BIOSAFETY MANUAL 2023

3rd Edition

UAB BIOSAFETY SECURITY

ENVIRONMENTAL HEALTH & SAFETY

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

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1.0 POLICY

The University of Alabama at Birmingham

BIOSAFETY POLICY

Effective Date: July 1st, 2021
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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 Committee 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.

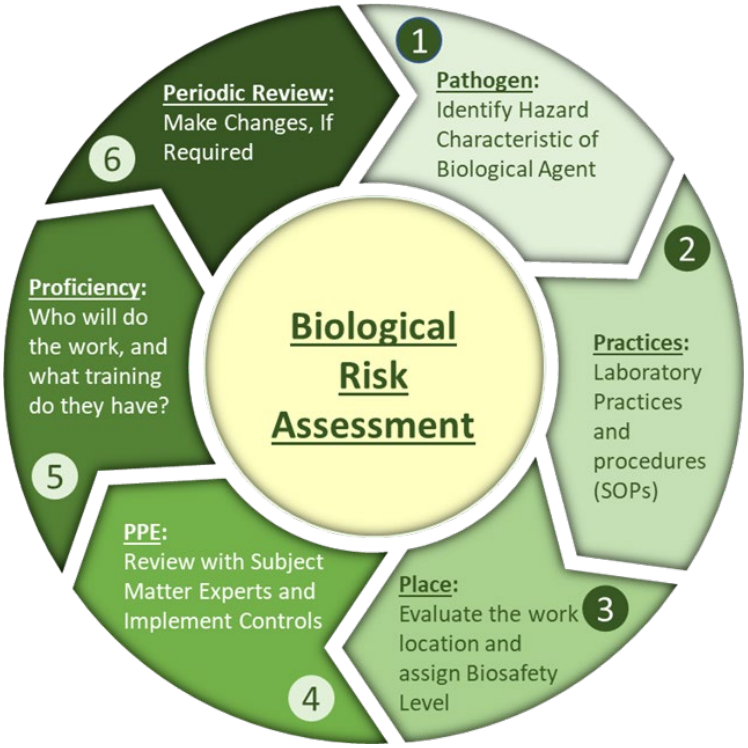
3.0 PRINCIPLES OF BIOSAFETY

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 that provides structure to the risk management process and reinforces an ongoing positive culture of biosafety by following PLAN, DO, CHECK, ACT principle.



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). This is a biological risk assessment template (**Appendix 3.1**) 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	• *Mycobacterium tuberculosis* • Chikungunya virus • SARS-associated coronavirus	• 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 3.1).

- **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.

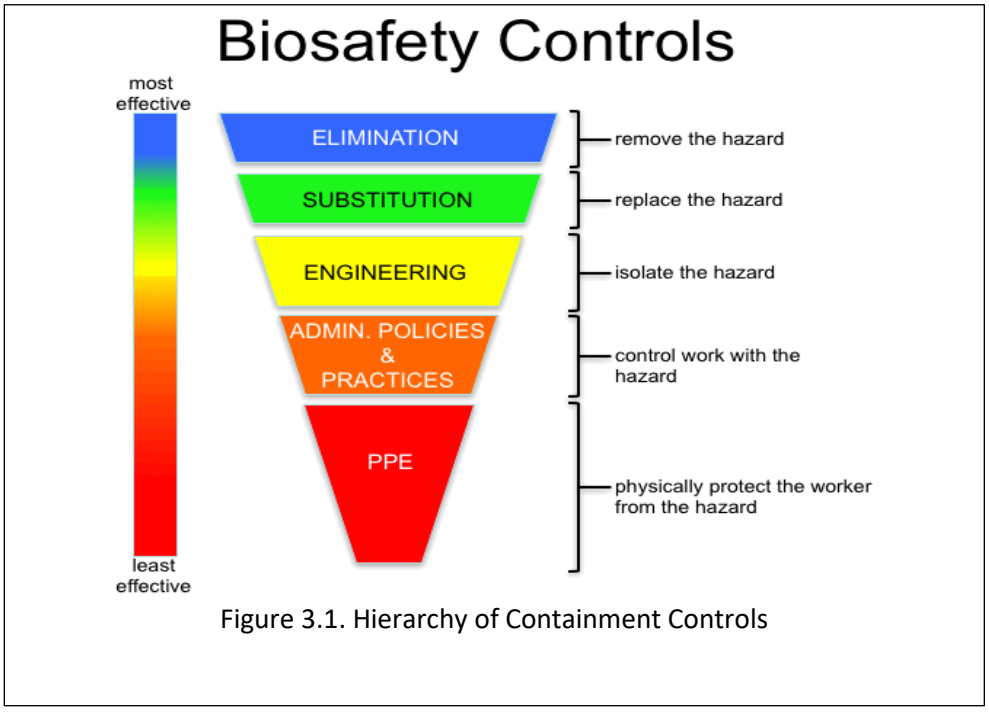


Figure 3.1. Hierarchy of Containment Controls

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 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 SARS-Vo2 virus, West Nile virus, Chikungunya virus, and *Mycobacterium tuberculosis* that causes tuberculosis. Some of the agents worked with at BSL-3 are considered Select Agents, which 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 August 2023) submitted by downloading RSC-EHS Project Registration Form at UAB Research Safety Committee website and sending 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 or (205) 276-5063. 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 ALL UAB Exposure Response Plans.

