transfer. To ensure compliance with the federal Select Agent Program (SAP), research with non-exempt quantities of Select Toxins at UAB requires additional safety, security, and incident response controls. Any proposed work involving non-exempt Select Agents and Toxins at UAB requires DSAT registration and approval, which is coordinated through UAB's Responsible Official (see https://www.selectagents.gov/sat/list.htm) for the current list of Select Toxins, exclusions, and exempt quantities). Toxins not listed by DSAT, or exempt quantities of Select Toxins, may be excluded from the requirements of Select Agent Regulations. The guidelines below pertain to all research involving biological toxins at UAB.

Receipt and transfer of Select Toxins: Approval is required for receipt and transfer of the following Select Toxins in any amount (intramurally or extramurally). Biological toxins are regulated as Class 6 Dangerous Goods, Division 6.1 Toxic Substances. UAB does not offer the required training for packaging and shipping biological toxins. For help identifying the appropriate vendor for this training, contact EH&S at biosafety@uab.edu.

Table 5.1. Regulated Select Toxins

Select Toxin	Exempt Quantity
Abrin	≤ 1000 mg
Botulinum neurotoxins	≤ 1 mg
Short, paralytic alpha Conotoxins	≤ 200 mg
Diacetoxyscirpenol (DAS)	≤ 10,000 mg
Ricin	≤ 1000 mg
Saxitoxin	≤ 500 mg
Staphylococcal enterotoxins (Subtypes A, B, C, D, and E)	≤ 100 mg of all subtypes combined
T-2 toxin	≤ 10,000 mg
Tetrodotoxin	≤ 500 mg

Exempt Quantities: If you plan to purchase or obtain exempt quantities of any of these Select Toxins, you must complete an Exemption Checklist for Use of Select Toxins (SA-Ext) form and submit it for approval by the Responsible Official. If you plan to transfer exempt quantities of Select Toxins, specialized training is required for proper shipping and a Due Diligence for Transfer of Select Toxins Form must be submitted and approved (see instructions). Due Diligence is the responsibility of the Principal Investigator obtaining or transferring exempt quantities of Select Toxins. All records should be kept for 3 years.

Regulated Quantities: If you plan to purchase or maintain Select Toxins in excess of exempt quantities, or any of the pathogenic Select Agents, you must first consult with UAB's Responsible Official (RO) or Biosafety Officer (BSO) or Alternate Responsible Official (ARO) at biosafety@uab.edu. The RO will register the project with the Federal Select Agent Program (FSAP). FSAP approval is required before non-exempt work can be initiated, and this process may take 6 months or more to complete.

Contact details of RO and ARO

Brian LaGory (Biosafety Officer): blagory@uab.edu
Justin Roth (Director of Research Safety): jcroth@uab.edu
For more information, send email to biosafety@uab.edu

5.4 PLANNING AND APPROVAL FOR USE OF BIOLOGICAL TOXINS

1. Register all biological toxin projects with Research Safety Committee (RSC-EHS Project Registration Form) and obtain IBC approval before the work can begin. Simultaneously submit the SA-Ext form to the RO & ARO.
2. Develop a written SOP detailing the specific safety precautions and exposure response procedures for the toxin being used. An SOP template **(Appendix 5.2)** for safe work with toxins is available on the EH&S website and this template includes a section to document

training. A sample SOP specific for Diphtheria Toxin is also available to demonstrate the type of information that should be included.

3. Ensure the safety and exposure response SOP is available to staff at all times.
4. Provide and document training to personnel directly working with toxins, and any personnel authorized or required to be in the laboratory when this work is being conducted. A sample form is included in the template SOP referenced above.
5. Two or more toxin-trained individuals should be present in the laboratory during high-risk procedures (e.g., making up solutions from powdered stocks).
6. Designate a toxin storage area in a secure location.
7. Designate a laboratory, work space, and primary containment devices for toxin work. The laboratory facilities required might vary based on the level of hazard posed by the specific toxin and the procedures being performed.
8. Limit work with toxins to designated rooms and work areas that operate under negative pressure to adjoining spaces, rooms, and public corridors.
9. If possible, do not work with toxins in solid or powder form. If it is necessary to purchase toxins in powder or solid form, purchase pre-weighed vials with the minimum quantity necessary to perform work. Special precautions may be needed if working with powder or solid toxin.
10. Determine the appropriate chemical and/or physical inactivation method(s) for the specific toxin (refer to toxin inactivation Table 5.2). Ensure equipment/reagents needed for inactivation of toxin are available.
11. Ensure supplies for spill cleanup are appropriate for the specific toxin, maintained in a clearly marked spill cleanup kit, and readily available in the laboratory.

5.5 ENGINEERING CONTROLS

1. Designate a certified BSC, fume hood, glove box, or other approved containment. Do not use a laminar flow hood or cabinet for toxin work. Consider the properties of the specific toxin and procedures when selecting a containment device.
2. In-line HEPA filters are required if vacuum lines are used with toxins.
3. If centrifuging materials containing toxins, centrifuge safety cups or sealed rotors must be used and the outside surfaces routinely decontaminated. Open the sealed cups or rotors inside containment.

5.6 PERSONAL PROTECTIVE EQUIPMENT (PPE)

All personnel working with (or near) toxins are expected to wear PPE as appropriate, based on an assessment of the exposure risks associated with the toxin, the procedures, or location of use, etc. For example, work with materials or procedures that may generate aerosols may require the use of a face shield and respirator. Respirator use requires enrollment in UAB Employee

Health Respiratory Protection Program. Contact UAB Employee Health representatives at (205) 996-7817 for information.

At a minimum, personnel working with toxins are expected to wear:

1. Disposable gloves that are impervious to the toxin as well as the diluent. Double gloving is recommended. Change gloves immediately if contaminated, torn, or punctured and dispose of them immediately after removal.
2. A laboratory coat with long sleeves, smock, apron, or coveralls (Consider using disposable PPE).
3. Shoes that fully cover the feet.

Any additional PPE required shall be specified in the laboratory's toxin-specific SOPs.

5.7 TOXIN USE AND PRACTICES (RECONSTITUTION, DILUTION, ADMINISTRATION)

1. Post sign on room door when toxins are in use stating, "Toxins in Use - Authorized Personnel Only."
2. Biosafety Level 2 (BSL-2/ABSL-2) practices are appropriate for most toxin work. However, some toxins or procedures may require BSL-3/ABSL-3 facilities or practices (e.g., aerosolization studies, or use of non-exempt quantities of Select Toxins).
3. Work with toxins in a BSC, fume hood, etc. over plastic-backed absorbent pads. After completion of tasks, neutralize or dispose of pads in waste streams effective for the toxin used (see Table 5.2).
4. Transport toxins only in labeled, leak/spill-proof, non-breakable secondary containers.
5. Utilize safe sharps procedures (i.e. sharps container in the immediate vicinity). Needle locking syringes or disposable syringe needle units are recommended and should be properly disposed of promptly after use.
6. Restrain or anesthetize the animals prior to administration, when possible.
7. Decontaminate containers before they are removed from the fume hood, BSC, or glove box. Also decontaminate the exterior of the closed primary container and place it in a clean secondary container.
8. Decontaminate the BSC or approved containment and all surfaces used upon completion of tasks with appropriate inactivating agent and contact time.
9. All potentially contaminated disposable items (such as gloves used in preparation) must be placed in a hazardous waste bag and autoclaved or incinerated, depending on the toxin used (see Table 5.2).
10. Wash hands upon completion of tasks.

5.8 TOXIN SPILL CLEANUP

Toxin spills must be cleaned up immediately by properly protected and trained personnel. For questions on spill cleanup, contact EH&S at biosafety@uab.edu or (205) 917-4766 or call UAB Police at (205) 934-3535 for emergency assistance.

5.8.1 Liquid Spills

1. The required PPE for cleaning up liquid toxin spills includes a lab coat or smock, goggles, and two pairs of nitrile gloves.
2. Refer to Table 5.2 to determine the appropriate inactivation method and waste stream for the toxin and any potentially contaminated surfaces or materials.
3. For chemical inactivation, cover the spill with absorbent paper towels and inactivate by applying the appropriate chemical agent, starting at the perimeter and working toward the center. Allow the prescribed contact time before clean up. Return to the spill site and clean the area with more of the inactivating agent, allowing prescribed contact time, then soap and water. The inactivated spill waste can be double bagged and disposed of in accordance with the toxin-specific SOP.
4. For physical inactivation use absorbent paper towels to wipe up liquid. Place waste in hazardous waste plastic bag and autoclave/incinerate, as appropriate. If chemical inactivation is possible, return to the spill site and clean the spill area with inactivating agent, allowing prescribed contact time, then soap and water. Inactivated spill waste is disposed of in accordance with the toxin-specific SOP. If chemical inactivation is not possible, clean the spill site with soap and water, and autoclave/incinerate all waste, as appropriate.

5.8.2 Powder Spills inside a BSC or containment

1. The required PPE for cleaning up contained spills includes a lab coat or smock, goggles, and two pairs of nitrile gloves.
2. Refer to Table 5.2 to determine the appropriate inactivation method and waste stream for the toxin and any potentially contaminated surfaces or materials.
3. Gently cover powder spill with dampened absorbent paper towels to avoid raising dust.
4. For toxins amenable to chemical inactivation, apply the appropriate chemical inactivating agent, starting at the perimeter and working toward the center. Allow the prescribed contact time before cleanup. Return and clean the spill area with inactivating agent, allowing prescribed contact time, then soap and water. Inactivated spill waste is disposed of in accordance with the toxin-specific SOP. Waste not amenable to chemical inactivation should be physically inactivated.
5. For physical inactivation, use dampened paper towels to wipe up the powder spill. Place waste in hazardous waste plastic bag and autoclave/incinerate, as appropriate, according to the toxin-specific SOP. Return and clean the spill area with inactivating agent, allowing prescribed contact time, then soap and water. The inactivated spill waste can be double bagged and disposed of in accordance with the toxin-specific SOP. If chemical inactivation

is not possible, clean the spill site with soap and water, and autoclave/incinerate all waste, as appropriate.

5.8.3 Powder spills outside of primary containment

Includes a BSC, fume hood, glove box or other containment

1. Remove all personnel from the laboratory, exit, and restrict access; do not attempt to clean up the spill.
2. Immediately call EH&S at (205) 917-4766 or UAB Police at (205) 934-3535 for emergency assistance.
3. Be prepared to provide the following information:
   - Name and phone number of a knowledgeable person that can be contacted
   - Name of the toxin, concentration, amount spilled, and liquid or solid type spill
   - Number of injured, if any (refer to Section VII Acute Exposure)
   - Location of spill

This information can also be used in reporting to the Emergency Department (ED) after a potential exposure.

5.9 EXPOSURE RESPONSE PLANS

In the event of an exposure, follow your Laboratory's Toxin-specific Exposure Response Plan. The steps described below for are broadly applicable to biological toxin exposures:

1. Provide First Aid Immediately
   - Sharps injury (needlestick and subcutaneous exposure): Scrub exposed area thoroughly for 15 minutes using warm water and soap
   - Skin exposure: Use the nearest sink (localized exposure) or safety shower (gross exposure) for 15 minutes. If using a sink, continue rinsing for 15 minutes. If using a shower, continue for 15 minutes, while removing clothing. Use a clean lab coat or spare clothing for cover-up.
   - Eye exposure: Use the eye wash for 15 minutes while holding eyelids open.
   - Inhalation: Move to an area physically separated from the contaminated space
2. Get Help
   - Report the hazard and exposure to other personnel in the area and seek medical help immediately.
   - Call 911 from any campus phone, or (205) 934-3535 from a mobile phone, and go to the UAB Emergency Department (ED) located at 1802 6th Avenue South, Birmingham, AL 35233
   - Provide details of the exposure (i.e., agent, dose, route of exposure, time since exposure). Bring the SDS and SOP for the specific biotoxin to the ED.
   - Notify your supervisor as soon as possible for assistance.

- Ensure the area is secure before leaving.

3. Report the Incident
   - All incidents should be reported to Human Resources by following instructions on the On-The-Job-Injury/Illness Program website.
   - After acute response/reporting requirements are addressed, report the incident to biosafety at biosafety@uab.edu.

Please refer to Appendix 4.3 for UAB Exposure Response Flowchart

5.10 INACTIVATION AND DISPOSAL

According to the CDC, inactivation of a biotoxin means to render the toxin non-functional so that it is no longer capable of exerting its toxic effect. This is different from inactivation of biological agents, which renders the agent non-viable, or no longer capable of growing, replicating, infecting, or causing disease. Inactivation methods used for biotoxins must be specific for the toxin, published and validated, or developed and validated with thorough testing. Note that disinfection solutions and products may not inactivate biotoxins.

1. Inactivate any waste toxin chemically or physically (usually autoclaving) before disposal.
2. Place used PPE, disposables, or spill cleanup debris in a hazardous waste bag. Autoclave if toxin is suspectable; otherwise, dispose via Stericycle for incineration.
3. For mixed waste (i.e. toxin waste mixed with radioactive waste) consult Biosafety at biosafety@uab.edu for disposal instructions.
4. Refer to the information in Table 5.2 on inactivation of selected toxins, which was adapted from the publication Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition. Centers for Disease Control and Prevention. Appendix I: Guidelines for Work with Toxins of Biological Origin.
5. If using bleach, prepare fresh solutions daily for inactivation of biotoxins and decontamination of surfaces. Undiluted, commercially available bleach solutions typically contain –~5% (w/v) NaOCl (sodium hypochlorite).
6. Since Diphtheria Toxin is not included in the BMBL tables, a review was made of inactivation methods for Diphtheria Toxin at various research institutions. The most common physical inactivation method was steam autoclaving at 121°C for 60 minutes. Although no consensus was apparent for a specific chemical inactivation agent and concentration, the commonly used chemicals included 1% NaOCl, 10% bleach, 1N NaOH, and combinations of NaOCl and NaOH. A 30-minute contact time was allowed to complete inactivation.
7. Toxins inactivated by autoclave are disposed of as medical waste through Stericycle. Chemically Inactivate liquid and powder stocks of toxin, as described in table 5.2, and dispose inactive, non-hazardous solutions down sanitary sewer. Decontaminate and deface stock vials prior to disposal. Dispose of all potentially contaminated solid waste through Stericycle

as incineration waste (labeled as “Incinerate Only”; This require a yellow Stericycle QR code stciker).

8. Toxins should not be sent to the Support Facility for disposal unless they’ve been made inactive and are part of chemical waste listed on a manifest.
9. The UAB BARB Core offers a number of lab close-out services, which includes toxin inactivation and disposal for the toxins listed in Table 5.2.
10. In-lab inactivation may not be possible or practical for all toxins. In this case, consult with UAB by email biosafety@uab.edu.

Tables 5.2 was adapted from the BMBL 6th Ed guidelines for work with toxins of biological origin (Appendix I, Tables 1 & 2) and is intended for use as a starting point for SOP development. The PI is responsible for ensuring the methods chosen are appropriate for the toxin used.

Table 5.2. Inactivation of Biological Toxins

TOXIN	AUTOCLAVE 1hr @ 121°C	NaOCl (30 min)	NaOCl + NaOH or NaOH only (30 min)
Abrin [1]	Yes	≥0.7% [a]	ND
Alpha Conotoxin [2, 3]	ND	≥0.5%	10 N NaOH
Anthrax Lethal Toxin (PA, LE) [1]	Yes	≥0.5%	ND
Botulinum neurotoxin A-G [1]	Yes [b]	≥0.1%	ND
Brevetoxin (PbTx-2) [2,]	No[d]	≥2.5% [c, e]	0.25%+0.25 N [c, e]
Cholera toxin [1]	Yes	0.5%	ND
Clostridium perfringens epsilon toxin [1]	Yes	0.5%	ND
Conotoxin [2]	ND [d]	0.5%	ND
Diacetoxyscirpenol (DAS), Deoxinalenol (DON), Zearalenone (ZEA) [2]	No [d]	≥2.5%	0.25%+0.25 N
Diptheria toxin [1]	Yes	0.5%	ND
Microcystin [2]	No [d]	≥0.5% [c]	0.25%+0.25 N [c]
Palytoxin [2]	No [d]	≥0.1% [c]	0.25%+0.25 N [c]
Pertussis toxin [1]	Yes	0.5%	ND
Ricin [1]	Yes	≥1.0% [c]	>0.1%+0.25 N [c]
Saxitoxin [2]	No [d]	≥0.1% [c, f]	0.25%+0.25 N [c, f]
Shigatoxin and Shiga-like ribosome inactivating proteins [1]	Yes	≥0.5%	0.25%+0.25 N

Staphylococcal Enterotoxins [1]	Yes [b]	≥0.5%	ND
T-2 mycotoxin [2]	No [d]	≥2.5% [c, e]	0.25%+0.25 N [c, e]
Tetanus toxin [1]	Yes	0.5%	ND
Tetrodotoxin [2]	No [d]	≥0.5% [c, f]	0.25%+0.25N [c, f]

❖ **Inactivation methods for specific toxins:**

1. *Autoclave liquid and powder stocks, waste, and disposable materials and dispose through Stericycle as medical waste.*
2. *Inactivate liquid and powder stocks, as described in table, and dispose the inactive, non-hazardous solutions down sanitary sewer. Decontaminate and deface stock vials prior to disposal. Dispose of all potentially contaminated solid waste through Stericycle as medical waste (labeled as "Incinerate Only").*
3. *Conotoxins can also be inactivated using reducing agents such as dithiothreitol β- mercaptoethanol or tris (2-carboxyethyl) phosphine (100 mM) at 65–100° C for 15 min.*

Specific notes:

- ***a –** Exposure of crude abrin solution and dried abrin to 0.67% NaOCl eliminate over 90% of cytotoxicity within 5 min.*
- ***b –** Steam autoclaving should be at ≥121°C for 1 h. For volumes larger than 1 liter, especially those containing Clostridium botulinum spores, autoclave at ≥121°C for 2 h to ensure that sufficient heat has penetrated to kill all spores.*
- ***c –** The minimal effective concentration of NaOCl was dependent on toxin and contact time; all LMW toxins tested were inactivated at least 99% by treatment with 2.5% NaOCl, or with a combination of 0.25% NaOCl and 0.25 N NaOH.*
- ***d –** non-burnable (non-autoclavable) waste should be chemically inactivated*
- ***e –** For T-2 mycotoxin and brevetoxin, non-burnable waste should be soaked in 2.5% NaOCl with 0.25% N NaOH for 4 h., whereas cages and bedding should be treated with 2.5% NaOCl + 0.25 N NaOH for 4 h.*
- ***f –** Exposure for 30 min to 1% NaOCl is an effective procedure for the laboratory (working solutions, equipment, animal cages, working area and pills) for the inactivation of saxitoxin or tetrodotoxin.*
- ***N**- Normality of NaOH solution.*
- ***ND –** Indicates "not determined" from available decontamination literature.*

General Notes:

- *Commercially available Bleach contains 5% NaOCl.*
- *Decontaminate work surfaces and spills with solutions appropriate for the specific toxin (Table 5.2) for 30 min.*
- *The UAB BARB Core provides toxin inactivation services listed in Table 5.2 (standard fees apply).*
- *If you have any questions about inactivation of toxins, contact Biosafety Office at biosafety@uab.edu*

5.11 ADDITIONAL RESOURCES

Contacts:

- Work with toxins of biological origin: Biosafety at biosafety@uab.edu
- Spills: UAB PD (205) 934-3535 (Emergencies) or EH&S On Call (205) 917-4766
- Waste collection and disposal information: EH&S Environmental Management Program visit https://www.uab.edu/EH&S/waste-manifests

- For mixed waste (i.e. toxin waste mixed with radioactive waste) consult with Biosafety at biosafety@uab.edu for disposal instructions.

Links and Forms

- EH&S Hazardous Waste Manifest Form
- Appendix 5.1 – Example Toxin SOP - Diphtheria Toxin
- Appendix 5.2 – Toxin SOP Template
- Appendix 5.3 – Select Toxin Exemption Checklist (SA-Ext) form

Note: Appendix 5.4 - Destruction of Select Agent Form and Appendix 5.5 - Risk Group 3 Agent Transfer Request Form are available upon request. Send email to Responsible Official (RO) at biosafety@uab.edu

References:

- Centers for Disease Control and Prevention. Section VIII-G Toxin Agents, Appendix F: Select Agents and Toxins, and Appendix I: Guidelines for Work with Toxins of Biological Origin of Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition (June 2020).