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 August 2023, the Federal Select Agent Program regulates the possession, use, and transfer of 68 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.

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.

5.3 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
Conotoxins	≤ 100 mg
Diacetoxyscirpenol (DAS)	≤ 10,000 mg
Ricin	≤ 1000 mg
Saxitoxin	≤ 500 mg
Staphylococcal enterotoxins	≤ 100 mg of all subtypes combined
Tetrodotoxin	≤ 500 mg
T-2 toxin	≤ 10,000 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

Justin Roth (Biosafety Officer, ARO): jcroth@uab.edu
Brian LaGory (Responsible Official, RO): blagory@uab.edu

In addition, 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 for safe work with highly hazardous chemicals 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 ALL UAB Exposure Response Plans.

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 any used PPE, disposables, or spill cleanup debris in a hazardous waste plastic bag and autoclave, if susceptible, or route for incineration using a Stericycle burn box.
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) 5th 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 3 – 6% (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-inactivated toxins are manifested as chemical waste according to the chemicals used for inactivation. See the Hazardous Waste page on the EH&S Environmental Management webpage or send email to biosafety@uab.edu for disposal instructions. Complete a Hazardous Waste Manifest form. Email the form to: chemwasteman@uab.edu.

Attach a completed copy of the manifest to the packaged waste box, and retain a copy for your records.

8. In-lab inactivation may not be possible or practical for all toxins. In this case, a consult with UAB's Biosafety Officer (BSO) or Responsible Official (RO) by email biosafety@uab.edu. The RO/ARO will provide a Select Agent Destruction (DSA) Form to be filled out and returned to the RO/ARO for signature. The RO/ARO will sign and return the completed form and make arrangements for pickup and destruction. Attach a completed copy of the form to the packaged waste box, and retain a copy for your records.

   The following table was modified from the BMBL 5th Ed Guidelines for work with toxins of biological origin (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. Contact EH&S for guidance.

- **N –** Indicates "not determined" from available decontamination literature.
- **a –** 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.
- **b –** 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 0.25N NaOH
- **c –** non-burnable waste should be chemically inactivated, manifest all other waste for incineration
- **d –** 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 0.25% NaOCl + 0.025N NaOH for 4 h.
- **e –** 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.
- **f -** Exposure of crude abrin solution and dried abrin to 0.67% NaOCl eliminated over 90% of cytotoxicity within 5 min.

Table 5.2. Inactivation of Biological Toxins

TOXIN	AUTOCLAVE 1hr @ 121°C	NaOCl (30 min)	NaOCl + NaOH (30 min)	Comments
Abrin	Yes	≥0.7% [f]	ND	Decontaminate work surfaces and spills with soap and water; autoclave all waste and disposable materials
Alpha Conotoxin	ND	≥0.5%	10 N NaOH	Decontaminate work surfaces and spills with 0.5% NaOCl for 30 min. 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,
Anthrax Lethal Toxin (PA, LE)	Yes	≥0.5%	ND	Decontaminate work surfaces and spills with ≥0.5% NaOCl for 30 min; autoclave all waste and contaminated disposable materials
Botulinum neurotoxin A-G	Yes[a]	>0.1%	ND	Decontaminate work surfaces and spills with >0.1% NaOCl or 0.25N NaOH for 30 min; autoclave all waste and disposable materials
Brevetoxin (PbTx-2)	No[c]	≥2.5% [b,c,d]	0.25%+0.25 N [b,c,d]	Decontaminate work surfaces and spills with ≥2.5% NaOCl for 30 min; decontaminate and manifest solid and liquid waste (EH&S); contaminated disposables go in a Stericycle burn bin
Cholera toxin	Yes	0.5%	ND	Decontaminate work surfaces and spills with 0.5% NaOCl for 30 min; autoclave all waste and disposable materials
Clostridium perfringens epsilon toxin	Yes	ND	ND	Decontaminate work surfaces and spills with soap and water; autoclave all waste and disposable materials
Conotoxin	ND [c]	0.5% [c]	ND	Decontaminate work surfaces and spills with 0.5% NaOCl for 30 min; decontaminate and manifest solid and liquid waste (EH&S); contaminated disposables go in a Stericycle burn bin
Diacetoxyscirpenol (DAS), Deoxinalenol (DON), Zearalenone (ZEA)	No [c]	≥2.5% [c]	0.25%+0.25 N [c]	Decontaminate work surfaces, and spills with ≥2.5% NaOCl for 30 min; decontaminate and manifest solid and liquid waste (EH&S); contaminated disposables go in a Stericycle burn bin
Diptheria toxin	Yes	0.5%	ND	Decontaminate work surfaces and spills with 0.5% NaOCl for 30 min; autoclave all waste and disposable materials
Microcystin	No [c]	≥0.5% [b,c]	0.25%+0.25 N [b,c]	Decontaminate work surfaces, and spills with ≥0.5% NaOCl for 30 min; decontaminate and manifest solid and liquid waste (EH&S); contaminated disposables go in a Stericycle burn bin
Palytoxin	No [c]	≥0.1% [b,c]	0.25%+0.25 N [b,c]	Decontaminate work surfaces and spills with ≥0.1% NaOCl for 30 min; decontaminate and manifest solid and liquid waste (EH&S); contaminated disposables go in a Stericycle burn bin
Pertussis toxin	Yes	0.5%	ND	Decontaminate work surfaces and spills with 0.5% NaOCl for 30 min; autoclave all waste and disposable materials
Ricin	Yes	>1.0% [b]	>0.1%+0.25 N [b]	Decontaminate work surfaces and spills with >1% NaOCl for 30 min; autoclave all waste and disposable materials
Saxitoxin	No [c,e]	≥0.1% [b,c,e]	0.25%+0.25 N [b,c,e]	Decontaminate work surfaces, and spills with ≥0.1% NaOCl for 30 min; decontaminate and manifest solid and liquid waste (EH&S); contaminated disposables go in a Stericycle burn bin
Shigatoxin and Shiga-like ribosome inactivating proteins	Yes	0.5%	2.5%+0.25 N	Decontaminate work surfaces and spills with 0.5% NaOCl for 30 min; autoclave all waste and disposable materials
Staphylococcal Enterotoxins	Yes[a]	>0.5%	ND	Decontaminate work surfaces and spills with >0.5% NaOCl for 30 min; autoclave all waste and disposable materials
T-2 mycotoxin	No [c]	≥2.5% [b,d]	0.25%+0.25 N [b,d]	Decontaminate work surfaces and spills with 0.25% NaOCl + 0.25N NaOH for 30 min; decontaminate and manifest solid and liquid waste (EH&S); contaminated disposables go in a Stericycle burn bin
Tetanus toxin	Yes	0.5%	ND	Decontaminate work surfaces and spills with 0.5% NaOCl for 30 min; autoclave all waste and disposable materials
Tetrodotoxin	No [c,e]	≥0.5% [b,c,e]	0.25%+0.25N [b,c,e]	Decontaminate work surfaces and spills with ≥0.5% NaOCl for 30 min; decontaminate and manifest solid and liquid waste (EH&S); contaminated disposables go in a Stericycle burn bin

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 Select Toxin SOP - Diphtheria Toxin
- Appendix 5.2 – Select Toxin SOP Template
- Appendix 5.3 – Destruction of Select Agent Form
- Appendix 5.4 – Risk Group 3 Agent Transfer Request Form
- Appendix 5.5 – Select Toxin Exemption Checklist (SA-Ext) form

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 UAB GUIDANCE FOR PRION RESEARCH

6.1 BIOCONTAINMENT FOR PRIONS

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.

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.

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.

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.

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.

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. .

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

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

7.0 BIOHAZARD DISPOSAL, DECONTAMINATION, AND DISINFECTION

7.1 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 incinerated at UAB. 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.

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 Stericylce pickup. These containers are available in a number of sizes and are provided by Stericycle upon request (described in Table 7.1).

- 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 must be secured in an ASTM-D certified red bag before being placed in a Stericycle medical waste transport 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 I0, "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 thoroghly after disposal of waste.

Table 7.1. 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 “Incinerate Only” 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 “Incinerate Only” 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 “Incinerate Only” 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 “Incinerate Only” sticker