6.0 DUAL USE RESEARCH OF CONCERN AND PATHOGENS WITH ENHANCED PANDEMIC POTENTIAL

6.1 BACKGROUND

Life science research is aimed at gaining a deeper understanding of living organisms and their biological processes, which ultimately leads to the development of new treatments for diseases and advancing public health, agriculture, and environmental protection. Biological research is considered 'dual-use' in nature if the methodologies, materials, or results could be used to cause harm, either inadvertently or deliberately. Dual-use research of concern (DURC) is a subset of life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, or national security.

A pathogen with enhanced pandemic potential (PEPP) is a type of pathogen with pandemic potential (PPP) resulting from experiments that enhance a pathogen's transmissibility or virulence, or disrupt the effectiveness of pre-existing immunity, regardless of its progenitor agent, such that it may pose a significant threat to public health, the capacity of health systems to function, or national security. Wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs but may be considered PPPs because of their pandemic potential.

Funding agencies, institutions, and scientists share responsibility for overseeing DURC-PEPP research to promote responsible conduct and communication that is supported by a comprehensive system that integrates both federal and institutional oversight processes.

6.2 PURPOSE

The United States Government Policy (USG) for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) is going into effect on May 6th, 2025. The purpose is to establish a unified federal oversight framework for conducting and managing certain types of federally funded life sciences research on biological agents and toxins that may pose risks to public health, agriculture, food security, economic security, or national security.

6.3 SCOPE

Scope of The USG Policy for Oversight of DURC and PEPP applies to federally funded life sciences research involving biological agents and toxins or pandemic risks from enhanced/extinct pathogens as mentioned in Section 4.1.1 and 4.2.1 of Policy. Investigators and research institutions should review grant applications and existing research to determine whether the work falls within the scope of DURC-PEPP policy. Qualifying research must not proceed (at any stage of the funding cycle) until the proper approvals are in place.

6.4 DEFINITIONS

Dual use research: Research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for benevolent or harmful purposes.

Dual use research of concern (DURC): Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be misapplied to do harm with no, or only minor, modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

Pathogen with enhanced pandemic potential (PEPP): Type of pathogen with pandemic potential (PPP) resulting from experiments that enhance a pathogen's transmissibility or virulence, or disrupt the effectiveness of pre-existing immunity, regardless of its progenitor agent, such that it may pose a significant threat to public health, the capacity of health systems to function, or national security. Wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs but may be considered PPPs because of their pandemic potential.

Pathogen with pandemic potential (PPP): Pathogen that is likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe disease and/or mortality in humans.

Institutional review entity (IRE): Entity established by the research institution to execute the institutional oversight responsibilities ensuring that research is conducted responsibly, with appropriate safeguards to minimize risks involving PEPPs and PPPs.

Institutional Contact for Dual Use Research (ICDUR): Official designated by the research institution to serve as a subject matter expert for application of this Policy as well as the liaison (as necessary) between the Principal Investigator, the IRE and the Authorized Organizational Representative and/or funding agency on matters of qualifying research and risk mitigation.

6.5 CLASSIFICATION

United States government's framework for overseeing life sciences research that could potentially pose significant risk is classified into two categories, Category 1 for DURC and Category 2 for PEPP and PPP.

6.5.1 CATEGORY 1: To qualify as "Category 1 research," all three of the following criteria must be true: (1) it involves one or more of the biological agents and toxins listed below; and (2) it is reasonably anticipated to result, or does result, in one of the nice experimental outcomes; and (3) based on current understanding, the research institution and/or federal funding agency assesses that the research constitutes DURC.

6.5.1.1 Biological Agents: Involves any of the following biological agents or toxins within the scope of Section 4.1.1 of the Policy.

1. All Biological Select Agents and Toxins# Listed by the Federal Select Agent Program.
2. All Risk group 4* pathogens listed in Appendix B of the NIH Guidelines.

3. A subset of Risk Group 3 pathogens listed in Appendix B of the NIH Guidelines **except** the following:
   - HIV (Human Immunodeficiency Virus); HTLV (Human T-cell Lymphotropic Virus); SIV (Simian Immunodeficiency Virus); Mtb (including Mycobacterium Bovis); Clade II of MPVX viruses unless containing nucleic acids coding for clade I MPVX; virus virulence factors; Vesicular Stomatitis Virus; Coccidioides Immitis; Coccidioides Posadasii; Histoplasma Capsulatum; Histoplasma Capsulatum var. Duboisii
4. Biological agents affecting humans that have not been assigned a risk group in NIH guidelines but are recommended to be handled at Biosafety Level 3 (BSL-3) or BSL-4*, per the BMBL 6th Edition guidelines. Examples: Newly emerging pathogen or chimeric agent etc.

***Note:** Risk group-4 pathogens, or those requiring Biosafety Level-4 (BSL-4) containment are not allowed at UAB.

Category 1 oversight considers the anticipated experimental outcomes, regardless of the amount of toxin involved.

6.5.1.2 Category 1 Experimental Outcomes: Is reasonably anticipated[1] to result, or does result, in one or more of the following experimental outcomes listed in Section 4.1.2 of the Policy.

1. Increase transmissibility of a pathogen within or between host species
2. Increase the virulence of a pathogen or convey virulence to a non-pathogen
3. Increase the toxicity of a known toxin or produce a novel toxin
4. Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin
5. Alter the host range or tropism of a pathogen or toxin
6. Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods
7. Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions
8. Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of pre-existing immunity, via immunization or natural infection, against the pathogen or toxin
9. Enhance the susceptibility of a host population to a pathogen or toxin

6.5.1.3 Category 1 Risk Assessment: Is performed by principal investigator, research institute and Federal agency as mentioned in Section 4.1.3 of the Policy.

[1] *"Reasonably anticipated" means something that is likely or probable to occur, based on rational judgment and available information. This term is often used in legal or regulatory context to describe events or outcomes that can be logically foreseen or predicted with a reasonable degree of certainty, even if they are not guaranteed.*

Based on current understanding, the research can be reasonably anticipated to provide, or does provide, knowledge, information, products, or technologies that could be misapplied to do harm with no or only minor modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

6.5.2 CATEGORY 2: To qualify as "Category 2 research," the following three criteria must all be true: (1) it involves, or is reasonably anticipated to result in, a PPP; and (2) it is reasonably anticipated to result in, or does result in, one or more of the Category 2 Experimental Outcomes; and (3) based on current understanding, the research institution and/or federal funding agency assesses that the research is reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP.

6.5.2.1 Category 2 Biological Agents: Involves, or is reasonably anticipated to result in, a PPP or PEPP as mentioned in Section 4.2.1 of the Policy.

1. A PPP, or any pathogen that will be modified in such a way that is reasonably anticipated to result in development, use or transfer of a PEPP. This includes development of new PPPs from non-PPPs as well as the enhancement of existing PPPs.
2. Transfers, generation, uses, or reconstitution of an extinct or eradicated PPP, regardless of whether the extinct or eradicated pathogen will be enhanced relative to its wild-type form.

Examples:

1. *Genetic modifications to SARS-CoV that increase its virulence, transmissibility, or disrupt the effectiveness of pre-existing immunity in humans may be reasonably anticipated to result in a PEPP.*
2. *SARS CoV2, ancestral lineage would be characterized as PPP in 2020 due to lack of population immunity and treatments. But, in 2025 SARS CoV2 would not be considered a PPP because of the development of vaccines and effective medical counter measures as well as the rise of population immunity.*
3. *Ebola virus (2014-2016) is not considered as PPP in wild form based on nature and extent of spread and improved counter measures, however genetic modification to the virus, particularly enhancing transmissibility or disrupting the effectiveness of pre-existing immunity, may result in PEPP.*
4. *HPAI A(H5) and A(H7) viruses do not transmit efficiently in humans, they are not considered PPPs in their wild-type state, however genetic modification to the virus, that facilitate enhanced human-to-human transmission compared to their parental strains may result in PEPP.*
5. *Current eradicated and extinct PPPs include Variola major and minor and Influenza A virus subtypes H1N1 (1918) and H2N2 (1957-1968). Genetic modification may result in PEPP.*

*Note: Any microbial agent may fall under Category 2 Research if any of the outcomes below can be anticipated.

6.5.2.2 Category 2 Experimental Outcomes: Is reasonably anticipated to result, or does result, in one or more of the following experimental outcomes listed in Section 4.2.2 of the Policy.

1. Enhance transmissibility of the pathogen in humans
2. Enhance the virulence of the pathogen in humans
3. Enhance the immune evasion of the pathogen in humans such as by modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunization or natural infection; or
4. Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP.

6.5.2.3 Category 2 Risk Assessment: Is performed by principal investigator, research institute and Federal agency as mentioned in Section 4.2.3 of the Policy.
The research that can be reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function, or national security.

Research typically not within scope of Category 2 research. The following types of experiments are not typically within scope of Category 2 research because the outcomes or actions typically do not result in the enhancement of a pathogen's transmissibility or virulence or a disruption of the effectiveness of pre-existing immunity resulting in a PEPP.

1. *Surveillance activities, including collection of diagnostic and clinical specimens, sampling, sequencing, and basic viral characterization, in which the pathogen is not modified via genetic manipulation or laboratory adaptation to enhance transmissibility or virulence in humans.*
2. *Research on evaluating, testing, and/or producing vaccines and related biologics such as immunoglobulins and the generation of high-growth strains.*
3. *Experiments focused on evaluating and developing antivirals, including monoclonal antibodies, for treatment or prevention of disease caused by circulating human viruses.*

6.6 THE DURC PEPP REVIEW PROCESS AT UAB

The DURC-PEPP policy oversight framework at UAB involves following steps as shown in figure 6.1

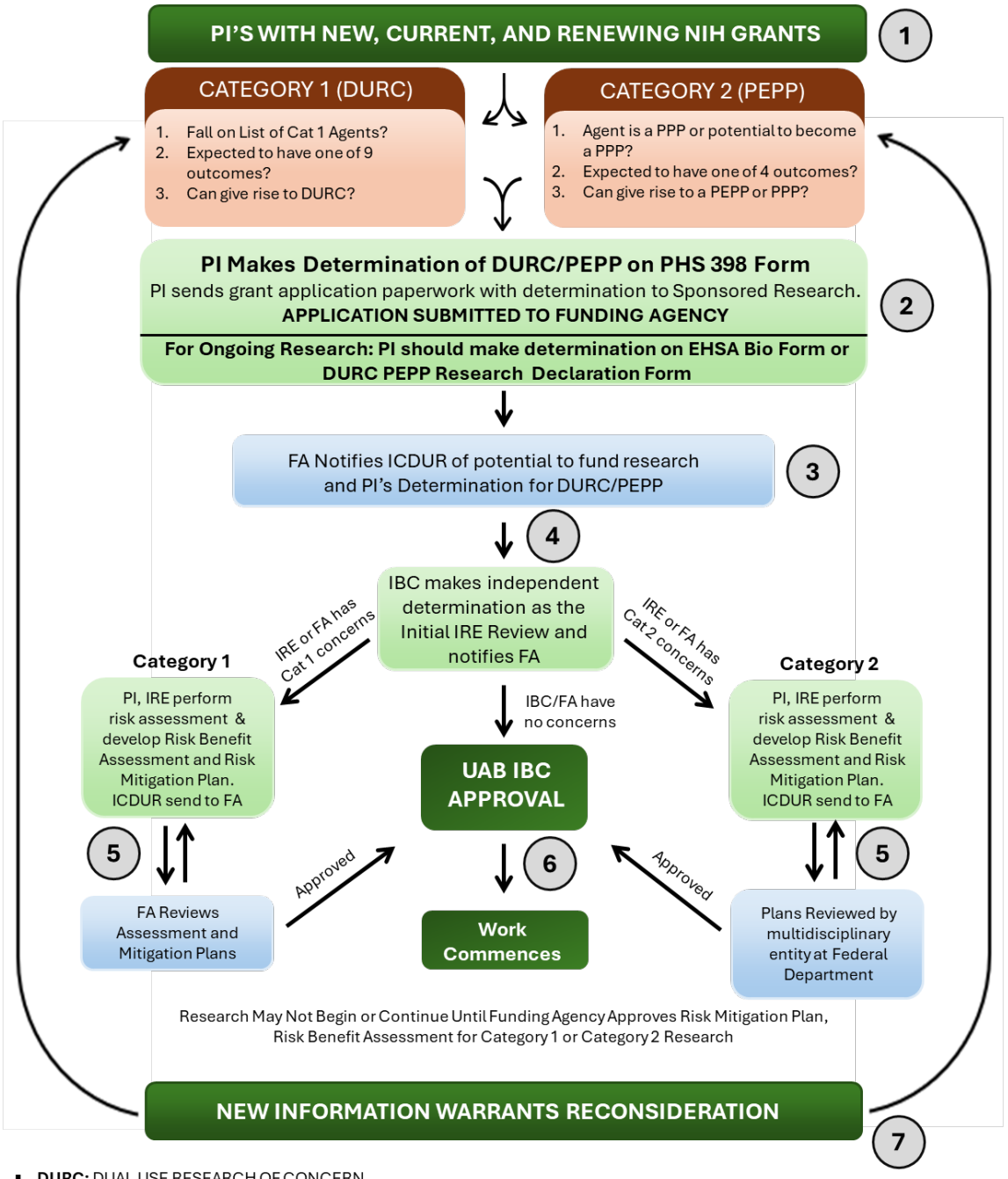


Figure 6.1. DURC-PEPP review process at UAB

1. Principal investigator (PI) makes initial assessment if their research (at proposal stage or ongoing research or renewal stage of grant application) may be within the scope of Category 1 research (DURC, as specified in Section 4.1.1, 4.1.2 and 4.1.3 of Policy) or Category 2 research (PEPP/PPP as specified in Section 4.2.1, 4.2.2 and 4.2.3 of Policy).

2. The PI designates the determination of DURC or PEPP-PPP information on the PH 398 Form (Grant Application), if their research falls under Category 1 or Category 2 based on the biological agent or toxin and the experimental outcomes. PIs should declare even if their research does not fall under these two categories on the PH 398 Form. For ongoing research PIs should make a determination on the DURC-PEPP Research Declaration Form. The PI sends the grant application with DURC-PEPP determination to Office of Sponsored Program, that the research may be within scope of Category 1 or Category 2. The Office of Sponsored Programs reviews the grant application and submit the application to funding agency (FA). The research institution is responsible for providing training and ensuring that PIs are aware of the Policy and executing their responsibilities promptly.

3. Federal funding agency review the research proposal and upon identifying potential funding eligibility, finding agency notifies the research institution through Institutional Contact for Dual Use Research (ICDUR).

4. The Institutional Biosafety Committee (IBC) reviews all research proposals involving Risk Group 2 or higher agents, regardless of whether the work involves recombinant material. This ensures the UAB IBC is operating as the Initial Institutional Review Entity (IRE) to determine if research funded through any source is within the scope of Category 1 or Category 2 research. If the IBC determines that the research meets 2 of the 3 requirements for designation as Category 1 or Category 2, then the IBC informs the IRE (Institutional Review Entity) to make a formal determination. If the IRE determines the work to fall within the scope of Category 1 or 2 research, the PI and the IRE collaboratively conduct a risk-benefit assessment and develop a risk mitigation plan. For NIH grants, these documents are submitted to the federal funding agency through the ICDUR. For all other funding sources, the IRE maintains records and internal oversight together with the ICDUR.

5. The federal agency reviews the risk mitigation plan and risk-benefit assessment as follows: *For Category 1 research*: Federal agency evaluates risk-benefit assessment and risk mitigation plan to determine whether the potential benefits justify the potential risks prior to the funding decision. *For Category 2 research*: Federal agency refers the proposed research for department-level review. Department convenes a multidisciplinary review entity to evaluate the research institution's risk-benefit assessments and risk mitigation plan. The multidisciplinary review entity will make recommendations to the federal funding agency

regarding the risk-benefit assessments, risk mitigation plan, prior to the federal funding agency making a funding decision on the research proposal.

6. Upon federal agency funding approval and IBC authorization, research commences at UAB. It is the responsibility of PI and research institute to make sure research is conducted as mentioned in the approved risk-benefit assessments and risk mitigation plan.

7. If new information emerges during experimentation that alters risk profiles, the PI must stop the ongoing research and report it to research institute and funding agency through ICDUR using the DURC-PEPP Declaration Form. The PI should contact biosafety@uab.edu to reach the ICDUR for consultations on the required assessments as mentioned in the Policy and Implementation Guidance. It is the responsibility of PIs and research institution to comply with the regulation as mentioned in Policy.

6.7 RESPONSIBILITIES

6.7.1 Principal Investigators (PIs):

1. Should be knowledgeable about and comply with all applicable institutional and U.S. government policies, requirements, and regulations for oversight of biological agent and toxin research.
2. Responsible for evaluating their research proposals and ongoing work to identify if it falls within Category 1 or Category 2 as defined by specific criteria. This assessment should be continuous throughout the research lifecycle to ensure proper categorization and oversight.
3. Following identification of potential Category 1 or Category 2 research, PI must contact biosafety@uab.edu.
4. Must work with the IRE to assess risks and benefits and submit the risk benefit assessment and draft risk mitigation plan for Category 1 and Category 2 research to the federal funding agency for review and approval. This includes submitting assessments and plans for new proposals, existing funded research, or when research is identified as Category 1 or 2 during experimentation.
5. Conduct Category 1 and Category 2 research in accordance with the provisions identified in the risk mitigation plan approved by the federal funding agency.
6. Provide annual progress reports for Category 1 research and semiannual progress reports for Category 2 research, and as requested by the federal funding agency for review, evaluation, assessment, and, where necessary, clarification or confirmation.
7. Ensure that all the laboratory personnel conducting life sciences research within the scope of this Policy have received and maintain education and training on all research oversight policies and processes and demonstrated competency.
8. Must communicate Category 1 and Category 2 research findings responsibly throughout the research process, not just at publication. It is PIs duty to communicate in responsible manner,

and follows any measures outlined in the risk mitigation plan approved by the federal funding agency.

6.7.2 Research Institutions

1. Establish policies for Category 1 and 2 research oversight and ensure that research is identified through PI and IRE review.
2. Establish an IRE with at least 5 members with existing IBC committee, or external committee having appropriate expertise.
3. Certify at the time of seeking funding that their research institution fully follows the research oversight framework under this Policy.
4. Conduct institutional oversight process through IRE for potential Category 1 or 2 research. IRE assesses scope, works with PI on risk-benefit analysis and mitigation plan.
5. Ensure that internal policies establish a mechanism for the PI to refer projects to the IRE when research involving the agents that can be reasonably anticipated to produce one or more of the experimental outcomes or actions.
6. Designate an Institutional Contact for Dual Use Research (ICDUR) which serves as liaison between research institution and federal funding agency.
7. Provide education and training on research oversight for Category 1 and 2 research including ethics and/or the responsible conduct of research.
8. Maintain records of personnel training on research oversight for at least three years after completion of funded project.
9. Maintain records of IRE reviews and completed risk mitigation plans for the term of the research grant, contract, agreement plus three years after its completion.
10. Establish a mechanism to ensure that the resulting biological agent or toxin from Category 1 and Category 2 research are properly accounted for and destroyed when no longer needed.
11. Report policy violations to federal funding agencies within 30 calendar days of awareness and include mitigation measures to prevent recurrences od similar failures.
12. Assist the PIs when questions arise about whether their research may entail further review or oversight.
13. Establish an internal mechanism for PIs to appeal institutional decisions regarding research that is determined by the IRE.
14. Annually provide a formal assurance to relevant federal funding agencies that the research institution is operating consistent with this Policy.
15. Make relevant information available to local authorities on Category 1 and Category 2 research, as appropriate.

6.7.3 Federal Funding Agencies

1. As a condition of funding, require all research institutions that they fund to fully follow this Policy. One mechanism for doing so is through a term and condition of award.
2. Respond to questions from research institutions regarding the federal funding agency's oversight of research as defined in this Policy and provide guidance to research institutions regarding this Policy.
3. Review Category 1 and 2 research projects continuously, notifying institutions of determinations and approving risk assessments and mitigation plans. The agency must determine that potential benefits justify risks before allowing experiments to proceed and communicate any concerns, disagreements or proposed modifications.
4. Refer Category 1 research to a federal funding agency review entity with diverse expertise including scientific research, biosafety, biosecurity and national security, ethics, as well as other relevant areas. This entity consults with relevant agencies and reviews risk-benefit assessments alongside funding decisions.
5. Direct Category 2 research to a department-level review entity with diverse expertise including scientific research, biosafety, biosecurity, medical countermeasure (MCM) development and availability, law enforcement and national security, ethics, public health preparedness and response, biodefense, Select Agent Regulations, public health policy, as well as other relevant areas. This entity assesses potential risks and benefits, ensuring the research meets stringent scientific, ethical, and security standards.
6. Respond to reports of concerns about implementation of this Policy and work with research institutions to address such concerns.
7. Assume additional responsibilities for non-U.S. institutions unable to meet certain criteria. The agency may act as the implementing IRE or take other necessary steps to ensure adequate biosafety and biosecurity oversight.
8. Implement this Policy in accordance with the federal funding agency's relevant and applicable authorities, regulations, and statutes.
9. Aim to complete the review process for Category 1 or 2 research within 90 calendar days of risk-benefit assessments and draft risk mitigation plans.
10. To align with the scope of this new Policy, federal departments and agencies support in-person inspections or site visits to ensure adequate biosafety and biosecurity measures for funded Category 1 and 2 research. This approach will be implemented in phases, subject to appropriations and authorities.
11. As necessary, request additional information or review of individual research proposals or projects to determine whether they may fall within scope of Category 1 or Category 2 research.
12. Develop review processes for Category 1 and Category 2 research under this Policy. Final decisions on whether to fund Category 1 research will be made at a level no lower than the Senior Executive Service level by the federal funding agency. Final decisions on whether to recommend and fund Category 2 research will be made by a senior official at a level no lower than Assistant Secretary.

13. Aid in Policy implementation through various efforts such as developing risk-benefit assessment tools, funding application forms, providing education and outreach, provide guidance to research institutions on the conduct, communication of research and research finding. Regular engagement with interested communities, other federal funding agencies, scientists, research administrators, security experts, scientific journals and publication outlets, and public health officials domestically and internationally to encourage the development of harmonized policy guidance.

6.8 PLANS AND DOCUMENTS:

6.8.1 Risk Mitigation Plan

Risk mitigation plans shall provide sufficient details on the research to enable the federal funding agency to adequately assess the institutions plan for managing the risks. Risk mitigation plan should be developed by PI and IRE encompassing the following information:

1. The name and contact information for the PI(s)
2. The name and contact information for the authorized institutional official
3. The name of the ICDUR (if different from the authorized institutional official)
4. The dates and details of the reviews and assessments of the research by the UAB DURC committee
5. The dates and details of the PI's initial review or ongoing assessment of the research
6. Identification of whether the research has been identified as Category 1 or Category 2 under the federal Policy
7. Details of the risks identified by the UAB DURC committee and an explanation of the risk mitigation strategies
8. Other materials, such as proposals and progress reports related to the research that may be requested by the relevant federal agency

6.8.2. Risk Benefit Assessment

The purpose of risk-benefit assessment is to assess the potential benefits and the potential risks of the proposed research in a clear and thorough manner. Weighing the risks and benefits of Category 1 and Category 2 research can be challenging because risks and benefits are not always easily quantified in ways that are comparable.

If the research is assessed to be Category 1 or Category 2, the research institution, through an IRE, should conduct risk-benefit assessments for the conduct and communication of the research. The federal funding agency evaluates the research institution's risk-benefit assessments and determines whether the potential benefits justify the potential risks prior to the funding decision.

6.8.3 Determination Letter

This letter is generated based on the research determination provided by the PI in EHSA Biosafety form (when it becomes available) or DURC PEPP Research Declaration Form. The letter should be

provided to the funding agency at the time of research proposal (in PH 398 Form). For ongoing research PIs should make a determination on the DURC PEPP Research Declaration Form.

The letter should contain following information:

1. PH 398 Form, Letter addressing to funding agency [Name and contact information]
2. Project Title: [Project Title]
3. Principal Investigator: [PI Name]
4. Institution: [Institution Name, Contact Information]
5. [Authorized Organizational Representative [Name, Title, Contact information]
6. **PI's determination mentioning if research fall under scope of "Category 1" or "Category 2" or "non-applicable".**
7. Enclosures: [List any additional documents included, such as a detailed risk assessment or institutional review summary, if applicable].

Resources:
Templates for Research Declaration Form, Risk Mitigation Plan and Risk-Benefit Assessment are available at UAB EH&S biosafety program website.

6.9 NIH IMPLEMENTATION

The DURC-PEPP Policy requirements apply to all NIH-funded research, including grants and cooperative agreements, Research and Development (R&D) contracts, NIH intramural research projects, and other funding agreements (e.g., Other Transactions).
For competing grant and cooperative agreement applications, NIH will request applicable DURC-PEPP materials to be provided as part of Just-in-Time (JIT) materials submitted on or after May 6, 2025. DURC-PEPP materials must be submitted by the Authorized Organizational Representative (AOR).
For active grants and cooperative agreements, NIH will request applicable DURC-PEPP materials to be provided as part of any non-competing applications, including Research Performance Progress Reports (RPPRs), due on or after May 6, 2025. Non-competing applications that include DURC-PEPP materials must be submitted by an AOR.

6.10 UAB CONTACT INFORMATION

Brian LaGory (ICDUR)
Biosafety Officer, Responsible Official
blagory@uab.edu

Biosafety Office
biosafety@uab.edu

FREQUENTLY ASKED QUESTIONS

Frequently Asked Questions, HHS Administration for Strategic Preparedness and Response (ASPR). DURC and PEPP FAQ

REFERENCES:

1. United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.
   USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf

2. IMPLEMENTATION GUIDANCE for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential
   USG-DURC-PEPP-Implementation-Guidance.pdf

3. NIH Implementation of the U.S. Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP).
   NOT-OD-25-061: NIH Implementation of the U.S. Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)

4. National Institutes of Health Special Research Considerations. Dual-Use Research.
   https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research

5. The Federal Select Agent Program, Select Agents and Toxins List Select Agents and Toxins

6. NIH Guidelines For Research Involving Recombinant Or Synthetic Nucleic Acid Molecules (NIH Guidelines) April 2024 Appendix B of the NIH Guidelines

7. Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition | CDC Laboratories

7.0 UAB GUIDANCE FOR PRION RESEARCH

7.1 BIOCONTAINMENT FOR PRIONS

6.1.1 Introduction

Prion diseases are degenerative disorders of the nervous system caused by abnormally shaped proteins, called "prions." The biochemical feature of prion diseases is the conversion of normal prion proteins, designated "PrP" to an abnormal, misfolded, pathogenic isoform, designated "PrP^{Sc}." Prion diseases or Transmissible spongiform encephalopathies (TSE) are neurodegenerative diseases that affect humans and a variety of domestic and wild animal mammal species. The most common human prion disease is sporadic Creutzfeldt-Jakob disease (sCJD). Prion diseases are transmissible by inoculation or ingestion of infected tissues or homogenates, and infectivity is present at high levels in brain or other central nervous system tissues, and at slightly lower levels in lymphoid tissues including spleen, lymph nodes, gut, bone marrow, and blood. There is no evidence of contact or aerosol transmission of prions from one human to another. Please refer to 6th Edition of BMBL for more information about prions.

6.1.2 Permits

USDA and CDC permits are required to import or export of prions or prion infected tissues capable of transmitting infection to human. Additionally, anyone involved in shipping prion related materials requires specific training. Contact the UAB Biosafety Officer (biosafety@uab.edu) for further information on shipping or permitting.

6.1.3 Containment Recommendations

In the laboratory setting, prions from human tissue and human prions propagated in animals should be manipulated at BSL-2 or higher depending on the type of work. BSE (bovine spongiform encephalopathy) prions can likewise be manipulated at BSL-2; however, due to the high probability that BSE prions have been transmitted to humans, certain circumstances may require the use of BSL-3 facilities. BSL-2 containment is appropriate for other animal-specific prions. Importantly, when a prion from one species is inoculated into another the resultant infected animal should be treated according to the guidelines applying to the source of the inoculum. Work with prions should always be conducted inside dedicated annually certified biosafety cabinets with proper signage on it. At UAB, prion projects require pre-approval from the IBC prior to initiation of the work. The IBC and Biosafety specify the containment criteria required, based on a risk assessment.

Due to their unique properties and resistance to traditional sterilization methods, it is crucial to handle prion-containing materials with utmost care to minimize the risk of exposure. Investigators planning to work with prions are required to communicate with the Biosafety Officer to perform Biological Risk Assessment and identify containment requirements such as PLACE, PROCEDURE, PPE, PERSONNEL TRAINING and PERIODIC REVIEW.

6.1.4 PPE requirements

Prions are unconventional infectious agents and their mode of transmission is distinct from traditional pathogens like bacteria or viruses. The exact PPE requirements would depend on the specific prions, procedures being conducted with prions, and the containment level of the laboratory. General PPE requirements are lab coats/Tyvek Suit, face shield, gloves, hair cap, dedicated lab shoes and shoe covers.

When working with highly pathogenic prions in a BSL-3 laboratory, personnel should adhere to stringent personal protective equipment (PPE) guidelines. This may include:

- Disposable full-body suits or coveralls to prevent skin exposure.
- Double gloves for added protection against potential contamination.
- Shoe covers to prevent tracking contaminants out of the laboratory.
- Respiratory protection, such as a fitted respirator (e.g., N95 or higher) to prevent inhalation exposure.

6.1.5 Precautions while handling prions

Investigators are required to follow precautions mentioned below while working with prions:

- Dedicated laboratory equipment must be used , i.e., equipment not shared with other laboratories..
- Must use disposable plastic ware, which can be treated and discarded as dry waste.
- Must conduct all prion manipulations such as handling, sonication, homogenizationinside annually certified biological safety cabinets.
- Great care must be exercised to avoid aerosol production, ingestion, cuts and punctures of the skin.
- All prion containing samples must be maintained within watertight containers. Primary and secondary containers must be individually labeled with the universal biohazard symbol.
- Personnel must wear appropriate PPE while handling prions or prion infected tissues.
- Access to the laboratory / animal facilities must be restricted to trained personnel only.

6.1.6 Inactivation of prions

Prions are characterized by relative resistance to conventional inactivation procedures including irradiation, boiling, dry heat, and harsh chemicals such as formalin, beta propiolactone, and alcohols. More effective treatments include enzymatic treatments with SDS, vaporized hydrogen peroxide, 4% SDS in 1% acetic acid at 65-134°C, or mildly acidic hypochlorous acid. Similarly, the use of conventional autoclaves as the sole inactivating treatment has not always resulted in complete inactivation of prions.

- Prion-contaminated work surfaces in biological safety cabinets and other work surfaces should be decontaminated with 1N NaOH or Sodium Hypochlorite (20,000 ppm available chlorine) for 1 h and rinsed with water.

- Animal tissues should be regarded as still infectious, even after prolonged exposure to 10 % buffered formalin. Histological tissue samples containing prions are substantially inactivated after exposure to 96 % Formic Acid for 1 h.

The safest and most unambiguous method for ensuring that there is no risk of residual infectivity on contaminated instruments and other materials is to discard and destroy them. UAB contracts with Stericycle for solid prion waste disposal. Treating reusable Instruments:
Current recommendations for inactivation of prions on instruments and other materials are based on the use of sodium hypochlorite, NaOH, and the moist heat of autoclaving. Combinations of chemical inactivation and heat followed by incineration are the most reliable method to destroy prions

- Contaminated Instruments should be immersed in 1 N NaOH or Sodium Hypochlorite (20,000 ppm available chlorine) for 1 hr and autoclave at 121 °C for 1 hr followed by proper rinsing in water.
- Surfaces or heat-sensitive instruments should be treated with 2 N NaOH or Sodium Hypochlorite (20,000 ppm) for 1 hour. Ensure surfaces remain wet for entire period, followed by proper rinsing in water. .

6.1.7 Waste treatment

- Solid Waste: Infectious solid prion waste should be discarded in a double biohazard bag and kept in fiberboard box US43. Biohazard bag should be securely tied to prevent any leak. Fiberboard box must be closed, securely taped and labeled on the box with an “Incinerate only” barcode. Store fiberboard box US43 at secure location and contact EH&S (biosafety@uab.edu) to schedule for stericycle pickup. If you have questions, contact biosafety team at EH&S.
- Liquid Waste: Infectious liquid waste contaminated with prions should be treated with 1 N NaOH or sodium hypochlorite (20,000 ppm available chlorine) for 1 hr followed by autoclave (gravity displacement) at 121 °C for 1 hr. After inactivation, liquid waste is manifested as chemical waste. Contact hazardous waste manifest team at chemwasteman@uab.edu for liquid waste pickup. For more information visit UAB Hazardous Waste Manifest

6.1.8 Incident Response

- For Exposures: Follow your agent-specific safety plan for acute exposure-response procedures, including flushing and decontamination.
- To seek treatment, call 205-934-3411 and ask for the ”needlestick and exposure team.”
- For spills, follow your agent-specific incident response plan. For assistance, call the EH&S on-call phone number at 205-917-4766 and ask to speak with a Biosafety Representative.
- Report all injuries and spills to biosafety@uab.edu
- For more information visit On-the-Job Injury & Illness Program

8.0 UAB GUIDANCE FOR ALPHA SYNUCLEIN RESEARCH

8.1 RECOMMENDATIONS FOR ALPHA SYNUCLEIN RESEARCH

8.1.1 Introduction:

Parkinson's Disease (PD), Dementia with Lewy Bodies (DLB), and Multiple System Atrophy (MSA) are a class of progressive neurodegenerative disorders, called synucleinopathies, that are characterized by the accumulation and aggregation of alpha-synuclein (α-syn) protein monomers in the brain and other tissues. α-syn is abundant in the presynaptic terminals of neurons and plays an essential role in regulating neurotransmitter release and synaptic function. However, α-syn monomers can also aggregate into pathological β-sheet structures, called "fibrils," which disrupt critical cellular processes, impair neuronal communication, and are manifested as loss of cognitive abilities and/or muscle control.

In experimental settings, certain forms of α-syn demonstrate prion-like properties, as they can seed and catalyze α-syn aggregation in cell culture and animal models. Although this suggests synucleinopathies may be transmissible via α-syn intermediates, this has never been demonstrated to occur naturally. Nevertheless, it highlights potential risks for α-syn research, which could involve procedures, concentrations, and forms of this protein that offer unique mechanisms for exposure. This guidance document highlights the relative risks associated with different forms or sources of α-syn, identifies processes that pose exposure risks, and provides guidance on proper containment controls to mitigate those risks.

8.1.2 Different physical forms of α-syn

1. **Monomers:** α-syn monomers are typically considered lower risk and standard BSL-1 precautions are adequate, as long as the solution is maintained under conditions that minimize the potential to fibrillize. Mutant forms (e.g., A53T, E46K) that can induce synucleinopathy phenotypes warrant extra precautions akin to fibrillized protein.
2. **Oligomers:** Intermediate forms of protein aggregation that occur during the process of fibril formation.
3. **Fibrils:** Fibrils are a specific type of aggregate with a distinct cross-β-sheet structure that pose a higher risk due to its ability to seed or induce aggregate formation in experimental models. These can be synthesized in the lab as "preformed fibrils" (PFF) or isolated from synucleinopathy subjects or animal models.
4. **Aggregates:** A broader term that encompasses various forms of α-syn assemblies, including oligomers, fibrils etc.,
5. **Tagged/Modified a-syn:** α-syn modifications (e.g., fluorescent tags, post-translational modifications, and mutations) may influence the potential for fibrilization and seeding potential.

8.1.3 Sources of α-syn

1. **Recombinant α-syn:** can be expressed and purified as recombinant protein monomers. These monomers can then be assembled or fibrillized under specific *in vitro* conditions. α-syn mutants (e.g., A53T, E46K) or variants with enhanced propensity to fibrillize may require additional precautions.

2. **Neuronal cell cultures**: Primary and continuous cultures are often used to study α-syn expression and aggregation. Once established, the aggregates can be isolated from these cultures to seed and propagate fibrillization in other cells or animal models.
3. **Transgenic animal models:** Various mouse models expressing (or overexpressing) wild-type, mutant, or human forms of α-syn are available. These animal are not inherently hazardous unless the model is expected to accumulate aggregates without the need for a seeding event.

4. α-syn monomers and fibrils can also be isolated from samples collected from normal humans and synucleinopathy subjects (CNS tissues, Blood or Cerebrospinal fluid, muscle, skin tissues etc.). While all human derived samples are assumed to be infectious and worked with using Standard Precautions, α-syn aggregates isolated from synucleinopathy subjects may require special handling precautions.

8.1.4 Biosafety recommendations:

Although protein work is typically outside of the scope of the NIH guidelines, UAB investigators must register any research that involves α-syn fibrils. Registration is achieved through the UAB IBC (projects@uab.edu) and committee approval is required before the start of work. Consults with UAB Biosafety (biosafety@uab.edu) are encouraged to ensure proper containment is in place for the scope of work proposed.

While no established biosafety guidelines exist for α-syn research in tissue culture or animal models, the UAB Biosafety Program and Institutional Biosafety Committee (IBC) will consider the following precautions to ensure personnel working with this material are protected:

1. **BSL-1 containment**: is appropriate for work with monomeric forms of α-syn monomers (unless used for fibrillization studies, this work is exempt from IBC approval requirements).

2. **BSL-2 containment is stipulated for**
   - α-syn fibrils (lab-created or isolated from patient/animal materials).
   - Samples obtained from animal models exposed to α-syn fibrils.
   - Human samples (normal and those derived from synucleinopathy subjects).
   - BSL-2+ (or BSL-2 enhanced) practices may be necessary for some higher-risk procedures

3. **ABSL-2 containment may be stipulated for animal studies.** UAB researchers are currently investigating whether fibril shedding can be detected in animal models.
   - Animals seeded with α-syn fibrils.
   - Animals exposed to any materials that induces endogenous or transgenic α-syn fibrillization.
   - Transgenic animal models of synucleinopathies.

8.1.5 Alpha-synuclein studies in animals

1. Administration of PFF, Viral Vectors, or other Seeding Material
   - All non-stereotaxis administrations should be conducted in a BSC
   - Stereotaxic Surgery:
     - Perform in isolated lab areas with limited foot traffic.
     - Use appropriate PPE (see PPE recommendations)
     - Use bench coating
     - Decontaminate surfaces upon completion (See Section 8.1.8)

2. Caging, Cage Changes, and Waste Handling for studies designated as "ABSL-2":
   - Static microisolators or ventilated caging that maintains negative pressure.
   - Cages should be labeled with Biohazard stickers.
   - The AUSI information and an "ABSL-2" sign must be posted on the door until room-level decontamination procedures have been conducted.
   - Cage changes must be carried out inside a BSC.
   - Use of sharps should be limited and safety alternatives considered.
   - All bedding and carcasses should be disposed of as medical waste
3. PPE Recommendations (refer to Table 8.1).
4. Training: Agent-specific awareness training and/or procedure-specific training is expected for all individuals who work with (or may be exposed to) the fibrillized material

8.1.5 PPE recommendation:

Appropriate PPE should be determined based on the specific material and procedure involved while performing experiments.

Table 8.1. Appropriate PPE when handling α-syn fibrils.

Type of Containment Specified	Recommended PPE
BSL-1	laboratory coat, gloves, and safety glasses
BSL-2	laboratory coat; gloves, goggles/safety glasses
BSL-2 (work in BSC)	laboratory coat; gloves
BSL2+	laboratory coat or disposable gown; double gloves, goggles/safety glasses, N-95 respirators may be needed
ABSL-2 (work in BSC)	Disposable gown, gloves

8.1.6 Safe work practices

Tables 8.2 and 8.3 provide details for working safely with each process, including general handling, purification, fibrillization, inactivation, cleanup after experiments or spills or when solutions are no longer needed and are ready to be discarded.