Table 7.2. 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	Item
All culture plates and tubes	Solid	Autoclave[b,c]	Autoclave bag	Autoclave	TBO1[e]	All culture plates and tubes
Human/animal cell cultures	Liquid	Autoclave[b,c]/Chemical disinfection	Autoclave bag/flask	Autoclave	TBO1[e]	Human/animal cell cultures
Vaccines-live and attenuated	Liquid	Autoclave	Autoclave bag	Autoclave	TBO1[e]	Vaccines-live and attenuated
Animal carcasses	Solid	N/A	Double bag	Incinerate[d]	TBO1[e], TBO2[e], TBO3[e] or Burn Box[e]	Animal carcasses
Animal body parts	Solid	N/A	Double bag	Incinerate[d]	TBO1[e], TBO2[e], TBO3[e] or Burn Box[e]	Animal body parts
Human body parts, organs, tissues, surgical specimens	Solid	N/A	Double bag	Incinerate[d]	TBO1[e] or Burn Box[e]	Human body parts, organs, tissues, surgical specimens
Vials or tubes of blood or bloody body fluids	Liquid	N/A	Sharps container/red bag	Autoclave	TBO1[e]	Vials or tubes of blood or bloody body fluids
Contaminated[a] solid waste	Solid	Autoclave[b,c]	Autoclave bag	Autoclave	TBO1[e]	Contaminated[a] solid waste
Contaminated[a]plastic-ware	Solid	Autoclave[b,c]	Autoclave bag	Autoclave	TBO1[e]	Contaminated[a]plastic-ware
Disposable contaminated[a] lab clothing	Solid	Autoclave[b,c]	Autoclave bag	Autoclave	TBO1[e]	Disposable contaminated[a] lab clothing
Reusable contaminated[a] lab clothing[f]	Solid	Autoclave[b,c]	Autoclave bag	Autoclave	Send to laundry service	Reusable contaminated[a] lab clothing[f]
Contaminated[a] disposable gloves	Solid	Autoclave[b,c]	Autoclave bag	Autoclave	TBO1[e]	Contaminated[a] disposable gloves
Needles, syringes, scalpel blades	Solid	Autoclave[b,c]	Sharps container	Autoclave	TBO1[e]	Needles, syringes, scalpel blades
Contaminated[a] reusable glassware	Solid	Autoclave[b,c]/Chemical disinfection	Bin with lid	Autoclave	N/A	Contaminated[a] reusable glassware
Disposable lab clothing – no contamination	Solid	N/A	N/A	N/A	N/A	Disposable lab clothing – no contamination
Disposable plasticware – no contamination	Solid	N/A	N/A	N/A	N/A	Disposable plasticware – no contamination
Disposable gloves – no contamination	Solid	N/A	N/A	N/A	N/A	Disposable gloves – no contamination
Medical waste containing radioactive or chemical wastes	Solid or Liquid	Consult with EH&S	Consult with EH&S			Medical waste containing radioactive or chemical wastes
Medical waste containing trace chemo or non-RCRA pharmaceuticals	Solid or Liquid	Consult with EH&S	Autoclave bag	Incinerate[d]	TBO1[e]	Medical waste containing trace chemo or non-RCRA pharmaceuticals
Disposable plasticware – no contamination	Solid	N/A	N/A	N/A	N/A	Disposable plasticware – no contamination

[a]Contaminated refers to waste containing bulk blood, microbes, infectious agents, or other biological agents

[b]Approved or recommended by EH&S

[c]When working with any DNA or RNA recombinants, Dengue virus cultures, West Nile Virus-like particles, verotoxigenic E. coli cultures (e.g.O157:H7), all Hepatitis viruses, Polio virus, pneumococcal species, Streptococcus pneumonia,

mycoplasma species, Lymphocytic choriomeningitis virus (LCMV), HIV cultures or any other easily transmitted human pathogens the waste must be autoclaved prior to placing the waste into the Stericycle container. Refer to IATA Table 3.6 D for a list of other agents that must autoclaved prior to placing waste in a Stericycle container.

[d]Container must be labeled incinerate with Stericycle supplied stickers

[e]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

[f]Do not take contaminated clothing home, contact your supervisor for proper handling and decontamination procedures

[g]BSL-3 laboratories will follow their approved protocols for waste handling and decontamination

Table 7.3. 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 - Sterne	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 “Incinerate Only” 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 7.4. 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 barcode and the current date. Use Stericycle “Incinerate Only” stickers, if applicable	

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 pickup by Stericycle. In order 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.
- All containers must be marked with the biohazard symbol that is readily visible.
- Label full containers with Stericycle bar 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 barcode 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 as long as 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.

7.2 STERILIZATION AND DECONTAMINATION

Sterilization: Any item, device, or solution is considered to be 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 a number of 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 7.5. 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 7.6. 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 7.7. 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.

8.0 TRANSPORT AND SHIPPING OF BIOLOGICAL MATERIALS

8.1 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 8.1, 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 8.1. 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

8.2 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.

8.3 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

8.4 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).

5) *Security*

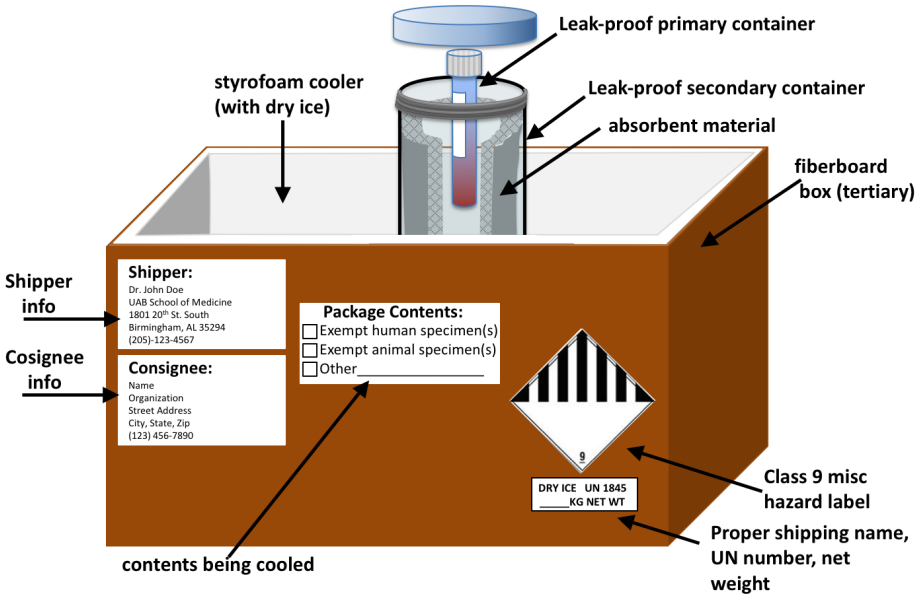
After preparing the package for shipment, the package must remain under the direct control of trained personnel until it is handed over to the carrier. This reduces the chances of tampering, theft, destruction, or invalidating the shipper's signature that signifies the package has been prepared in accordance 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