Table 8.2. Work Processes and Safety

Process	Safe Work Practices
General	**DO** • Use appropriate personal protective equipment. Note: N95 respirators require enrollment in Occupational Medicine and annual fit testing. • Minimize footprint of activities involved with fibrillized material • Choose disposable supplies when possible • Consider screw-capped sample tubes; disposable bench paper. **DO NOT** • Eat or drink in an environment where α-syn fibrils are used. • Wear PPE outside the lab.
Purification	**DO** • Keep the concentration of α-syn below 1 mM. • Maintain pH> 6.5 to avoid spontaneous assembly. • Aliquot α-syn upon purification (1 to 5 mg/mL per fraction). **DO NOT** • Concentrate α-syn above 1 mM.
Fibrillization	**DO** • Use the minimal amount of α-syn needed for the experiment. • Assemble in sealed tubes. • Sonicate in closed/sealed tubes using appropriate apparatus such Vial Tweeter or cup-horn sonotrode (Tubes should be gasketed; do not use snap-cap tubes) • Open tubes in a BSC **DO NOT** • Sonicate in open containers using probe tip sonicator. This generates aerosols containing α-syn fibrils • Probe sonication is not allowed.
Animal Handling	**DO** • Lab personnel or ARP staff must be trained on the hazards, wear appropriate PPE, and use a BSC for cage changes and animal handling. • AUSI posted on the door. ABSL-2 posted outside the room used for housing. • Room level decon is needed to drop the containment from ABSL-2 toABSL-1 **DO NOT** • Open cages outside of BSC.

Storage	**DO** • Keep fibrils in closed tubes and dissociate with 1% SDS and 2% Hellmanex, discard in biohazard container immediately after use. • Keep α-syn fibrils in solution. **DO NOT** • Dry the fibrils on any surfaces, as this renders them more resistant to detergent solubilization / inactivation.

8.1.7 Inactivation of α-syn:

A solution of 1% Sodium Dodecyl Sulfate (SDS) (W/V) in water (MilliQ) has been determined to be the best solution for inactivation of α-syn in solution and for the removal and disassembly of α-syn from laboratory surfaces. Other commercially available detergent such as 2% Hellmanex is more effective than SDS but had corrosive properties on some surfaces. (see Bousset, *et al*.,).

Note:

- *Use 10% SDS to prepare working stock solutions. The final working concentration should account for dilution when used for decontamination of liquids. This 10% stock is table for 6 months at room temperature.*
- *Do not use Sodium Hydroxide (NaOH) or Sodium Hypochlorite (NaOCl) because they do not dissociate fibrils.*
- *Inactivation/washing solution (1% SDS, 2% Hellmanex II,): for inactivation of α-syn and washing instruments/supplies, use gentle agitation (e.g., 50 rpm on magnetic stirrer) for 1 hour at room temperature. This is followed by a rinse in glass beaker containing MilliQ water under same agitation conditions. All the operations should be performed in dark and allow to dry overnight at 37°C in the dark. (Bousset et al.,)*

Table 8.3. Inactivation, Waste disposal and Cleanup

Procedure	Recommendation
α-syn fibril in solution	• Dilute the solution 10-fold in inactivation solution • Incubate 1h at room temperature • Autoclave at 121 °C (gravity) for 1 hr
α-syn fibril contaminated reusable supplies	• Immerse completely in 1% SDS inactivation solution • Incubate 1h at room temperature under gentle shaking • Rinse with water • Autoclave at 121 °C (gravity) for 1 hr
α-syn fibril contaminated surfaces	• wipe the dirty equipment and bench surfaces with 1% SDS inactivation solution. • Discard tissues in solid biohazard waste

Other recommendations:

Note: Formaldehyde fixation does not inactivate α-syn. Do not dry the fibrils on any surfaces as this render them more resistant to detergents solubilization and inactivation.

8.1.8 Waste handling: Waste disposal and decontamination SOPs should be in place before the start of work

1. *Solid Waste:*
   - Infectious solid waste contaminated with α-syn should be placed in a double biohazard bag and disposed of as medical waste for incineration.

2. *Liquid Waste:*
   - Since components within solutions vary, please consult with biosafety on how to best inactivate and dispose of your liquid solutions.

3. *Animal carcasses:*
   - Animals that have been administered viral vectors expressing a-syn and/or a-syn fibril proteins must be disposed of as medical waste through our vendor.

If you have questions, contact biosafety (biosafety@uab.edu) at EH&S.

8.1.9 Incident response

- For Exposures: Follow your agent-specific safety plan for acute exposure-response procedures, including flushing and decontamination.
- To seek treatment, call 205-934-3411 and ask for the "needlestick and exposure team."
- For spills, follow your agent-specific incident response plan. For assistance, call the EH&S on call phone number at 205-917-4766 and ask to speak with a Biosafety Representative.
- Report all injuries and spills to biosafety@uab.edu.
- For more information visit On-the-Job Injury & Illness Program

References

- Bousset, L., Brundin, P., Böckmann, A., Meier, B. & Melki, R. An Efficient Procedure for Removal and Inactivation of Alpha-Synuclein Assemblies from Laboratory Materials. *J Parkinsons Dis.* **6**, 143–151 (2016).
- Section IV—Laboratory Biosafety Level Criteria. Biosafety in Microbiological and Biomedical Laboratories 6th Edition , pp 32-59. 2009. Centers for Disease Control and Prevention and the National Institutes of Health.
- Polinski NK, Volpicelli-Daley LA, Sortwell CE, et al. Best Practices for Generating and Using Alpha-Synuclein Pre-Formed Fibrils to Model Parkinson's Disease in Rodents. *J Parkinsons Dis*. 2018;8(2):303–322.
- Stanford University. Requirements for Research with Prions and Prion-Like Proteins. Retrieved September 5, 2019 from https://ehs.stanford.edu/manual/biosafety-manual/requirements-research-prions-and-prion-proteins
- UAB Institutional Animal Care and Use Committee. Animal Carcass and Waste Disposal. January 25, 2023. https://www.UAB.edu/research/home/policies-and-guidelines/animal-disposition.

9.0 BIOHAZARD DISPOSAL, DECONTAMINATION, AND DISINFECTION

9.1 MEDICAL WASTE MANAGEMENT FOR RESEARCH LABORATORIES

Regulatory Oversight

Medical waste (including biomedical and biohazardous waste) is regulated by the Alabama Department of Environment Management (ADEM) in accordance with Environmental Protection Agency regulations. Additional regulations by the United States Department of Transportation (US DOT) apply when regulated medical waste is transported on public roadways. UAB policies regarding medical waste management are designed to satisfy all applicable regulatory requirements. At UAB, medical waste is managed from the point of origin to its ultimate disposal. This means that anyone at UAB whose activities involve generation or contact with medical waste must be familiar and compliant with these policies. UAB EH&S has provided a training course Medical Waste Management for Labs through the UAB Campus Learning System to address medical waste management in research laboratories. This is a required course for anyone generating, packaging, storing, loading, unloading, or handling hazardous materials (regulated medical waste), prepares hazardous materials for transportation, and signing Stericycle medical waste manifests and must be completed every 3 years, or if regulations change.

"Medical Waste" shall be interpreted to be solid waste(s) which, because of its infectious characteristics, may pose a substantial hazard or potential hazard to human health or the environment when improperly treated, stored, transported, disposed, or otherwise managed.

***IMPORTANT: This does not include material contaminated with "Category A" infectious agents, which are capable of causing permanent disability or life-threatening or fatal disease to otherwise healthy humans or animals after exposure. Category A waste cannot be disposed of as "regulated medical waste" until chemically or physically inactivated. Autoclaves used for inactivating Category A material must be validated (after every 40 hrs. used for inactivation purposes) and validation records must be maintained. Inactivated Category A material can then be disposed of as "medical waste." Carcasses of research animals productively infected with Category A agents must be autoclaved before packaging as medical waste. This requires investigators and staff to actively segregate and package these animal carcasses for transport and disposal as hazardous waste, which differs from waste streams typically handled by Stericycle. Email biosafety@uab.edu for more information.

Materials considered medical waste, per the Alabama Department of Environmental Management Land Division 335-17 Medical Waste Program (ADEM), 49 CFR 173.134 Hazardous Materials Regulations and UAB policy:

- Animal Waste: Carcasses and body parts, regulated bulk blood and body fluids, surgical waste, and bedding from animals exposed to human infectious agents as a result of the animal(s) being in contact with biologicals and pharmaceuticals in testing, production and research.
    - Note: At UAB all animal carcasses and body parts (other than those infected with Category A materials) shall be treated as medical waste and returned to the area designated by the Animal Resources Program (ARP) for disposal by UAB or its contractors.
- Blood and Body Fluids: All human bulk blood, bulk blood components (serum and plasma) and bulk specimens of blood, tissue, semen, vaginal secretions, cerebrospinal fluid, synovial

fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid from patient treatment areas, clinical and research laboratories.

  - ADEM has interpreted bulk blood to mean a volume of blood that is fluid to the point of leaking but does not include materials that are stained or tainted with blood. Accordingly, ADEM uses the example of plastic tubing that contains enough blood that can flow out of the tubing would be sufficient quantity to be considered "bulk blood". Tubing that has a residue or stain of blood, but not fluid, would not be considered medical waste.

- Microbiological Waste: Discarded cultures and stocks of non-Category A infectious agents and associated microbiologicals; human and animal cell cultures from medical and pathological laboratories; waste from production of biologicals; discarded live and attenuated vaccines; culture dishes and devices used to transfer, inoculate, and mix cultures.
- Pathological Waste: All discarded human tissues, organs and body parts which are removed during surgery, obstetrical procedures, autopsy, laboratory, embalming, or other medical procedures, or traumatic amputation.
- Renal Dialysis Waste: All liquid waste from renal dialysis contaminated with peritoneal fluid or with human blood visible to the human eye. Solid renal waste is considered medical waste if it is saturated, having the potential to drip or splash regulated blood or body fluids.
- Sharps: Any used or unused discarded article that is capable of cutting or penetrating the skin or can cut or puncture packaging material during transportation and has been or is intended for use in animal or human medical care, medical research or in laboratories using microorganisms. (Ex: hypodermic needles, IV tubing with needles attached, scalpel blades and syringes with or without needles attached). Glassware, glass blood vials, glass pipettes, and similar items that are contaminated with blood, body fluids, or microorganisms are to be handled as sharps.

Stericycle

Stericycle Inc. has been contracted by UAB to provide collection, treatment, and disposal of regulated medical waste, daily. Stericycle autoclaves solid medical waste generated in hospitals, clinics, and research labs. Waste is then rendered unrecognizable before disposal in a landfill. Stericycle incinerates pathological waste, animal carcasses, animal bedding, and trace chemotherapy waste. If you have further questions, please review Stericycle's regulated medical waste acceptance policy. ONLY PERSONNEL WHO ARE CURRENT WITH BIO301L MEDICAL WASTE MANAGEMENT TRAINING MAY SIGN THE STERICYCLE MANIFEST AT TIME OF WASTE PICKUP. In order to maintain compliance, laboratory personnel must present their UAB One Card and BlazerID to the Stericycle representative before signing the waste manifest. This is verified and tracked by both UAB Biosafety and Stericycle. Another option is to fill out a presigned manifest, place it on the TB01 and email a copy to medwaste@uab.edu.

Stericycle Transfer Facility (ADEM Permit TRN102391-GA02)
1485 Hartman Industrial Blvd
Midfield, AL 35228

Segregation of Medical Waste

Medical waste is separated from non-hazardous waste and other hazardous waste streams (e.g., radioactive particles or chemicals) at the point of generation by placement into designated and approved medical waste containers. The appropriate medical waste container to use is based on the properties of the medical waste being disposed (e.g., sharps, solid vs. liquid, autoclave vs incinerate). For proper disposal, medical waste should be correctly packaged and placed in transport containers for Stericycle pickup. These containers are available in a number of sizes and are provided by Stericycle upon request (described in Table 9.1).

- Sharps – Medical waste considered as "sharps" is segregated from other medical waste at the point of generation by disposal in approved OSHA compliant sharps disposal containers (red, puncture-resistant, closable containers with leakproof sides and bottoms).
    - Engineering controls, including but not limited to protected needle devices or safety needle systems will be evaluated and used whenever possible, in an effort to reduce the potential for needlestick injury to the user as well as those working downstream, i.e., waste handlers, environmental services, and laundry personnel.
    - Small sharps containers can be placed directly into a Stericycle medical waste transport container.
    - Large sharps containers that cannot fit into a transprot container can be picked up by Stericycle if they are rated PG II (certified as a seconday container).

- Mixed hazard waste – Medical waste that also contains other potentially hazardous agents, such as radioactive waste, chemical waste or tissue from patients with Creutzfeldt-Jakob Disease may require different treatment and/or additional packaging and labeling (e.g., tissue containing formalin residue; blood labeled with H-3 or I-125). Please contact Biosafety at biosafety@uab.edu for instructions on packaging, labeling, and disposal of these types of waste.
- Biological toxin waste – See Chapter 5 (Section 5.10, "Inactivation and Disposal")
- Liquid Media/Culture Waste – Special considerations should be taken when collecting liquid culture waste for disposal
    - HEPA in-line filters should be installed on the tubing line nearest the vacuum port to prevent accidental contamination of the vacuum system during aspiration.
    - Bleach should be added to the vacuum flask prior to culture collection. The amount of bleach needed should be calculated to achieve at least 10% bleach concentration when the flask is no more than two-thirds full. This should be the maximum amount of all liquid collected in the culture flask so as not to aspirate liquid into the vacuum line.
    - When not maintained in a certified biosafety cabinet, all culture flasks should be stored in a secondary container (plastic tupperware container or autoclave bin).
    - Culture flasks should be labeled with the appopriate biohazard warning labels.
    - Sterilized or chemically disinfected liquid culture waste can be disposed of down the drain as long as chemical disinfectant is appropriately used and is not itself restricted for

disposal in the sanitary sewer system. The sink should be rinsed thoroughly after disposal of waste.

Table 9.1. Commonly Used Stericycle Medical Waste Transport Containers

Stericycle Container	Description	Special Instructions	Treatment
BX05 	• fiberboard box • 15 gal (2 ft^3) • 12” x 12” x 22” in size	• preferred for waste requiring incineration • When full, tape lid closed and all seams with packing tape place in pickup location	Autoclaved offsite, unless marked with yellow “QR Code” sticker
TB01 	• rigid plastic leak-proof container • hinged/lockable closure • 30 gal (4 ft^3)	• cannot exceed 64 lbs total (waste + container) • reused by Stericycle, so verify integrity before use	Autoclaved offsite, unless marked with yellow “QR Code” sticker
US43 	• fiberboard box • 31 gal (4.3 ft^3) • 18” x 18” x 22” in size	• preferred for waste requiring incineration • When full, tape lid closed and all seams with packing tape • place in pickup location	Autoclaved offsite, unless marked with yellow “QR Code” sticker
TB02 	• rigid plastic leak-proof container • hinged/lockable closure • 130 gal (17.4 ft^3)	• cannot exceed 250 lbs total (waste + container) • reused by Stericycle, so verify integrity before use	Autoclaved offsite, unless marked with yellow “QR Code” sticker

Table 9.2. Guide for medical waste disposal in non-clinical laboratories using BSL1 and BSL2 biocontainment practices and procedures.

Item	Liquid or Solid Waste[g]	Preferred Method of On-site Decontamination	Primary Biohazard Waste Container	Stericycle Treatment	Transport Container
Category A materials	Solid	Autoclave[b,c]	Double bag	Autoclave	TBO1[e]
Bacterial cultures	Liquid	Chemical disinfection[b,c]	UAB sanitary sewer post disinfection[h]	N/A	N/A
Vaccines vials (live and attenuated)	Liquid	N/A	Sharps container	Autoclave	TBO1[e]
Animal carcasses	Solid	N/A	Double bag	Incinerate[d]	TBO1[e], TBO2[e] or US43 box[e]
Animal body parts	Solid	N/A	Double bag	Incinerate[d]	TBO1[e], TBO2[e] or US43 box[e]
Human body parts, organs, tissues, surgical specimens	Solid	N/A	Double bag	Incinerate[d]	TBO1[e] or US43 box[e]
Containers of blood or body fluids	Liquid	Autoclave[b,c]/Chemical disinfection	UAB sanitary sewer post disinfection[h]	N/A	N/A
Contaminated[a] sharps waste or glass blood vials	Solid	N/A	Sharps container	Autoclave	TB01[e]
Contaminated[a] solid waste	Solid	N/A	ASTM-D bag	Autoclave	TBO1[e]
Contaminated[a] plastic-ware	Solid	N/A	ASTM-D bag	Autoclave	TBO1[e]
Disposable contaminated[a] lab clothing	Solid	N/A	ASTM-D bag	Autoclave	TBO1[e]
Reusable contaminated[a] lab clothing[f]	Solid	Autoclave[b,c]	ASTM-D bag	Autoclave	Send to laundry service
Contaminated[a] disposable gloves	Solid	N/A	ASTM-D bag	Autoclave	TBO1[e]
Needles, syringes, scalpel blades	Solid	N/A	Sharps container	Autoclave	TBO1[e]
Contaminated[a] reusable glassware	Solid	Autoclave[b,c]/Chemical disinfection	Bin with lid	Autoclave	N/A
Disposable lab clothing – no contamination	Solid	N/A	N/A	N/A	N/A
Disposable plasticware – no contamination	Solid	N/A	N/A	N/A	N/A
Disposable gloves – no contamination	Solid	N/A	N/A	N/A	N/A
Medical waste containing radioactive or chemical wastes	Solid or Liquid	Consult with EH&S	Consult with EH&S		
Medical waste containing trace chemo or non-RCRA pharmaceuticals	Solid or Liquid	Consult with EH&S	ASTM-D bag	Incinerate[d]	TBO1[e] or US43[e]
Disposable plasticware – no contamination	Solid	N/A	N/A	N/A	N/A

[a]Contaminated refers to waste that contains bulk blood, microbes, infectious agents, or other biological agents.
[b]Approved or recommended by EH&S

[c]Category A waste must be autoclaved BEFORE packaging as medical waste for pickup by Stericycle. Refer to IATA Table 3.6 D for a list of other agents that must autoclaved prior to placing into a Stericycle container.
[d]Container must be labeled with yellow QR code Stericycle supplied stickers
[e]Container must be lined with an ASTM-D rated bag. If individual bags are placed in the container, they must be ASTM-D rated bags and properly closed using a secure knot.
[f]Do not take contaminated clothing home; instead contact your supervisor for proper handling and decontamination procedures.
[g]BSL-3 laboratories will follow their approved protocols for waste handling and decontamination.
[h]Ensure that the disinfectant, along with its concentration, can be safely disposed of in the sanitary sewer.

Table 9.3. Biomedical Waste Disposal Guide for BSL3 or Special Medical Waste Categories

Waste Type	On-site Decontamination Required	Primary Biohazard Waste Container	Transport Container Type
Mycobacterium tuberculosis (cultures & solid waste)	Autoclave	Red bag*	Stericycle
SARS-CoV-2 cultures	Autoclave	Red bag*	Stericycle
Select Agents**	Autoclave	Red bag*	See User Permit
HIV research lab solid waste	Autoclave	Red bag*	Stericycle
HIV research lab liquid waste	Autoclave	Sanitary Sewer	N/A
Category A Agents*** (i.e., Dengue, LCMV, Rift Valley Fever, Bacillus anthracis)	Autoclave	Red bag*	Stericycle
Other Risk Group 3 microbial agents	Autoclave	Red bag*	Stericycle
Biological toxins	See Section 11.3 or Chemical Safety Manual	See Section 11.3 or Chemical Safety Manual	Label "Incinerate Only" Stericycle
CJD waste	N/A	Red bag*	Make arrangements with EH&S
Pathological specimens in ≤ 10% formalin	Dispose of formalin in sanitary sewer	Red bag*	Label "Yellow QR code" Stericycle
Medical waste containing radioactive or chemical wastes	Consult with EH&S	Consult with EH&S	Consult with EH&S

* Container must be lined with ASTM-D bag or if individual bags are placed in the container they must also be ASTM-D rated bags and closed using a proper knot
** See list at http://www.selectagents.gov/resources/List%20of%20Select%20Agents%20and%20Toxins_111708.pdf
*** See list at http://emergency.cdc.gov/agent/agentlist-category.asp

Packaging Medical Waste for Pickup

Stericycle autoclaves solid medical waste generated in hospitals, clinics, and research labs. A large grinder renders this waste unrecognizable for disposal in landfills. Stericycle can also incinerate pathological waste, animal carcasses and bedding, and trace chemo waste. Contact Biosafety at biosafety@uab.edu if you need help with medical waste disposal solutions.

Table 9.4. Packaging medical waste for a Stericycle pickup

Packaging medical waste for a Stericycle pickup	
1. Verify you are up to date on your Medical Waste Training for Labs (BIO301L). 2. Avoid overfilling bags to ensure they can be properly closed. Twist the top of the bag, as shown.	
3. Tie the twisted bag end in a knot or fold it over and secure with packing tape or a zip tie. The bag should not leak, even if inverted for extended periods.	 
4. Place the securely closed bag into the Stericycle transport container (TB01 pictured). The outermost bag must contain the ASTM-D marking and the universal biohazard symbol and the words “medical waste,” “biological waste,” or a combination thereof. 5. Close the lockable lid on the transport container and add the Stericycle QR code and the current date. Use yellow Stericycle QR code labels for incinerate only waste.	

6. Place full transport containers in the pickup location.	
7. When a Stericycle representative arrives to pick up the waste, present your OneCard ID and sign the waste manifest.	

Medical Waste Staging Areas (Including common/shared storage rooms)

Management of shared spaces in research laboratories and in medical facilities presents challenges with respect to medical waste that is placed in these areas prior to pick up by Stericycle. To effectively manage these areas a minimum of two competent individuals will be designated as primary and secondary contacts that will be responsible for managing shared spaces where medical waste is placed prior to Stericycle pickup. These designees will be responsible for implementing basic procedures which when monitored and enforced will control medical waste contamination and waste issues that may arise in the shared spaces. UAB Biosafety has provided a training course Medical Waste Management for Labs through the UAB Campus Learning System to address medical waste management in research laboratories.

- Good housekeeping practices must be followed. That means no medical waste debris (bag pieces, sharps, PPE, bandages, etc.) and no evidence of past spillage (wet or dry) is present on floors.
- All medical waste containers must be closed unless they are in the process of being filled.
- Loose sharps are prohibited from being placed directly into plastic red bags. Sharps that are contained in a closed disposable sharps container may be placed into red bags, or the sharps container can be placed directly in the TB01 container.
- All containers must be marked with the biohazard symbol that is readily visible.
- Label full containers with Stericycle QR code label (it must have “the University of Alabama at Birmingham”, the physical address of the building generating the medical waste, and a contact phone number on the label.
- Date the container on the QR codesticker when the full container is closed.
- Storage areas should be labeled (sign posted with appropriate contact information), secured, and only accessible to authorized personnel.

Training:

Applicable US Department of Transportation (see 49 CFR 171.8) and ADEM regulations state that anyone whose job involves generating, packaging, storing, loading, unloading, or handling hazardous materials (regulated medical waste), prepares hazardous materials for transportation or signs waste shipping manifests among other things must be trained.

- Training must be completed within 90 days after employment or when assigned a task related to the activities described above. During those 90 days, the employee may perform these activities if they are under the direct supervision of a properly trained and knowledgeable employee.
- Recurrent training is required every 3 years or if regulations or practices/procedures change. Failure to take the required medical waste management training and then signing Stericycle shipping manifests may result in fines of $77,000 per occurrence from the Department of Transportation.
- Principal investigators and/or laboratory directors/managers are responsible for maintaining safety-related laboratory records. These records include Medical Waste Management training and other records as appropriate.
- Manifests for medical waste transportation must be maintained for at least 3 years. Copies will be maintained by UAB Biosafety for 3 years.

9.2 STERILIZATION AND DECONTAMINATION

Sterilization: Any item, device, or solution is sterile when it is completely free of all living microorganisms, viruses, or prions. The definition is categorical and absolute (i.e., an item is either sterile or it is not). A sterilization procedure is one that kills all microorganisms, including high numbers of bacterial endospores. At UAB, sterilization can be accomplished by heat, ethylene oxide gas, and hydrogen peroxide gas.

- Autoclaves: When used properly, autoclaves are a safe and highly effective sterilization method for waste, equipment, and other materials. Generally, autoclaves use saturated steam under pressure to achieve a chamber temperature between 121°C and 132°C for a prescribed amount of time (15 to 30 minutes at desired temperature). Sterilization time will vary in relation to the size of the load and the packing density of the chamber. Autoclaves should be monitored by mechanical, chemical, and biological indicators to validate the process.
- Dry heat is sometimes used for materials (glassware, instruments, metallic objects) that are sensitive to moisture or the corrosion it may cause. In order to achieve sterilization without steam, dry heat requires higher temperatures and a longer exposure times than steam autoclaving. This method should also be validated.
- A typical validation program for steam or dry-heat sterilization requires the correlation of temperature measurements, made with sensory devices to demonstrate heat penetration and heat distribution, with the destruction of biological indicators (preparations of specific microorganisms known to have high resistance to the particular sterilization process). Autoclave tape is not a fail-safe indicator of sterilization because it blackens after only brief exposure to a temperature of 121°C. Periodic revalidation of any sterilization method is

recommended as good laboratory practice. However, this may be a requirement if sterilization of waste is required by the IBC (determined during project review).

Disinfection: Disinfection is a procedure that reduces the level of microbial contamination by eliminating nearly all recognized pathogenic microorganisms, but not necessarily all microbial forms (e.g., bacterial spores) on inanimate objects. Disinfection does not ensure an "overkill'' and therefore lacks the margin of safety achieved by sterilization procedures. Disinfectants and their application should be carefully considered, as their effectiveness is significantly altered by several factors. These include:

- the disinfectant used
- nature and number of contaminating microorganisms (especially the presence of bacterial spores)
- the amount of organic matter present (e.g., soil, feces, and blood)
- type and condition of instruments, devices, and materials to be disinfected
- temperature
- contact time with disinfectant

Table 9.5. Disinfectant Efficacy for Various Infectious Agent Categories

Liquid Disinfectants▪ ▪See product-specific SDS for safety information and read instructions carefully before use.	Requirements for Disinfection			Inactivation Efficacy			
	Effective Dilution Range	Contact Time (minutes)		Vegetative Bacteria	Lipovirus	Nonlipid Viruses	Bacterial Spores
		Enveloped Viruses	Broad Spectrum				
Quaternary Ammonium	0.1 – 2.0%	10	Not Effective	+	+		
Chlorine	500 ppm*	10	30	+	+	+	+
Ethanol	70 – 85%	10	Not Effective	+	+	variable, virus dependent	
Formaldehyde	0.2 – 8.0%	10	30	+	+	+	+
Glutaraldehyde	2%	10	30	+	+	+	+
Iodophor	25 – 1600 ppm	10	30	+	+	+	+
Isopropanol	70 – 85%	10	Not Effective	+	+	variable, virus dependent	
Phenolic	1.0 – 5.0%	10	Not Effective	+	+	variable, virus dependent	

*Commercially available chlorine bleach is 5.25% chlorine (52,200 ppm). A dilution of 1 to 100 will yield a 522-ppm solution, which is suitable for disinfecting purposes. (+) Very positive response.

Table 9.6. Decontaminants for Infectious Waste Management

	Ethylene Oxide	Para-form-aldehyde (gas)	Quaternary Ammonium Cmpds	Phenolic Cmpds	Chlorine Cmpds	Iodophor Cmpds	Alcohol (ethyl or isopropyl)	Form-aldehyde (liquid)	Glutar-aldehyde
Use Conditions									
Concentration of active ingredient	400-800 mg/l	0.3g/ft^3	0.1-2%	0.2-3%	0.01-5%	0.47%	70-85%	4-8%	2%
Temperature, ºC	35-60	>23							
Relative humidity, %	30-60	>60							
Contact time, minutes	105-240	60-180	10-30	10-30	10-30	10-30	10-30	10-30	10-600
Effective Against ✷									
Vegetative bacteria	✚	✚	✚	✚	✚	✚	✚	✚	✚
Bacterial spores	✚	✚			◁			◁	✚
Lipo viruses	✚	✚	✚	✚	✚	✚	✚	✚	✚
Hydrophilic viruses	✚	✚		◁	✚	◁	◁	✚	✚
Tuberclbacilli	✚	✚		✚	✚	✚	✚	✚	✚
HIV	✚	✚	✚	✚	✚	✚	✚	✚	✚
HBV	✚	✚		◁	✚	◁	◁	✚	✚
Applications ✷									
Contaminated liquid discard				✚				◁	
Contaminated glassware	◁		✚	✚	✚	✚		◁	✚
Contaminated instruments	◁			✚	✚			◁	✚
Equipment total decon	◁	✚							

✷ (✚) very positive response; (◁) less positive response; blank, a negative response or not applicable.
See product-specific SDS for safety information and read instructions carefully before use.

Adapted from *Laboratory Safety, Principles and Practices*, D. Fleming, J. Richardson, J. Tulis, D. Vesley; American Society for Microbiology, 1995: 226-227.

Table 9.7. Other Important Disinfectant Properties

Disinfectants		Important Characteristics										
Type	Category	Shelf Life	Corrosive	Flammable	Residue	Inactivated by Organic Matter	Compatible for Optics*	Compatible for Electronics	Skin Irritant	Eye Irritant	Respiratory Irritant	Toxic
Liquid	Quaternary ammonium compounds	+				+	+		+	+		+
	Phenolic compounds	+	+		+				+	+		+
	Chlorine		+		+	+			+	+	+	+
	Iodophor	+	+		+	+			+	+		+
	Alcohol, ethyl	+		+						+		+
	Alcohol, isopropyl	+		+						+		+
	Formaldehyde	+			+				+	+		+
	Glutaraldehyde	+			+		+		+	+		+
Gas	Ethylene Oxide	N/A		~			+	+	+	+	+	+
	Paraformaldehyde	N/A		~	+		+	+	+	+	+	+
	Chlorine Dioxide	N/A						+		+	+	+
	Vaporized H_2O_2	N/A						+		+	+	+

See product-specific SDS for safety information and read instructions carefully before use.

~ Under specific conditions—see product SDS.

* Special considerations (compatible for optics): Usually compatible but consider interferences from residues and effects on associated materials such as mounting.

10.0 TRANSPORT AND SHIPPING OF BIOLOGICAL MATERIALS

10.1 TRANSPORT OF BIOLOGICAL MATERIALS ON CAMPUS

Transport of potentially infectious biological agents on campus, either between or within buildings requires that the person transporting has knowledge of the agent, including how to properly package it for transport, and how to respond to a potential spill or exposure. Packaging of potentially infectious samples for hand transport on campus should resemble the packaging required for shipment, unless transport is between sites within a contiguous space (see Table 10.1, below). After the sample is properly packaged, it can be transported on a cart or hand-carried to the destination. Avoid public or high-traffic walkways and never leave the package unattended during transport.

The containment level assigned to an agent is particularly important in regard to transport. Receipt or transport of agents requiring BSL3 containment can only occur with guidance and approval by EH&S Biosafety. Agents that are rendered inactive are exempt from this requirement, but the procedures used for inactivation must be validated before containment restrictions are lifted.

Table 10.1. Transport of Biological Materials Within and Around UAB: Biological materials that are transported within and between university buildings must be packaged and transported in the manner indicated

Transport Route	Containment Required	Labels Required
Within contiguous lab space	Primary[1] tubes/vials secured with a tight-fitting cap, parafilm, or lab tape	Not required
Outside contiguous space but within building	Primary and secondary[2] separated by absorbent material for liquids	Not required
Outside contiguous space but within interconnected buildings	Primary and secondary separated by absorbent material for liquids	• Agent-specific info on primary • Biohazard label on secondary
Outside of interconnected buildings	• Primary and secondary separated by absorbent material • Tertiary[3]	• Agent-specific info on primary • Biohazard label on secondary • Emergency contact info on tertiary

[1]primary container: Screw cap tube or vial that houses the biological agent
[2]secondary container: Leak-proof zip-sealed plastic bag, screw-top conical tube, or pressure-sealed plastic box containing material sufficient to absorb the volume of the sample
[3]tertiary container: a rigid outer container sufficient to maintain containment if the shipment is dropped

Transport of potentially infectious biological agents on campus by vehicle (UAB Vehicle Safety Management Program):
If biological samples cannot be transported by foot, there are several options for the use on vehicles on campus.

- Email to **biosafety@uab.edu** for more information on how to move your samples.
- **UAB Vehicles or Personal vehicles -** Individuals using a UAB or personal vehicle to move samples must abide by the *UAB Vehicle Safety Management Program* and complete *Bloodborne Pathogens and Category B/ UN 3373 IATA shipping training*.
- **DO NOT** move samples using cabs, Birmingham city buses, Lyft, Uber, Blazer shuttles, etc.
- **CATEGORIES OF INFECTIOUS MATERIALS:**
    - **Category A:** An infectious substance in a form capable of causing permanent disability or life threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. (ID number; UN 2814 for affecting humans and UN 2900 for affecting animals)
    - **Category B**: An Infectious substance not in a form generally capable of causing permanent disability or life-threatening or fatal disease in healthy humans or animals when exposure to it occurs (ID number UN 3373).
    - Genetically Modified Organism (GMO) (ID number UN 3245).
    - Exempt Human or Animal Specimens

10.2 TRANSPORT OF BIOLOGICAL MATERIALS OFF CAMPUS

State and Federal laws apply to transportation of hazardous biological materials to or from campus. If a commercial courier cannot be used, contact Biosafety at biosafety@uab.edu for help determining the proper transport method. Remember, shipping training is required for anyone who packages hazardous material for transport.

Before shipping anything internationally, please submit the UAB International Shipments – Export Control Review Form. A review will be performed in consideration of the item being shipped; its destination; its recipient; and its use abroad.
Contact, Donna Williamson (dsw@uab.edu), Executive Director, Research Safety and Security if you have any questions.

10.3 OVERVIEW OF SHIPPING REQUIREMENTS FOR BIOHAZARDOUS MATERIALS

Shipping of biohazardous materials and infectious substances (including material that could contain pathogens harmful to humans) requires specific labeling, packaging, and documentation. Infectious materials are regulated by the U.S. Department of Transportation (DOT), Hazardous Materials Title 49 Code of Federal Regulations Parts 171-180 and the International Air Transport Association Dangerous Goods Regulations (IATA-DGR). Although not

a biohazard, dry ice is considered to be a hazardous material and therefore regulated by the same agencies. In order to meet the requirements set forth by these regulatory agencies, UAB Biosafety provides online training for Shipping with Dry Ice (BIO200), Shipping Infectious Substances, Category B (BIO201), and Shipping Infectious Substances Category A (BIO202) at UAB Campus Learning System. If you ship any materials that are classified as Category A or B Biological/Infectious substances or Dry Ice, you must complete the applicable online training every 2 years or if regulations change (i.e. regulatory changes warrant a change in the training material). Failure to properly pack and ship these materials is a violation of the law and is punishable with fines and/or imprisonment. All parties involved in the shipment have unique responsibilities:

1) Shipper's Responsibilities: When shipping packages containing Biological Substances, Category B, Genetically Modified Organisms (GMOs), Exempt Human or Animal Specimens, from UAB, you have the responsibility to properly:
- Classify the substance or material
- Identify the substance or material
- Select the appropriate packaging system
- Pack the substance or material
- Mark and label the package correctly

2) Operator or Carrier Responsibilities:
- Must detect errors
- Use acceptance checklist
- Ensure safe loading, storage, and transport
- Inspect for damage or leaks
- Report any problems to the proper authorities

3) Receiver or Consignee Responsibilities:
- Provide assistance with import permits
- Inspect received packages for damage or leaks. Report any damages to hazardous biological materials immediately to Biosafety at biosafety@uab.edu or (205) 917-4766.
- Verify itemized list of contents
- Report receipt to the shipper
- Report leaking packages to the appropriate authority

10.4 DRY ICE

If you choose to ship a package using Dry Ice, International and Federal requirements dictate that you must be trained to do so every two years or when regulations change. Additional training may be required depending on the samples/materials that are being shipped with Dry Ice. If you need to send shipments that are refrigerated, you may choose to use gel packs or Solid Carbon Dioxide (Dry Ice). Gel packs are not regulated. Wet ice, or ice made from water, is not allowed due to the likelihood of leaks.

Dry Ice refrigerated packages are normally shipped by air. The requirements for shipping with Dry Ice as a refrigerant are combined with the shipping requirements that apply to the actual samples/materials you intend to refrigerate.

1) Classify and Identify the Material
Proper identification requires both a UN number and the Proper Shipping Name (PSN). UN numbers are taken from the list of dangerous goods and are used to identify a substance or group of substances. The Proper Shipping Name (PSN) is assigned by IATA, ICAO, or 49 CFR, and is the name used on shipping documents to describe substances. The UN number always precedes the PSN when labeling packages or filling out paperwork. For Dry Ice, the UN Number is UN 1845. The Proper Shipping Name is "Dry Ice" or "Carbon Dioxide, Solid." Together the proper identification would look like this: "UN 1845 Dry Ice" or "UN 1845 Carbon Dioxide, Solid." You must also properly classify and identify the samples or materials you are shipping with the Dry Ice

2) Packaging Requirements
Packaging components for certain hazardous samples must pass testing requirements as a system. Mixing and matching packaging components from different manufacturers is not allowed for Category A or B shipments. All packaging intended for shipment with Dry Ice must be designed and constructed to allow release of Carbon Dioxide gas, preventing the build-up of pressure. Shippers must make arrangements with the carrier before Dry Ice may be transported.

The outside packaging is typically a fiberboard box or container used to hold the gas-permeable insulated cooler, preferably Styrofoam, containing the Dry Ice. Outside packaging also serves as a surface for displaying clear Marks, Labels, and other important information. Dry Ice should never be shipped (or stored) in a sealed container. Carbon dioxide gas will expand as the dry ice sublimates causing a potential rupture or explosion if the contents are trapped in an airtight container.

The actual samples being shipped must first be properly classified, identified, and packed appropriately. You can then begin the process of packing it according to Dry Ice regulations (Packing Instructions 954).

3) Marks and Labels
Dry Ice shipments require the labels described below:

- A Class 9 Miscellaneous hazard black & white diamond-on-point label
- Proper Shipping Name and UN Number (which is either "UN 1845 Dry Ice" or "UN 1845 Carbon Dioxide, Solid")
- The weight of the Dry Ice (in kilograms) must be included adjacent to the black & white on-point label or the Proper Shipping Name (PSN)
- Any additional substance-specific Marks and Labels required of the material being refrigerated by the Dry Ice

- If you are not shipping Category A or B substances but are shipping with Dry Ice, you must label the contents being cooled.

4) Documentation

- *Shipper's Declaration:* A Shipper's Declaration is required for UN 1845 Dry Ice only when it is used as a refrigerant for Infectious Substances, Category A. If it contains Dry Ice as the packing refrigerant, then the Dry Ice must also be listed on the Shipper's Declaration. Refer to 49 CFR 173.127 to confirm that all requirements have been met.
- *Waybill:* If the items you are shipping do not require a Shipper's Declaration (non-dangerous goods, "Biological Substance, Category B," or Exempt Human/Animal Specimens) then the following information must be included on the waybill in the "Nature and Quantity of Goods" section:
- *UN* Number: UN1845
- *Proper* Shipping Name: "Carbon Dioxide, Solid" or "Dry Ice"
- *The* Class or Division Number: 9
- The number of packages
- The Net Weight of the Dry Ice in each package
- "UN3373, Biological Substances, Category B" (if appropriate).


SHIPPER'S DECLARATION FOR DANGEROUS GOODS

FedEx

WARNING

NON-RADIOACTIVE RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS

5) Security

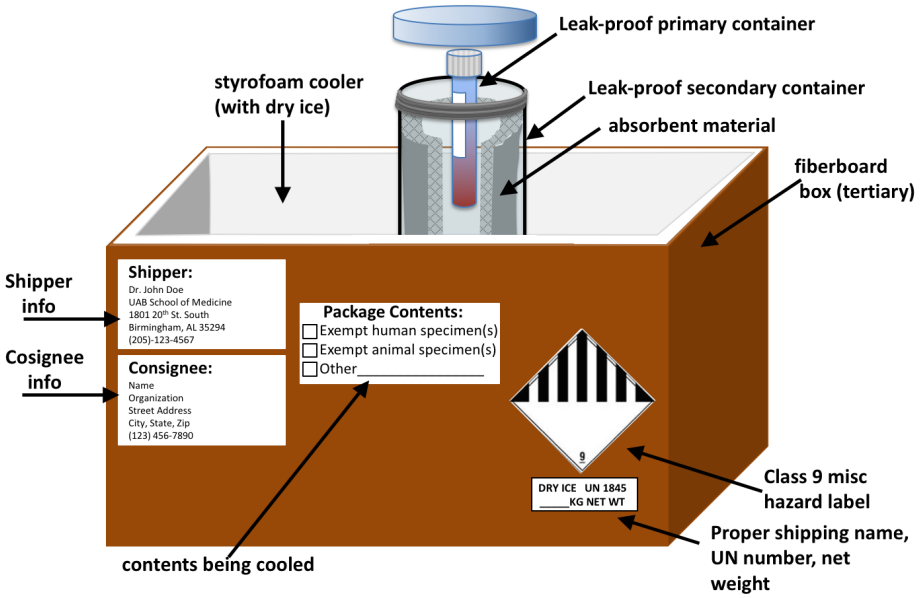
After preparing the package for shipment, the package must remain under the direct control of trained personnel until it is handed over to the carrier. This reduces the chances of tampering, theft, destruction, or invalidating the shipper's signature that signifies the package has been prepared in accordance with 49 CFR/IATA regulations. If you suspect a package has been tampered with, notify Biosafety immediately at (205) 917-4766.

6) Exceptions

Overpacks: If multiple fully compliant Dangerous Goods packages are placed within a fiberboard box, it is considered an overpack. All Marks and Labels on the inner packages must be reproduced on the overpack. The word "overpack" must also be placed on the outside of the fiberboard box.

Non-Dangerous Goods: There are exceptions in the regulations for non-dangerous goods shipments by air within the U.S. when using less than 2.5Kg (5.5 pounds) of Dry Ice. The packages must allow for the release of the CO2 gas, be marked "Dry Ice", list the quantity of Dry Ice and the contents of the package. These packages can be checked on commercial air flights as long as the airline knows ahead of time.

Shipping Nonhazardous or Exempt Specimens on Dry Ice
Follow IATA Packaging Instruction 954



10.5 EXEMPT HUMAN OR ANIMAL SPECIMENS

If your sample is not Category A or B, it may fall under the definition of an Exempt Human or Animal Specimen. These Exempt Human or Animal Specimens are those which have minimal likelihood of pathogens being present. Do not assume your sample is an Exempt Human or Animal Specimen. Professional judgement is required to determine if a substance is exempt. Any professional judgment made should be based on known medical history, symptoms, and the likelihood of pathogens present in the local population from which the sample was obtained. If professional judgement is not available, the specimen must not be shipped as Exempt Human or Animal Specimen. If you have questions, please contact Biosafety at biosafety@uab.edu to get further clarification.

Examples of Exempt Human or Animal Specimens often include:

- Blood or urine samples for diagnostic testing
- Biopsies to detect cancer
- Test specimens to monitor organ function in humans and animal with non-infectious diseases.

Packages Containing Exempt Human or Animal Specimens must be:

- Packed to prevent leakage
- Include the complete name and address of the Shipper and Consignee
- Marked with the Proper Shipping Name
- Either:
- Exempt Human Specimen
- Exempt Animal Specimen
- DO NOT use a UN 3373 Diamond-on-Point Label. Remember to remove or completely cover any irrelevant Marks or Labels from the package.

10.6 GENETICALLY MODIFIED ORGANISMS (GMO)

Packages containing Genetically Modified Organisms (GMO) should include:

- The complete name and address of the Shipper and Consignee (Receiver)
- The name and telephone number of a responsible person
- The label: “UN 3245 Genetically Modified Organisms”
  Or “UN 3245 Genetically Modified Microorganisms” mark
- Remove or completely cover any irrelevant Marks or Labels
- If you have any questions about the appropriate required marks and labels, contact UAB Biosafety at biosafety@uab.edu.

10.7 BIOLOGICAL SUBSTANCE, CATEGORY B

Samples that do not meet the criteria for Infectious Substances, Category A (not capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals) may qualify for classification as Biological Substances, Category B. If there is doubt as to whether or not an agent should be shipped as category A or B it must be shipped as category A. Not all couriers/carriers will transport all Biological Substances, Category B, and not all countries or states in the U.S. accept Biological Substances, Category B.
Where there are variations (restrictions) by state/country or courier/carrier, they may be more restrictive than the IATA DGR or ICAO TI, but never less restrictive.

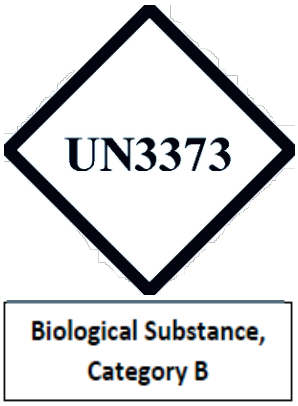
The airline industry is very strict about transporting biological materials. You cannot carry these materials/samples onto a passenger plane no matter now it is packaged. You must use commercial couriers such as UPS, USPS, FedEx, or DHL. There are quantity limitations,

depending on the samples being shipped, and on the courier's method of transport. For more information, please check with Biosafety and/or your courier

Shippers Responsibility:

1) Identifying the substance or material

- The proper shipping name is "Biological Substances, Category B," and is always listed with the UN number "UN 3373."
- UN 3373 Biological Substances, Category B



2) Packaging Requirements

- Packaging components for Biological Substances, Category B must pass testing requirements as a system, so mixing and matching packaging components from different manufacturer's is not allowed. For example, you cannot ship Biological Substances, Category B in an EXAKT-PAK TM secondary container and in a SAF-T-PAK TM outer container (fiberboard box).
- The recommended outside packaging must be sturdy and rigid. The outside packaging is typically corrugated fiberboard box and should be the appropriate size for the intended content. The box also serves as a surface for displaying clear Marks, Labels, and other important information.
- You should always use boxes that meet approved standards. Always look for the UN mark. It indicates that the box has been tested and meets standards. If you have questions about which boxes are approved, please email to biosafety@uab.edu.
- Inside packing for Biological Substances, Category B are prescribed by IATA Packing Instructions 650. Other points of interest include:
  - Exempt Human Specimens do not have designated Packaging Instructions so they should be triple- packed (Primary Container→Secondary Container →Tertiary Container) to prevent any release or leak of substance. Non-infectious Genetically Modified Organisms (GMOs) are packed using PI 959.
  - Any substances identified as UN 3373 must be triple packaged in approved boxes only.
  - Shipping liquids are of special concern when traveling by air due to air pressure changes that may occur during a flight. If the shipment is liquid, then the primary or secondary container must be able to withstand air pressure changes without leakage. Documentation of testing is available from the manufacturer.

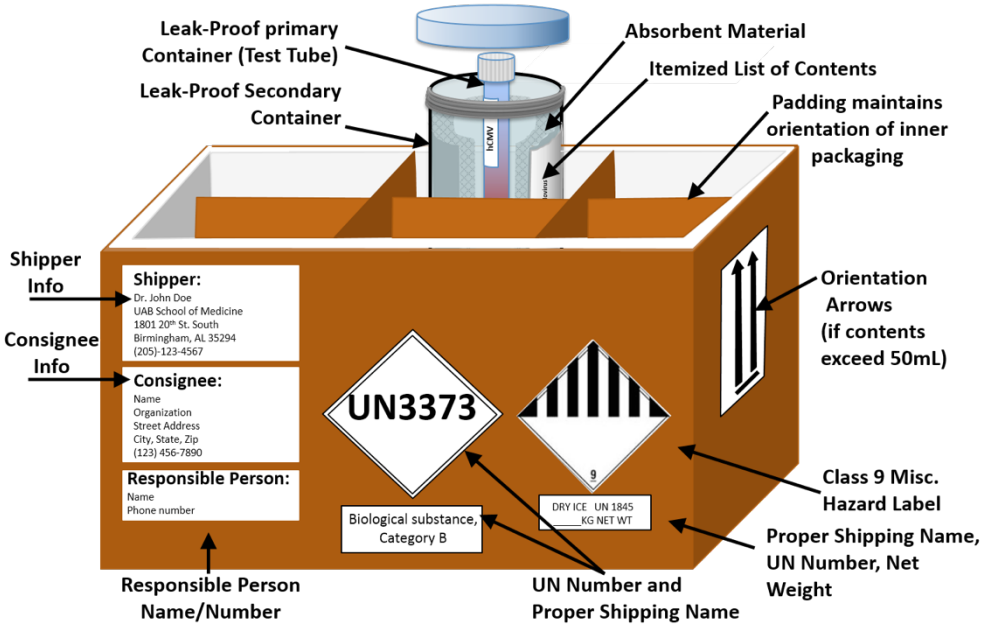
3) Marks and Labels

Biological Substances, Category B shipments require the following labels:

- A Biological Substances, Category B black & white Diamond-on-Point label
- Proper Shipping Name and UN Number (which is "UN 3373 Biological Substances, Category B")
- Complete name and address of the Shipper and Consignee (Receiver)

- Name and telephone number of a responsible person. This must be a reliable and responsible person that will answer the phone (no voicemail and no answering machines). They should be able to answer any questions about the content, shipper, recipient details, and/or permit inquiries.

Shipping Biological Substances, Category B, on Dry Ice
Follow Commercial System Instructions; IATA Packaging Instructions 650 & 954



4) Documentation

- *Shipper's Declaration:* No Shipper's Declaration is required for Biological Substances, Category B. Required information is placed on the waybill.
- *Waybill: You must include the following information on the waybill:*
  - UN Number
  - Proper Shipping Name
  - The Class or Division Number: 9
  - The number of packages
  - The Net Weight of the Dry Ice in each package, if appropriate
- *Permits*
  - Additional documentation (i.e., permits or certificates) may be required when shipping any biological substance, particularly those designated Infectious Substances. Federal permits are required to import/export disease causing agents for humans and animals, vectors for those agents, animal products, plants, plant products, and plant pests. Chemically inactivated agents are exempt from Dangerous Goods Regulations, but may still require permits for receipt and/or transfer.
  - Permits may also be required for domestic transport of some agents. The recipient of the material must obtain any required permits. If you are the shipper, request a copy

of any applicable permits from the recipient and include a copy of the permit with the shipping documents.
    - The U.S. receiver (importer) is responsible for the package being sent to them from a foreign country. The receiver must assure that the foreign shipper has packed and labeled the material according to U.S. Public Health Service and IATA regulations. The importer must send the proper shipping labels and a copy of their import permit to the shipper. Complying with foreign import regulations should prevent packages from being held at customs or denied entry.
- *USDA/APHIS (Animal and Plant Health Inspection Service) Permits* USDA/APHIS regulates transport of materials that could potentially harm U.S. agricultural products including livestock, poultry and crops.
    - APHIS permits may be required for import, export, and interstate transport of animal or plant pathogens, pathogen vectors, animals, animal products, plants, plant products, and the introduction of genetically modified or invasive organisms into the environment. See: USDA/APHIS Import/Export links.
    - USDA/APHIS Import/Transport permits must be obtained by the intended receiver of the material before shipment is made and are good for one year and are amendable/renewable.
    - The application form is for foreign import or interstate transfer and can be found here and **requires 6 to 8 weeks for processing.**
    - To determine if a permit is needed to import or transport a GMO, contact the APHIS Biotechnology permit branch via a letter of notification.

    - Animal-Related:

      USDA/ADPHIS permits are required for imports and exports and interstate transport of:
        - Animal or plant pathogens including challenge material from the USDA
        - Specimens reasonable believed to contain animal or plant pathogens [1]
        - Vectors of animal or plant disease [1]
        - Potentially hazardous animal or plant products

    - Plant Related: USDA/APHIS Regulation 7 CFR Part 330 Federal Plant Pest Regulations covers the transport of plant pests.

[1] *USDA/APHIS regulation 9 CFR Animals and Animal Products Parts 94, 95, and 122 covers transport of organisms or vectors that can cause infectious diseases of animals. The regulation defines material requiring a permit as, "(d) Organisms. All cultures or collections of organisms or their derivatives, which may introduce or disseminate any contagious or infectious disease of animals (including poultry). (e) Vectors. All animals (including poultry) such as mice, pigeons, guinea pigs, rats, ferrets, rabbits, chickens, dogs, and the like, which have been treated or inoculated with organisms, or which are diseased or infected with any contagious, infectious, or communicable disease of animals or poultry or which have been exposed to any such disease.*

- *Centers for Disease Control (CDC) Import/Transport Permits:* The Department of Health and Human Services, through the CDC, regulates the transport of biological materials that could cause illness in humans, including pathogens and biological toxins.

- In general, a permit is needed for any infectious agent known or suspected to cause disease in humans that you wish to import into the United States. In some cases, acquisition and/or subsequent distribution of an agent (e.g., viruses requiring BSL-3 or BSL-4 containment) is prohibited within the United States and requires CDC *authorization/permit prior to transfer to another location within the U.S. Select Agent* permits may only be obtained through UAB's Responsible Official, in coordination with the Federal Select Agent Program.
- A list of Select Agents and Toxins can be found here. Domestic transport may or may not require a permit. To determine if your shipment requires a permit visit the CDC Import Permit Program website.

Agents Requiring a Permit for Subsequent Distribution

Subsequent transfers are not permitted for materials suspected or known to contain the following infectious biological agents:

- *Mycobacterium tuberculosis*
- Coronaviruses (SARS-CoV-2, MERS-CoV)
- Influenza viruses (H2N2, H6N1, low pathogenic avian H7N9)
- Viral hemorrhagic fevers (e.g., Tick-borne encephalitis viruses – Central European subtypes, Old World hantaviruses that cause hemorrhagic fever with renal syndrome (HFRS)
- Mpox (clade II) (formerly known as: Monkeypox – West African clade)
- Poliovirus (serotypes 1, 2, 3)

All subsequent transfers of these agents require the intended recipient to submit a new permit application for approval.

Refer: Agents Requiring a Permit for Subsequent Distribution | Import Permit Program | CDC

- Foreign imports of the following materials require a Permit to Import or Transport Agents or Vectors of Human Disease:
  - etiologic agent
  - arthropod or other animal host or vector of human disease
  - exotic living arthropod or other animal capable of being a host or vector of human disease
  - all non-human primate material (e.g., blood, plasma, tissue, urine, feces) requires an import permit, unless it has been specifically treated and rendered non-infectious.
- *Department of Commerce Export Permits*: Exports of designated biological agents and toxins that have the potential to pose a threat to human, animal or plant life may require a license from the U.S. Department of Commerce, Bureau of Industry and Security (BIS). The scope of items subject to this licensing requirement is broader than "select agents," and researchers must consult with the University's Export Controls Officer to conduct a separate review to determine if a BIS export license is required. Export Control at UAB is

mediated through the University Compliance Office. BIS may require a license for the export of:

- Designated human, animal and plant pathogens, zoonoses and toxins
- Genetically modified microorganisms or genetic elements that contain nucleic acid sequences associated with the pathogenicity of a controlled organism or that code for a controlled toxin
- Genetic material and products which might be used for culture of large amounts of agents

For further guidance on whether or not the agents you are shipping/receiving require permits, please contact Biosafety at biosafety@uab.edu.

5) Security:

After preparing the package for shipment, the package must remain under the direct control of trained personnel until it is handed over to the carrier. This reduces the chances of tampering, theft, destruction, or invalidating the shipper's signature that signifies the package has been prepared in accordance with 49 CFR/IATA regulations. Before handing the package over to the carrier for shipment, it is the shipper's responsibility to ensure that all Federal and International regulations are met. International shipments may require additional permits.

Department of Commerce Export Licenses:

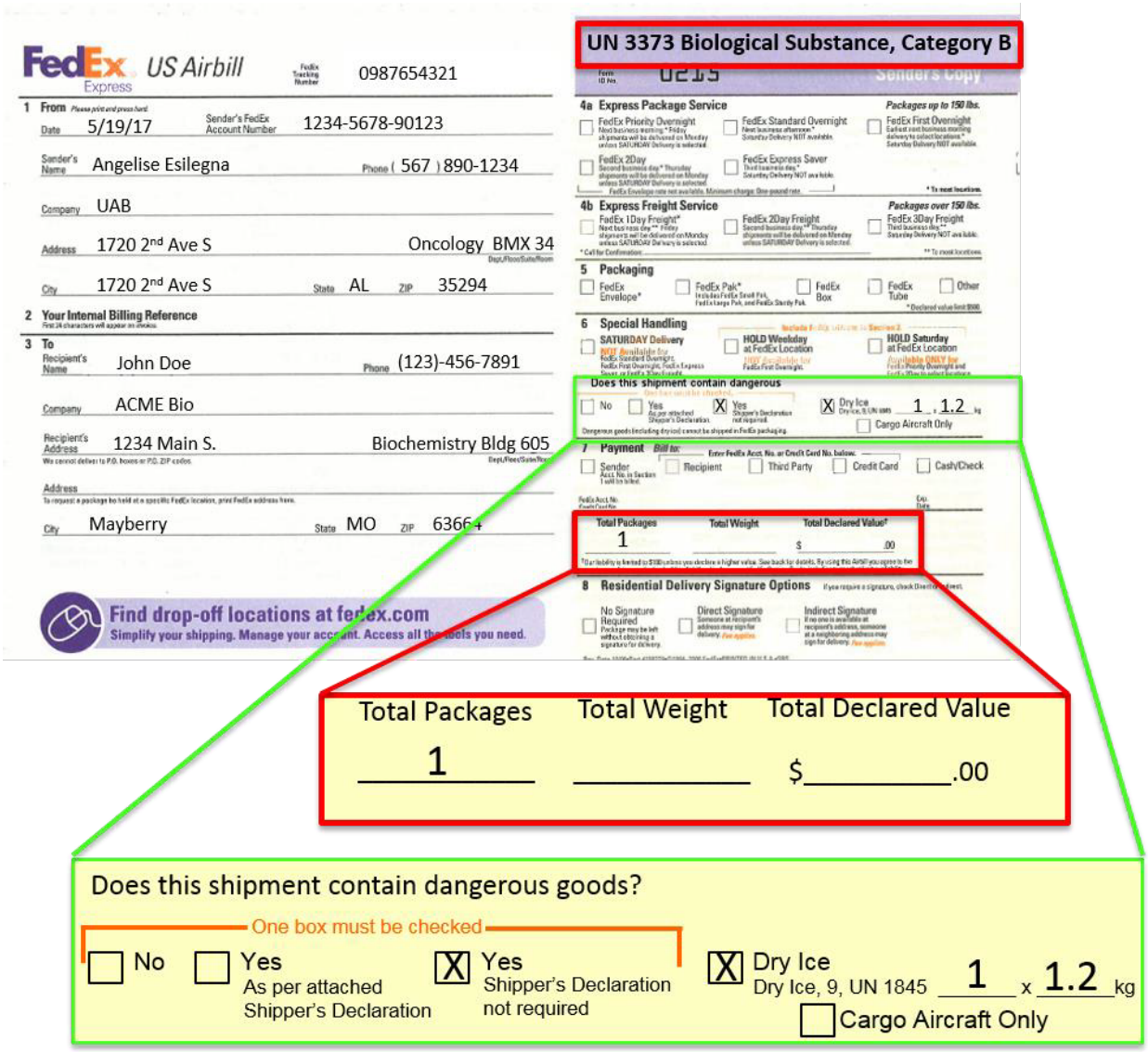
Exports of designated biological agents and toxins having the potential to pose a threat to human, animal, or plant life require a license from the U.S. Department of Commerce Bureau of Industry and Security (BIS). The scope of items subject to this licensing requirement is broader than "select agents," and researchers must consult with the University's Export Controls Officer at exportcontrol@uab.edu, or (205) 996-2735, to conduct a separate review to determine if a BIS export license is required.

Export Control at UAB is mediated through the Director of Export Control & International Compliance, located within the Office of Research Regulatory Oversight. BIS may require a license for the export of:

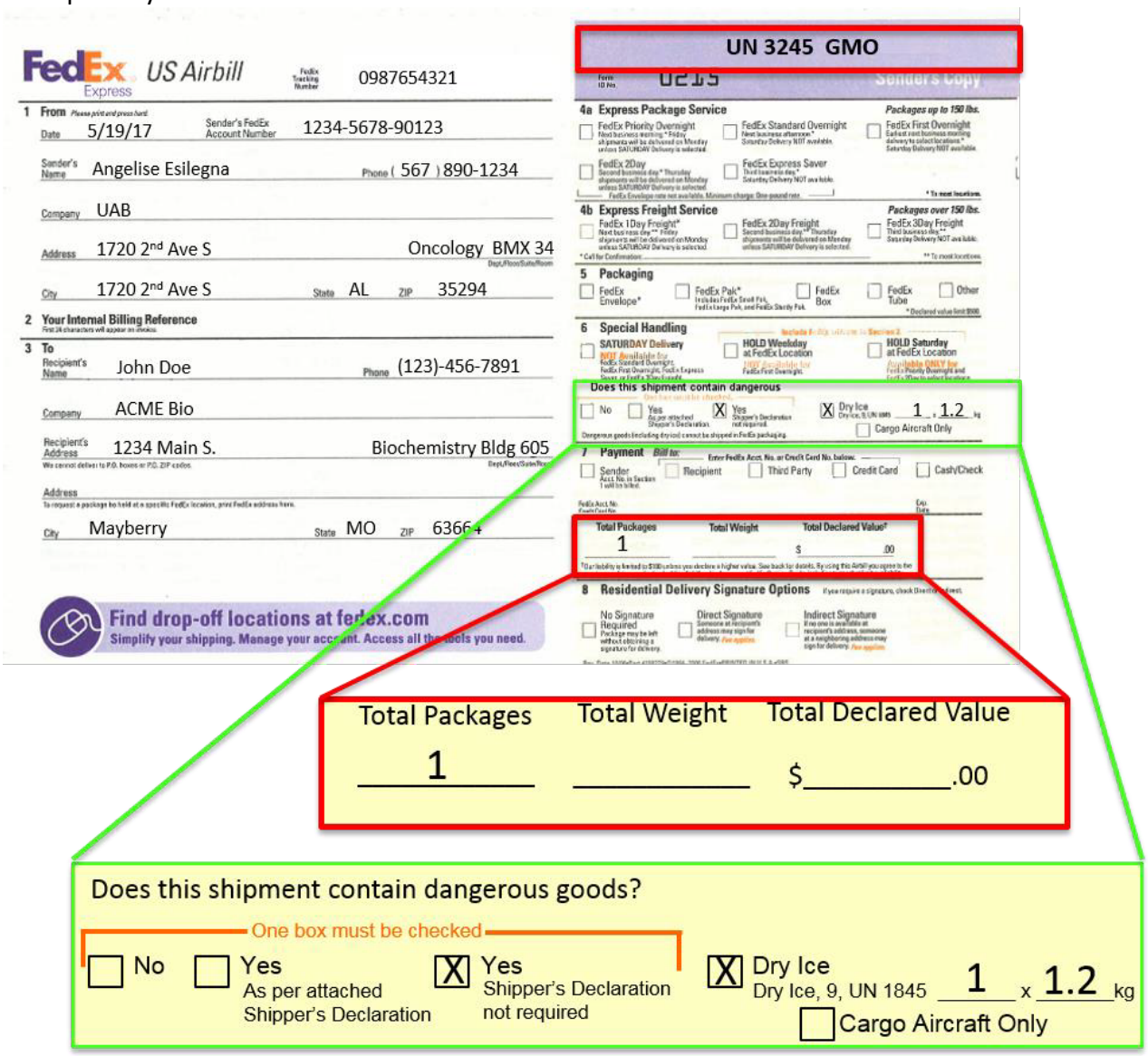
- Designated human, animal and plant pathogens, zoonotic agents, and toxins
- Genetically Modified Microorganisms or genetic elements containing nucleic acid sequences associated with the pathogenicity of controlled organisms or that code for a controlled toxin
- Genetic material and products which might be used for the culture of large amounts of agents.

For further guidance on whether or not the agents you are shipping or receiving require permits, contact Biosafety at biosafety@uab.edu.

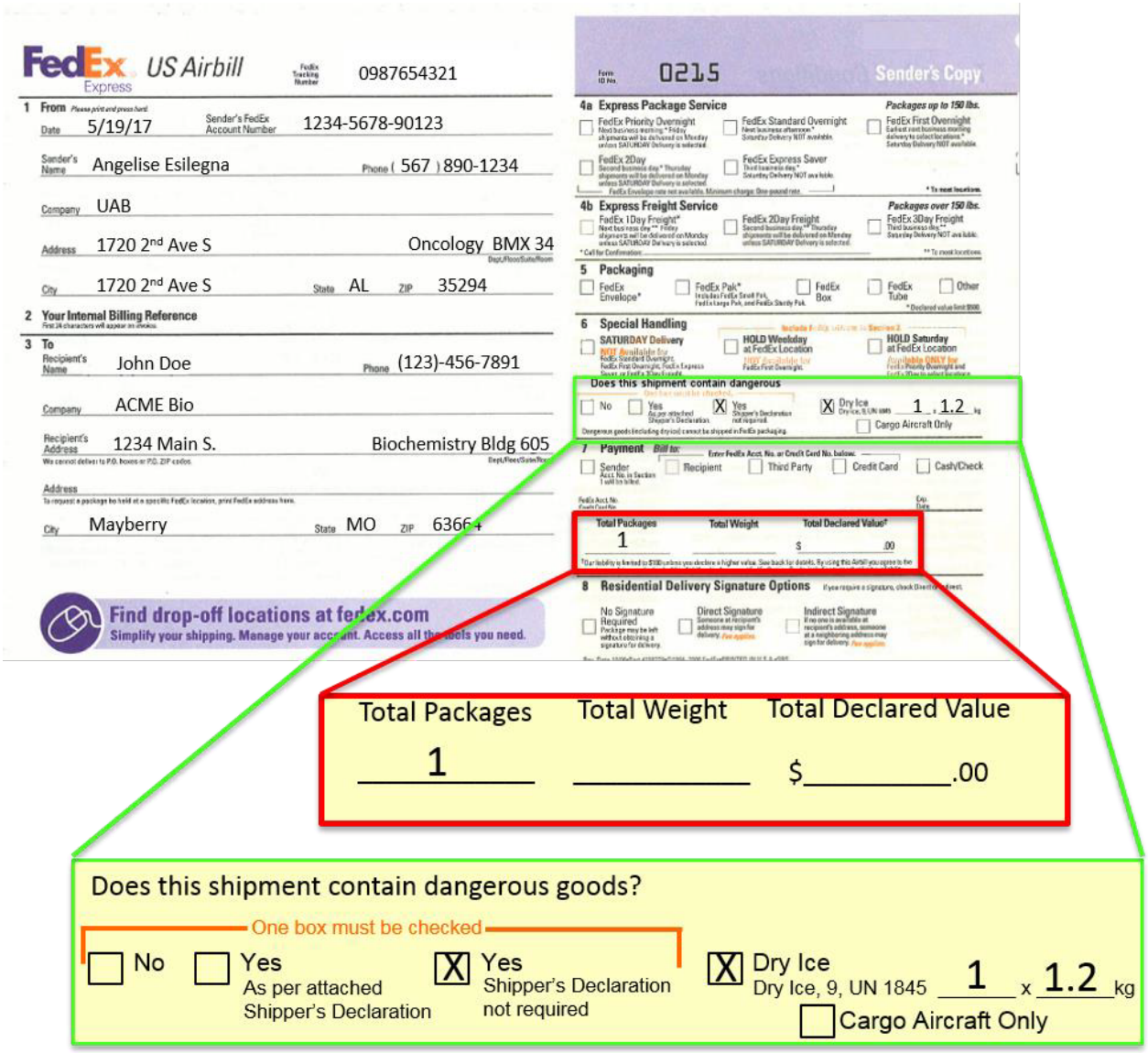
Example waybill for UN 3373:



Example waybill for UN 3245:



Example waybill for Exempt Human or Animal Specimens:



Receiver/Consignee Responsibilities

If you expect to receive packages containing Biological Substances, Category B at UAB, you have the responsibility to:

1) Inspect the documents
2) Inspect the package
3) Get an import permit if necessary
4) Report any damages to the shipper and UAB Biosafety
5) Notify the sender that the package has arrived
6) Keep all shipping documents for a minimum of three years

10.8 INFECTIOUS SUBSTANCE, CATEGORY A

Infectious Substances, Category A are those which are capable of posing a risk to health and safety. These substances are capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals when exposure occurs. Work with these substances requires high containment.

Shipper's Responsibilities

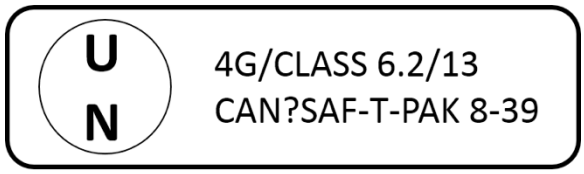
1) Classifying the substance or material

- If your sample happens to be a Genetically Modified Organism (GMO) and meets the classification of an Infectious Substance, Category A, then it must be classified and shipped as an Infectious Substances, Category A. Check with your carrier if you are unsure or have questions
- Infectious Substances, Category A have two Proper Shipping Names – one refers to Infectious Substances affecting animals and the other affecting humans:
  - UN 2900 Infectious Substances, affecting animals (refers to the Infectious Substances that affect animals and is only allowed if the Infectious Substance is an animal pathogen and can in no way pose a threat to humans)
  - UN 2814 Infectious Substances, affecting humans (if the Infectious Substance can pose a threat to humans as well as animals)

  The Technical Name is the substance's Genus and Species. This must be added to the end of the Proper Shipping Name on the Shipper's Declaration when shipping Infectious Substances, Category A. It should be written or typed in parentheses. For example, an isolate of West Nile Virus cultured from a mouse has the ability to affect a human. Therefore, the Shipping Document for this sample would show: UN 2814 Infectious Substance, affecting humans (West Nile Virus). ***Remember, the Technical Name goes on the Shipper's Declaration – not the package.***

2) Packaging Requirements

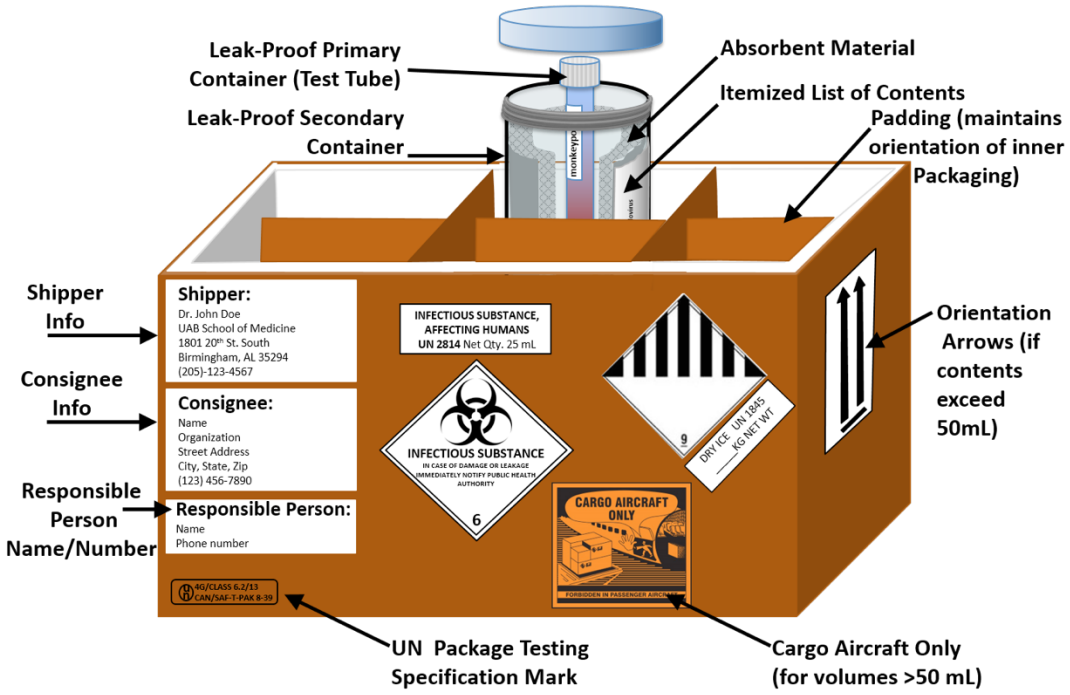
- Packaging components for Infectious Substances, Category A must pass testing requirements as a system, so mixing and matching packaging components from different manufacturer's is not allowed. When choosing the correct packing materials, only use packaging in the tested and certified configuration. For example, you cannot ship Infectious Substances, Category A in an EXAKT-PAK TM secondary container and in a SAF-T-PAK TM outer container (fiberboard box) since the containers have not been tested and certified together.



- The recommended outside packaging must be sturdy and rigid. The outside packaging is typically corrugated fiberboard box and should be the appropriate size for the intended content. The box also serves as a surface for displaying clear Marks, Labels, and other important information.
- Never use boxes except those that conform to approved standards. Always look for the UN mark. It indicates that the box has been tested and meets standards. If you have questions about which boxes are approved, please email Biosafety at biosafety@uab.edu.

- With regard to inside packaging, either the primary or secondary container must be able to withstand internal pressure of 95 kPa in a temperature of -40 degrees Centigrade (-40°C) to 55 degrees Centigrade (55°C). All packaging components for Infectious Substances, Category A must be assembled per the manufacturer's packing instructions specific to the packing system purchased.

Shipping Category A, Infectious Substances on Dry Ice
Follow Commercial System Instructions; IATA Packaging Instructions 620 & 954



3) Marks and Labels

- Marks and Labels are used to provide information about the contents of the package, the nature of the hazard, and any special handling requirements. Any Marks and Labels should be:
  - Durable
  - Placed so that they are completely visible
  - Not obscured by any other Labels or Markings
  - Placed all on the same face of the package, if possible

- Infectious Substances, Category A shipments require the labels described below:
  - An Infectious Substance, Category A black & white Diamond-on-Point Label
  - In case of damage or leakage, immediately notify a UAB Biosafety at biosafety@uab.edu
  - Proper Shipping Names and Number
  - UN 2900 Infectious Substances, affecting animals
  - UN 2814 Infectious Substances, affecting humans
  - Complete name and address of the Shipper and Consignee (Receiver)
  - Name and telephone number of a responsible person. This must be a reliable and responsible person that will answer the phone (no voicemail and no answering machines). They should be able to answer any questions about the content, shipper, recipient details, and/or permit inquiries.

  - Orientation Marks or the words "this side up" on packages containing liquids. Two orientation marks or the words "this side up" should be on two opposite sides of the box. However, they must match. Both sides must be orientation marks or both sides must be marked "THIS SIDE UP".

4) Documentation

- *Shipper's Declaration:* A Shipper's Declaration for Dangerous Goods is a legal document and is required for each shipment of Infectious Substances, Category A. It is also one of the main reasons packages get rejected (incorrectly prepared). To keep your Shipper's Declaration from being rejected, here are some things that you must do:
  - Prepare three copies – one for the shipper and two for the carrier. However, some carriers may require more. Check with your courier before submitting.
  - Keep your copies for two years – in case there are questions later.
  - If you have made prior arrangements with the courier, submit your Shipper's Declaration information electronically. Fill out each line or space correctly.
  - If shipping through FedEx, use FedEx ship manager to generate shippers declaration for dangerous goods, shipping labels and Airway bill.
- *Permits:* Additional documentation (i.e., permits or certificates) may be required when shipping any biological substance, particularly those designated Infectious Substances, Category A. Federal permits are required to import/export disease causing agents for humans and animals, vectors for those agents, animal products, plants, plant products, and plant pests. Chemically inactivated agents are exempt from Dangerous Goods Regulations, but may still require permits for receipt and/or transfer. Permits may also be required for domestic transport of some agents. The recipient of the material must obtain any required permits. If you are the shipper, request a copy of any applicable permits from the recipient and include a copy of the permit with the shipping documents.
  - In some cases, acquisition and/or subsequent distribution of an agent (e.g., viruses requiring BSL-3 or BSL-4 containment) is prohibited within the United States and requires CDC authorization/permit prior to transfer to another location within the U.S. Select Agent permits may only be obtained through UAB's Responsible Official, in coordination with the Federal Select Agent Program. A list of Select Agents and Toxins

can be found here. Domestic transport may or may not require a permit. To determine if your shipment requires a permit visit the CDC Import Permit Program website.
    - **See "Permits" under "Biological Substance, Category B" on page 96 for more information.**

5) Security

- *ICAO* and IATA require that any company or institution that handles or transports dangerous goods provide associated security training for any staff who come in contact with the dangerous goods. This training should encompass the nature of the risks, recognition of risks, practices used to reduce risks, and procedures for a security breach.
    - Before handing the package over to the carrier for shipment, it is the shipper's responsibility to ensure that all Federal and International regulations are met. International shipments may require additional permits.
    - Ensure package tracking is available through the courier.
    - Restrict dangerous goods access to properly trained and qualified staff.
    - After preparing the package for shipment, the package must remain under the direct control of trained personnel until it is handed over to the carrier. This reduces the chances of tampering, theft, destruction, or invalidating the shipper's signature that signifies the package has been prepared in accordance with 49 CFR/IATA regulations.
    - Inventory dangerous goods stocks to track theft or loss.
    - Report all suspicious activity/persons to UAB Police at (205) 934-3535.
    - Exposure/Incident Response Plans are in place to define procedures in the event of a release or exposure.
    - Select Agents transfer requires additional CDC/APHIS approval through coordination with UAB's Responsible Official.

Receiver/Consignee Responsibilities: The following security guidelines are applicable to Category A Shipments of Risk Group 3 agents at UAB:

- Make arrangements to receive the shipment at the EH&S Support Facility by submitting an ETXSA Form to UAB Biosafety.
- UAB Biosafety will ensure all of the proper paperwork and approvals are in place before granting permission to receive the agent.
- UAB Biosafety will coordinate the receipt and transfer of all Risk Group 3 agents between the EH&S Support Facility, and appropriate investigators/staff at SEBLAB.
- For more information on working with Risk Group 3 agents at UAB, contact UAB Biosafety at biosafety@uab.edu

Please refer to Appendix 10.1 Guidance for Transport and Shipping of COVID-19+/ SARS-Co-V-2 Patient Samples at UAB.

11.0 SPILLS AND EMERGENCY RESPONSE

11.1 BASIC BIOLOGICAL SPILL RESPONSE

Despite any precautions that may be taken, accidental spills can be expected to occur in the laboratory. When infectious materials, recombinant or synthetic nucleic acid molecules, or organisms containing recombinant or synthetic nucleic acid molecules are involved, here are a few steps to remember (**refer to Appendix 11.2 Spill Clean Up** for a visual guide):

1. The area should immediately be isolated to prevent spread of the spillage. Alert others in the area, and begin spill cleanup according to your laboratory spill response plan
2. Asses the spill size (more than 500ml or less than 500ml) and retrieve the spill kit. Don PPE needed to clean up the spill
3. Cover with paper towels or other absorbent material and soak with appropriate disinfectant
4. Allow the disinfectant to remain on the spill area for the recommended amount of contact time to ensure all material will be neutralized
5. Clean up the spill with tongs taking care to pick up all absorbent material
6. Place the soaked absorbent material in a red biohazardous bag
7. The red biohazardous bag should be disposed of as medical waste (normal waste stream for any biohazardous material generated in the lab)
8. Remove PPE, discard any disposable PPE, and then wash hands thoroughly

A good laboratory practice is to post a spill response plan or checklist near the spill kit and to provide training for all lab members on how to use the spill kit. EH&S Biosafety highly recommends that you post spill response procedures in the lab and make available a spill response plan for new lab members to review. The laboratory spill response plan should contain the following elements:

How to assess the extent and nature of the spill

Large spills require a different approach to response and cleanup in order to account for areas outside of the immediate spill being affected. A key component to large spill response is to prevent the spill from spreading outside of the immediate area to other areas that may be unaware of the hazard (e.g. spill leaking under wall to another room or through the floor to a space below). Similar considerations should be taken for spills of a concentrated biological stock or culture. Higher concentrations of disinfectant along with a longer contact time may be needed. The surface in which a spill occurs (e.g. smooth vs porous, lab bench vs lab furniture) may also influence the ability of a disinfectant.

Personal protective equipment (PPE) needed for clean up

Wear appropriate PPE when infectious materials, recombinant or synthetic nucleic acid molecules, or organisms containing recombinant or synthetic nucleic acid molecules may be encountered. This may include gloves, lab coat, face shield, goggles, dust mask, HEPA mask, etc. Be aware of exposure routes and protect yourself accordingly. If the spilled material can be transmitted via the inhalation route, clear the area and warn others of the spill. Wait a period of time and then enter the area. This will allow aerosols to settle or be captured by the building exhaust. Keep in mind that the fact that a spill means that aerosolization has taken place.

Disinfectants and methods of disinfection
Cover the spill with absorbent towels and carefully pour the appropriate disinfectant on the area. When pouring the disinfectant, start at the edge and spiral in toward the center of the spill. Select a disinfectant that is specific for the agent(s) used in your lab. Heavy soil load or high protein content may alter a disinfectant's efficacy and pre-cleaning may be required (e.g. blood spills, spills containing tissues). There are two key factors associated with proper disinfection: concentration of the disinfectant and contact time. Please use the disinfectant specified in the Agent-Specific Safety and Data Plan. Follow the manufacturer's directions or contact Biosafety for further assistance.

Spill waste disposal
After the area has been thoroughly disinfected, dispose of all waste materials as medical waste (See Chapter 6). Contaminated glass should never be handled with hands (even gloved hands). Use tongs, dustpan and broom, hemostats, etc. to carefully place the broken glass in an approved sharps container. The rest of the spill cleanup waste and disposable PPE can then be placed in red biohazardous waste bags for proper disposal as medical waste. Carefully wash your hands with soap and water. Report incident to lab manager or PI as soon as possible and if warranted to Biosafety as directed by lab manager or PI.

Reporting requirements
All spills outside of primary containment (biological safety cabinet or other device) that involve infectious materials, recombinant or synthetic nucleic acid molecules, or organisms containing recombinant or synthetic nucleic acid molecules must be reported immediately after acute exposure issues are addresses to the Biosafety Officer (biosafety@uab.edu) or (205) 917-4766 who will notify the IBC. The IBC Director may notify the NIH Office of Biotechnology Activities, if required. Reporting incidents is not to place blame, but to allow for root cause analysis that may result in positive change for other laboratories.
Refer to Appendices 11.1 and 11.2 for more information on spill cleanups.

11.2 SPILLS IN A BIOSAFETY CABINET

- If a spill is confined to the BSC while the blowers are running, the spill should present little hazard to the surrounding laboratory area.
- Leave BSC blower motor turned on during cleanup
- If necessary, flood work surface, as well as drain pans and catch basins below the work surface, with appropriate disinfectant
- Wipe cabinet walls, work surfaces, and inside the front view screen with appropriate disinfectant
- Lift front exhaust grill and tray in order to wipe clean all surfaces. Ensure no paper towels or soiled debris has blown into the area below the grill.
- Expose non-autoclavable materials to appropriate disinfectant before removing from the biosafety cabinet.
- Run biosafety cabinet for 10 minutes after cleanup either before resuming work or turning cabinet off.

- If the spill overflows into the interior of the cabinet, contact UAB EH&S Biosafety at biosafety@uab.edu for an evaluation in the event more extensive decontamination of the cabinet is required.

11.3 SPILLS IN A CENTRIFUGE

Because of the potential for aerosols, infectious materials should be centrifuged using safety centrifuge cups that are only opened and closed within biosafety cabinet. Alternatively, small centrifuges may be operated directly in a biosafety cabinet, but the setup should be tested to verify containment is maintained. Although centrifugation without primary containment devices is strongly discouraged, the following precautions will minimize the risk of exposure:

- Open lid of centrifuge slowly.
- If there has been no breach of containment, spray rotor with 70% EtOH.
- If inside of rotor is contaminated, decontaminate in the BSC. As a precautionary measure, decontaminate the centrifuge chamber.
- If rotor buckets are damaged, close centrifuge lid.
- Alert personnel in the vicinity. Evacuate room.
- Wait 30 min. Meanwhile, notify PI and a Biosafety Officer/Specialist biosafety@uab.edu.
- If assistance is needed, discuss with Biosafety Officer.
- Open lid slowly and add paper towels.
- Spray walls of chamber and rotor with 70% EtOH.
- Close centrifuge lid for 20 min. contact time.
- Finish centrifuge clean-up as for major spill outside the BSC. Transport rotor to BSC.
- Open and decontaminate rotor/buckets in the BSC.
- With PI, write up a report and submit to Biosafety Officer

11.4 BIOLOGICAL SPILLS ON A PERSON

If a biological material is spilled on a person, emergency response is based on the hazard of the biological agent involved, the amount of material spilled, and whether significant aerosols were generated. If aerosol formation is believed to have been associated with the spill, notify others, leave the contaminated area immediately, and relocate in another laboratory space to minimize potential aerosol exposure to hallways and common areas. Follow the Agent-Specific Safety and Data Plan for specific exposure response procedures.

Exposure Response:

Wash the exposure site:

- dermal/percutaneous: 15 minutes with soap and water
- mucous membranes: 15 minutes with water only

Seek treatment immediately:

Please refer to Appendix 4.3 for UAB Exposure Response Flowchart.

If you are seeking medical treatment at the Workplace Clinic, have a colleague or supervisor fill out an Initial Medical Evaluation Authorization form. Have your supervisor sign the form (if your supervisor is unavailable, seek a signature from an alternate departmental superior or EH&S representative).

Based on the nature of the spill (compounding injuries resulting in percutaneous inoculation or exposure to open wound) and the potential hazards of the biological material, subsequent medical evaluation, surveillance, and treatment may be provided by UAB Employee Health as appropriate and written records maintained as required.

11.5 OTHER SPILLS OR ENVIRONMENTAL RELEASES

- Notify the Institutional Biosafety Officer at biosafety@uab.edu or (205) 917-4766 immediately if the material spilled requires BSL-2 or greater containment, if there has been a release to the environment, or animal escape.
- Clear area of all personnel. Wait at least 30 minutes for aerosol to settle before entering spill area. The use of respiratory protection may be indicated if immediate entrance to spill area is required. The use of respirators requires prior fit-testing and training. Contact EH&S UAB Employee Health for information.

11.6 SPILLS AND/ OR EXPOSURE REPORTING PROCEDURES

Spills, incidents and accidents that result in overt exposures to research related infectious materials, recombinant or synthetic molecules or organisms containing recombinant or synthetic nucleic acid molecules, environmental releases, the escape or improper disposition of a transgenic animal must be immediately reported to the Biological Safety Officer, who will conduct incident evaluations and report to the UAB Institutional Biosafety Committee and/or federal agencies as applicable.

Other significant problems, violations of the NIH Guidelines, or significant research-related accidents and illnesses must be reported to NIH OBA (Office of Biotechnology Activities) within 30 days. Reports requiring NIH/OBA notification will be prepared by the IBC Director using the template available on the NIH website and sent to NIH/OBA at Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

The supervisor should contact Biosafety Officer (BSO) at EH&S to report the incident as soon as possible.

- **During work hours (8 AM – 5 PM): call (205) 917-4766 and ask to be connected with a Biosafety representative Or email to biosafety@uab.edu**
- **After hours or weekends: call UAB PD Dispatch at (205) 934-4434 or EH&S On-call (205) 917-4766.**

Spills or accidents involving recombinant or synthetic molecules or organisms containing recombinant or synthetic nucleic acid molecules must be reported immediately to NIH OBA by the BSO. Contact EH&S at (205) 917-4766 and ask to speak with the BSO:

Medical evaluation, surveillance, and treatment will be provided as appropriate and written records maintained as required.

11.7 OTHER EMERGENCIES

Whether it's fire, severe weather, a bomb threat or just an electrical power outage, it is important to know what to do. Check the UAB General Safety website for more details.

Loss of electrical power

The sudden interruption of electrical power and/or refrigeration can result in a disastrous sequence of events for laboratories working with labile biological material should the problem persist. At the first indication of power or refrigeration trouble, contact the Maintenance Dispatch Office: (205) 934-5353 for campus buildings and (205) 934-6181 for hospital buildings.

Fire

If you detect FIRE or SMOKE, no matter how minor it may appear to be, follow the UAB Fire Safety Program CARE procedures and:

- Stay calm and use common sense.
- Confine the fire by closing all doors. As you leave the room where the fire is located, close the room door, fire doors located in the corridors, at elevator lobbies, and stairs. Secure biologicals and turn off oxygen equipment, including gas and air outlets to biosafety cabinets.
- Activate the fire alarm – a small red box located on the wall near each exit. Follow the instructions on the alarm.
- Report the fire, Dial 911 from any UAB phone (UAB Police). Identify yourself and provide the exact location of fire or smoke and what is burning, if know.
- Evacuate faculty, staff, students, and visitors immediately. Do not use elevators. Proceed to the nearest exit and move away from the building, assembling in a location predetermined by each department or building.
- Do not return to the building unless told to do so by the fire department, police, or the Safety Office.

Tornado Watches/Warnings

A tornado watch means conditions are favorable for the development of tornadoes or very intense straight-line winds capable of causing severe damage. The watch will be issued by the National Weather Service for a specified period of time. No specific action should be taken during a watch except to stay alert to weather conditions and updates.

A tornado warning means a tornado has been spotted in or near Jefferson County. Personnel must stay alert to any sudden changes in weather conditions or weather announcements and be prepared to seek shelter immediately in the lower level and/or along the interior walls. Personnel should stay away from the windows as much as possible.

12.0 TRAINING

12.1 BIOSAFETY TRAINING AND RESPONSIBILITIES

Biosafety training will be provided to all individuals working with biological materials in UAB laboratories or classrooms. In addition, personnel who work with Risk Group 1 and 2 microbiological agents must have standard training in microbiological practices to ensure proper handling of the agent. Research staff and students working with Risk Group 2 agents must also have additional, agent-specific training. It is the responsibility of the Principal Investigator, Laboratory Manager or instructor to provide this training. Agent-specific training should include discussions about signs and symptoms of illness following an exposure to biological materials, potential hazards from exposure, and methods available to employees to prevent exposure. An Agent-Specific Safety Data Plan template is available to facilitate the biological risk assessment process and develop appropriate response and training measures.

Employees and students must be adequately trained prior to beginning any work with microbes, human source materials and other potentially infectious materials (OPIM), non-human primate materials, biological toxins and recombinant or synthetic nucleic acid molecules. Annual Bloodborne Pathogens training is required for all UAB employees with potential exposure to human blood, unfixed tissues and cells, and OPIM.

PIs are encouraged to review this biosafety manual, lab-specific safety manuals, and agent-specific safety data plans with their employees and students to address the following topics:

- The biology of the microbes used in experiments or that may be in the materials used, with emphasis on potential biohazards;
- Good aseptic technique;
- Proper techniques for decontamination and disinfection;
- Emergency procedures;
- A review of all relevant safety practices, the potential hazards of the work, and what to do if there is a suspected or confirmed exposure to biohazardous materials.

12.2 BIOSAFETY TRAINING

The following courses may be required for working with infectious biological agents at UAB. Please refer to Table 12.1 for course descriptions and training requirements. For more information and to register for any courses, please visit the UAB Campus Learning System.

Table 12.1. Biosafety Training Requirements

Course	Course Title	Description	Required
ID: E-5VNQVM	**Basic Biosafety**	Provides individuals working with infectious agents with information on how to conduct a biological risk assessment.	**Once**
ID: E-7VR7VE	**Medical Waste Management for Labs**	Intended for those who generate, pack, or handle medical waste.	**Every 3 years, or if regulations change**
ID: E-E04XR0	**Bloodborne Pathogens**	This course is designed to train UAB Campus Employees on the principles and requirements of the OSHA BBP Standard.	**Annually**
ID: E-P0WZ0J	**Shipping with Dry Ice**	Required for anyone that will be mailing shipments refrigerated with solid Carbon Dioxide (Dry Ice). *Additional training may be required depending on the samples/materials that are being shipped with Dry Ice.	**Every 2 years, or if regulations change**
ID: E-E1LZV4	**Shipping Biological Substances, Category B**	Required for anyone that will be shipping samples considered Biological Substances, Category B Genetically Modified Organisms, Exempt Human, or Animal Specimens**.**	**Every 2 years, or if regulations change**
ID: E-71KDVJ	**Shipping Infectious Substances, Category A**	Required for anyone that will be shipping samples that are considered Infectious Substances, Category A.	**Every 2 years, or if regulations change**
ID: E-XVDPV2	**Biosafety cabinets and Fume hoods**	Required for all individuals using Biosafety cabinets and fume hoods in laboratory	**Once**
ID: E-J0EZ90	**Using PPE (Personal Protective Equipment) in the Laboratory**	Required for individuals working with or around hazardous materials or substances	**Once**
ID: E-O06RQV	**Hazard Communication**	Required for all individuals working in laboratory	**Once**

13.0 UAB EMPLOYEE HEALTH PROGRAM

UAB Employee Health is designed to anticipate, recognize, evaluate, and control potential health, safety, and environmental factors that may affect the well-being, comfort, or productivity of the UAB campus community.

UAB Employee Health accomplishes these goals through risk assessment, risk management, risk education, and preventive medicine. A critical component of Employee Health is medical surveillance that involves the evaluation of health risks associated with an employee's exposure to animals and hazardous agents.

The "Enrollment Form" is the initial evaluation that establishes the employee's baseline health status. Every two years the “Enrollment Form” is due unless the employee’s job changes or work exposures change, then an “Enrollment Form” is required. Some employees may require a clinical examination and vaccinations.

13.1 ELIGIBILITY

This program is designed for UAB Employees who:

- Have direct contact with animals, their viable tissues, body fluids, wastes or living quarters. This includes, but is not limited to, Animal Care Staff, Investigators, laboratory staff, and some Maintenance and building Services personnel.
- Work in the laboratory and have direct contact with material of human origin.
- Have direct contact with material capable of causing disease or injury in humans.
- Have direct contact with raw sewage through plumbing activities.
- Are exposed to excessive levels of noise (>85 db.).

Individuals not employed by UAB, but who will be conducting work with any of the above at UAB, must enroll. Examples of non-employees that must enroll for the UAB Employee Health program include:

- Non-paid students
- Volunteers and minors
- Individuals from private companies conducting work at UAB, contractors and vendors
- Visiting Scientists

13.2 ENROLLMENT

UAB Employee Health Enrollment Form is the start of this process for the eligible employee. The Employee Health professional reviews the work exposures and medical history in order to determine what services to provide the employee to ensure a safe and healthy work environment.

The enrollment process is initiated when an individual completes the Enrollment Form and submits this form to UAB Employee Health for review. An individual has successfully met the requirement when they have enrolled in the UAB Employee Health Program and have received either:

- An employee health notice of clearance indicates no further medical evaluation is necessary (or)

- An employee health risk assessment notification that indicates further medical evaluation is necessary and they have received the evaluation and any required interventions such as immunizations.

Every two years an Enrollment Form is due, unless the employee's job changes or work exposures change, then an updated Enrollment Form is required. Annual updates for certain forms may be required. Email reminders will be sent to the employee's UAB email account due to confidentiality requirements. For more information about UAB Employee Health and Forms please click here

13.3 HEALTH SERVICES

UAB Employee Health provides a variety of services. Those offered to you are dependent upon the potential risks posed by the work you conduct at UAB. All mandatory items must be completed in order to maintain compliance.

Once UAB Employee Health receives the Enrollment Form, Employee Health professionals will review the work description and medical history to determine if services should be offered.

If the UAB Employee Health professionals determine that an immunization or screening is warranted, an email will be sent to schedule an appointment. Missed appointments will result in non-compliance with the program.

13.4 ADDITIONAL SERVICES

HAZMAT Physicals

Employees whose job responsibilities include the role of HAZMAT (Hazardous Materials for First Responders) First Responder will be required to complete a HAZMAT physical. This physical includes examination and testing to:

- Assess changes in the fitness status of the individual,
- Ensure that the individual is capable of wearing proper personal protective equipment, and
- Determine exposure levels of certain substances.

Respiratory Protection Program

Respirators are used in the workplace to protect employees from inhaling hazardous materials present in the air. These materials can be in the form of gases, vapors, mists or dust. To provide proper protection, respirators must be the right type, must be worn correctly at all times, and must be maintained properly.

Participation in the UAB Respiratory Protection Program is required when the workplace use of a hazardous material itself cannot be eliminated or reduced to a level not associated with adverse health effects or there is no less hazardous alternative material that can be utilized. Employees will be evaluated for existing health conditions that may not be compatible with respirator use. Once medically cleared by the UAB Employee Health, employees may be fit tested for a respirator. For more information about UAB Employee Health and Forms please click here

13.5 COST

The UAB Employee Health Program is provided to UAB employees at no cost to the employee. All expenses (vaccinations, examinations, screenings, allergy evaluations, etc.) are covered by

UAB. If an employee is referred to an allergist for evaluation, the UAB Employee Health Program will cover the evaluation. Any cost associated with medications or treatments recommended by the allergist, however, will be the responsibility of the employee.

Compliance:

The Public Health Service (PHS) requires that an animal care and use program include an UAB Employee Health program for personnel with substantial animal contact. The UAB Employee Health Program has been approved by the UAB Institutional Biosafety Committee and the UAB Institutional Animal Care and Use Committee (IACUC) in conjunction with the UAB Department of Environmental Health and Safety and legal counsel. The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) will evaluate the program periodically to ensure it is functional.

Personnel should be cognizant of the disease hazards associated with using animals for teaching and research. Measures are taken to ensure that the animals brought into UAB are free of disease. Every effort must be taken to prevent the possible transfer of disease from animals to humans and from humans to animals.

All individuals employed by UAB and listed on protocols involving the use of animals for research purposes must enroll in the UAB Employee Health Program and must satisfy all mandatory requirements in order to gain access to animals and facilities housing animals.

For all eligible UAB employees, vaccinations and screenings will be offered based upon job duties and medical history outlined in the UAB Employee Health Enrollment Form and Annual Renewal Forms. If the vaccination or screening is deemed mandatory, the employee must comply with the requirement in order to perform the associated job duties. If the vaccination or screening is recommended, it will be offered to the employee. The employee must either accept or formerly decline in writing (the appropriate form will be supplied by UAB Employee Health).

To schedule an appointment call: (205) 996-7817 or visit UAB Employee Health website here

Table 13.1. Vaccination and Screening Requirements and Recommendations

Work Involves Exposure to	Recommended	Required
Non-Human Primates	• Hepatitis A • Hepatitis B • Current Tetanus • Annual Influenza	• Annual TB Screen • Measles Status (positive immune status required)
Ferrets	• Current Tetanus • Annual Influenza	
All other animals	• Current Tetanus	
Noise above 85 dBA	• Current Tetanus	• Hearing Conservation Program
HAZMAT First Responders	• Current Tetanus	• HAZMAT Physical • Respiratory Protection Program • Applicable Screening Assays
Maintenance	• Current Tetanus • Hepatitis A • Hepatitis B • Annual Influenza • Respiratory Protection Program (required for some employees)	• Annual TB Screen
Material of Human or Non-Human Primate Origin	• Current Tetanus • Hepatitis B	
Mycobacterium tuberculosis Research	• Current Tetanus	• Annual TB Screen
SARS-CoV-2	• Current Tetanus	• Covid19 Vaccination
Neisseria meningitidis	• Current Tetanus	
Risk Group 3 Biologic Agents		• Entrance to room evaluated on a case-by-case basis
Hepatitis C	• Initial titer	• Exit titer
Streptococcus pneumoniae	• Pneumovax	
Zika virus		• Employees of childbearing age must receive counseling
Rabies	• Rabies Vaccination	• Positive immune status required
Polio	• Polio Vaccination	• Positive immune status required

14.0 APPENDICES

Appendix 3.1 Agent Specific Data and Safety Plan Template

Appendix 3.2.a Containment Devices (Engineering Controls)

Appendix 3.2.b Laboratory Autoclaves Safety and Sustainability Guidelines

Appendix 3.3.a UAB Lab-Specific Biosafety Plan Template for BSL-2

Appendix 3.3.b UAB Lab-Specific Biosafety Plan Template for Clinical Trials

Appendix 3.4 ASM Guidelines for Biosafety in Teaching Laboratories

Appendix 3.5 Appendix to the Guidelines for Biosafety in Teaching Laboratories

Appendix 4.1.a Exposure Control Plan Template for Researchers

Appendix 4.1.b Exposure Control Plan Template for Environmental Services and Maintenance

Appendix 4.1.c Exposure Control Plan Template for PD

Appendix 4.2 UAB Campus Medical Waste Management Plan

Appendix 4.3 UAB Exposure Response Flowchart

Appendix 5.1 Example Select Toxin SOP – Diphtheria Toxin

Appendix 5.2 Select Toxin SOP Template

Appendix 5.3 Select Agent Program – Select Toxin Exemption Checklist

Appendix 5.4 Destruction of Select Agent Form (Available on request. Send email to biosafety@uab.edu)

Appendix 5.5 Risk Group 3 Agent Transfer Request Form (Available on request. Send email to biosafety@uab.edu)

Appendix 10.1 Guidance for Transport and Shipping of COVID-19+/ SARS-Co-V-2 Patient Samples at UAB

Appendix 11.1 Spill Response

Appendix 11.2 Spill Clean Up

UAB BIOSAFETY PROGRAM

Environmental Health & Safety
933, 19th St. S. (CH19 # 445)
Email: biosafety@uab.edu
Phone: (205) 934-2487

Revised July 2025