8.5 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.

8.6 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.

8.7 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.

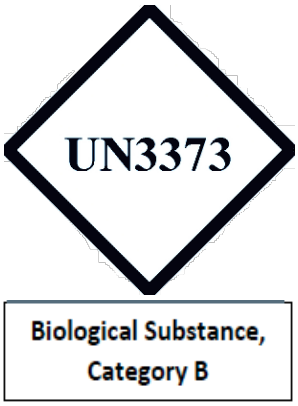
The airline industry is very strict about transporting biological materials. You cannot carry these materials/samples onto a passenger plane no matter now it is packaged. You must use commercial couriers such as UPS, USPS, FedEx, or DHL. There are quantity limitations,

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.

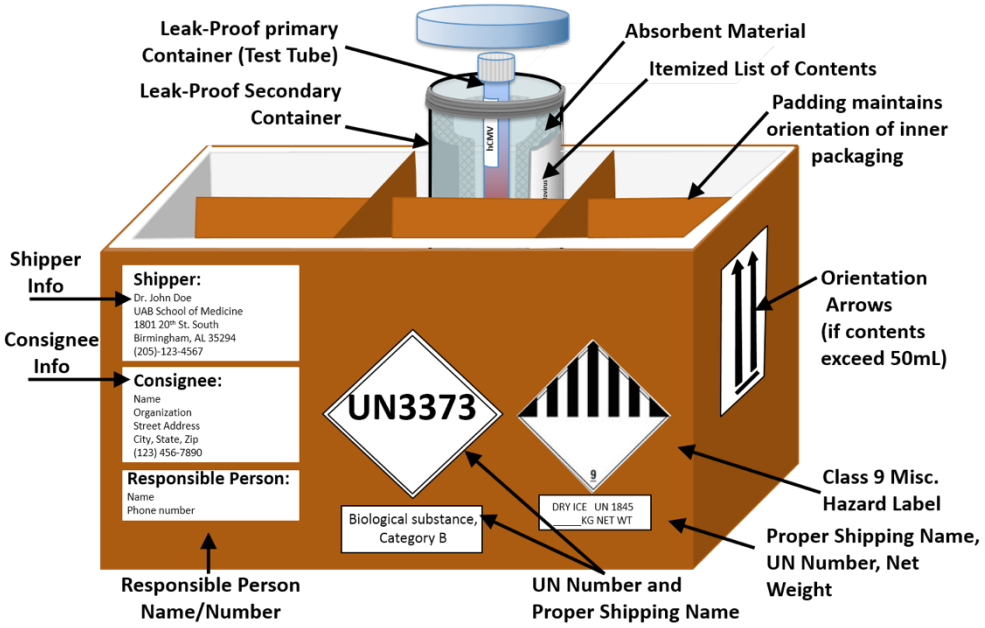
3) Marks and Labels

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.

- 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:

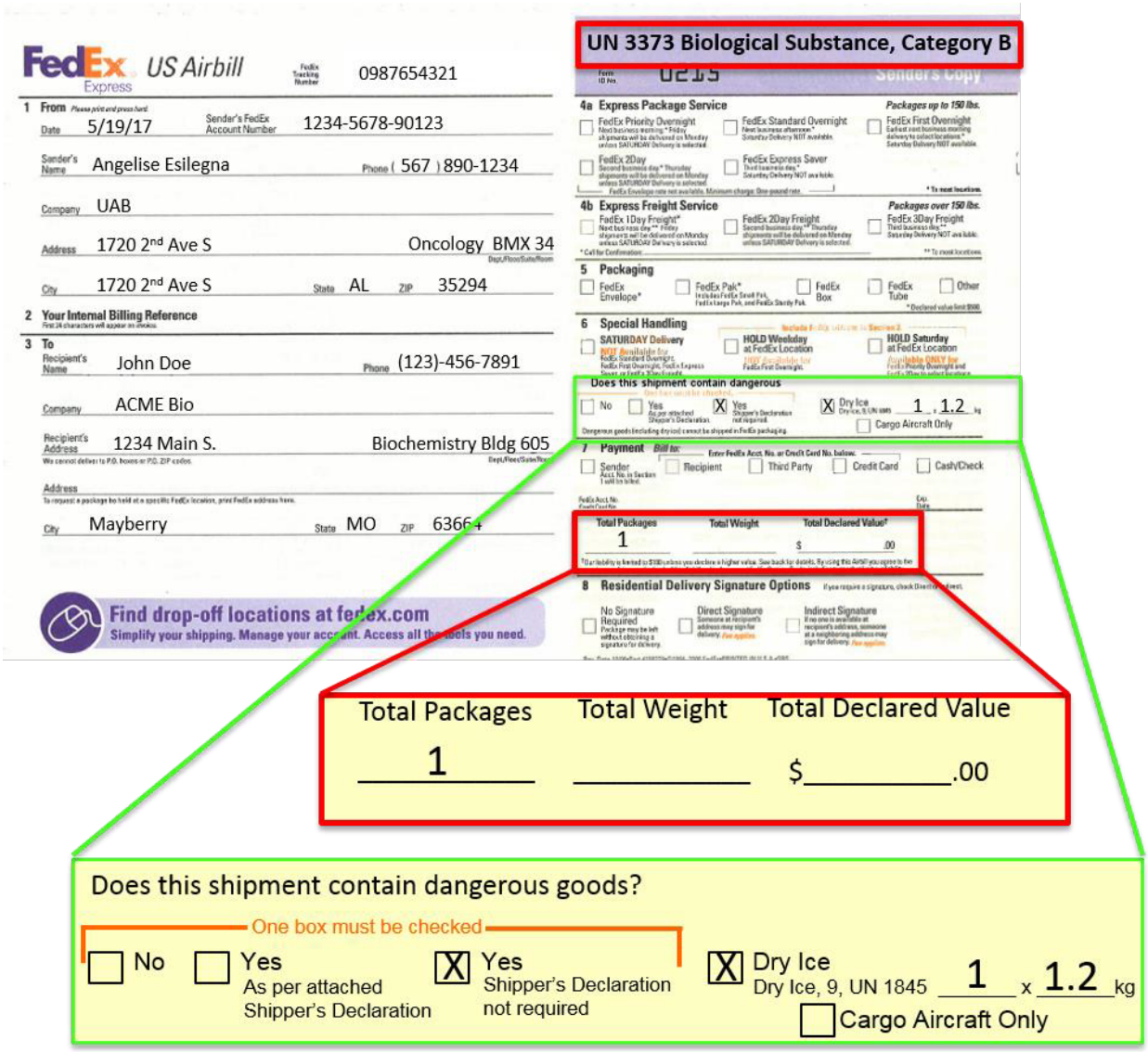
Exports of designated biological agents and toxins having the potential to pose a threat to human, animal, or plant life require a license from the U.S. Department of Commerce Bureau of Industry and Security (BIS). The scope of items subject to this licensing requirement is broader than "select agents," 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:

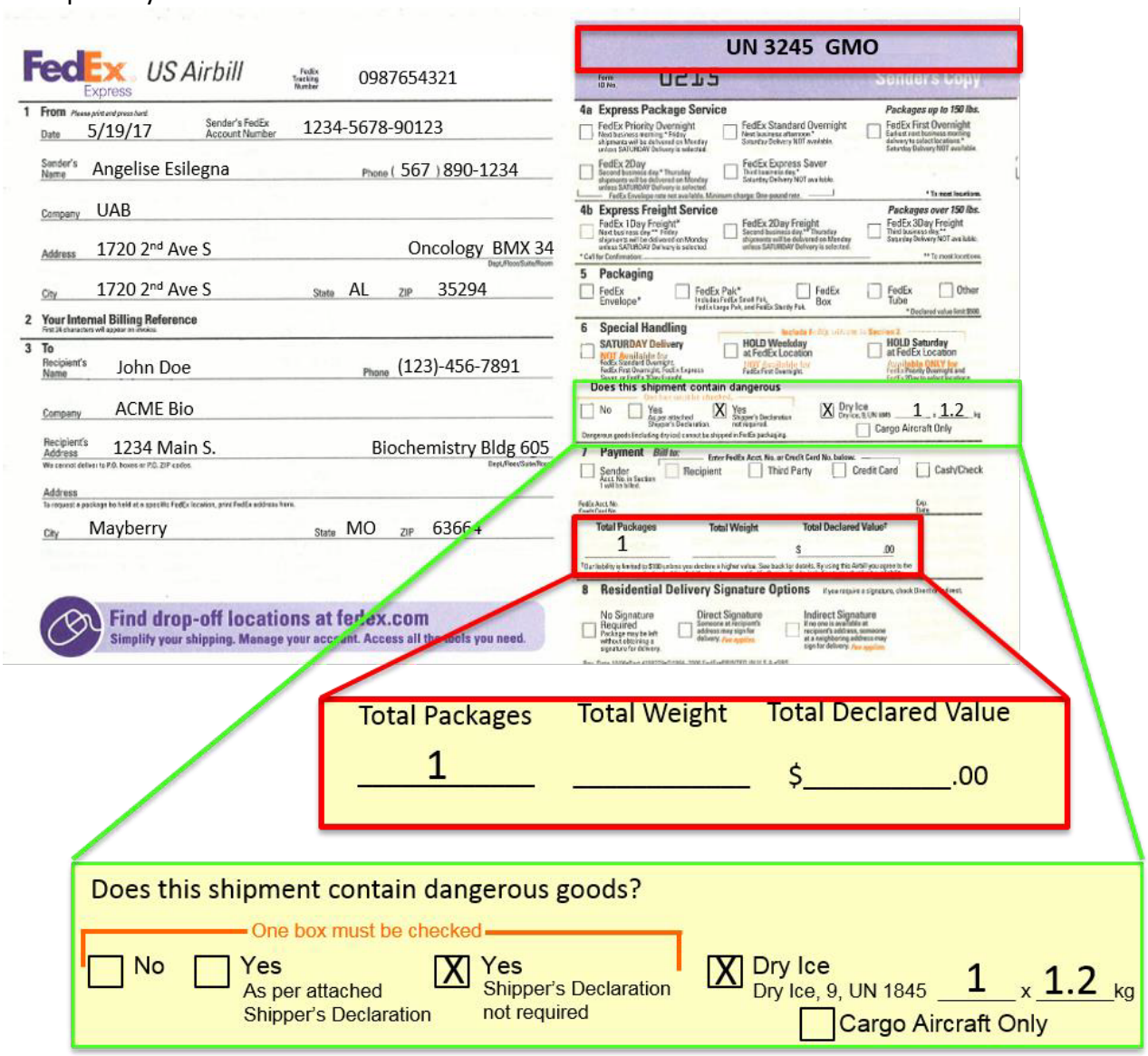
- Designated human, animal and plant pathogens, zoonotic agents, and toxins
- Genetically Modified Microorganisms or genetic elements containing nucleic acid sequences associated with the pathogenicity of controlled organisms or that code for a controlled toxin
- Genetic material and products which might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

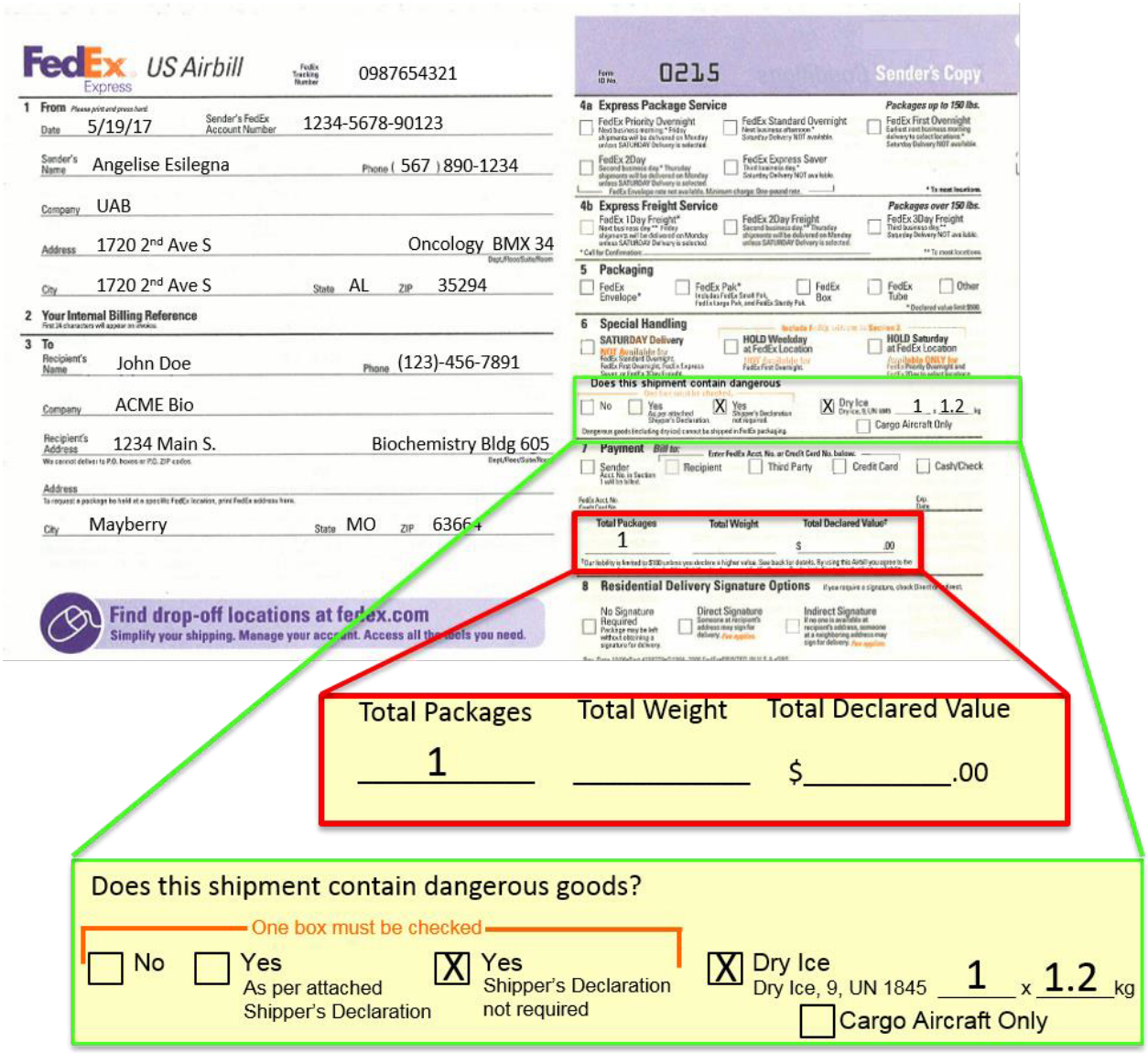
Example waybill for UN 3373:



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

8.8 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

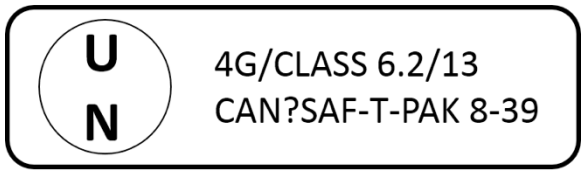
1) Classifying the substance or material

- 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

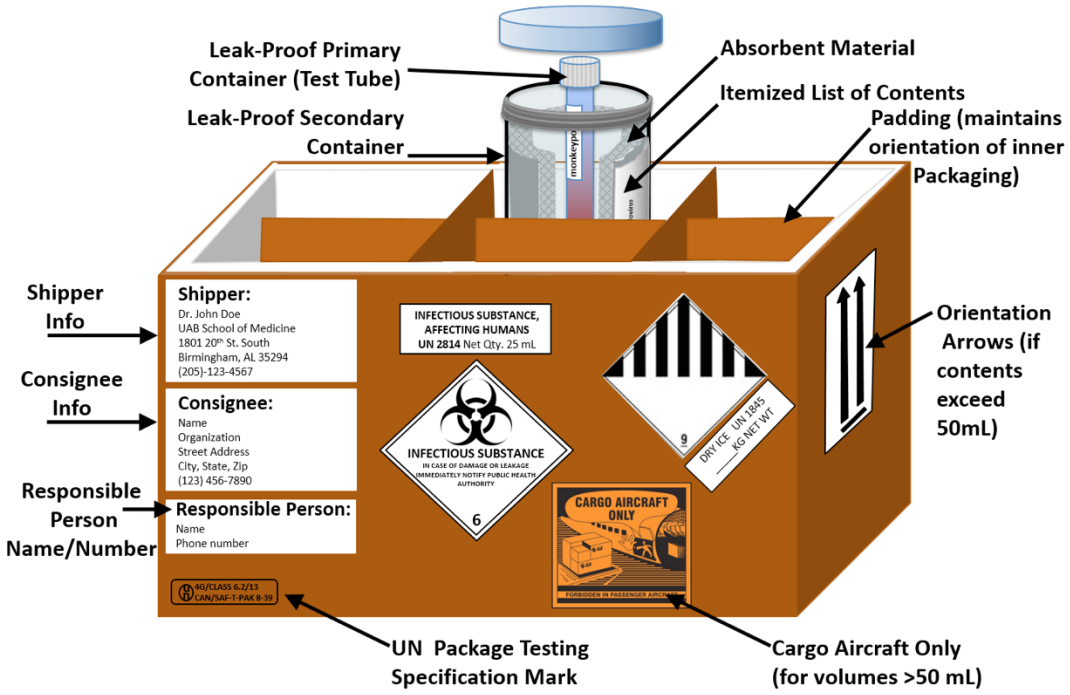
- Packaging components for Infectious Substances, Category A must pass testing requirements as a system, so mixing and matching packaging components from different manufacturer's is not allowed. When choosing the correct packing materials, only use packaging in the tested and certified configuration. 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.
- *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 7 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 8.1 Guidance for Transport and Shipping of COVID-19+/ SARS-Co-V-2 Patient Samples at UAB.

9.0 SPILLS AND EMERGENCY RESPONSE

9.1 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 9.1 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, dust pan 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 8.1 and 8.2 for more information on spill cleanups.

9.2 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 10 minutes after cleanup 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.

9.3 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

9.4 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 in order 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 ALL UAB Exposure Response Plans.

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.

9.5 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.

9.6 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.

Please refer to Appendix 4.3 for ALL UAB Exposure Response Plans.

9.7 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.

10.0 TRAINING

10.1 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.

10.2 BIOSAFETY TRAINING

The following courses may be required for working with infectious biological agents at UAB. Please refer to Table 10.1 for course descriptions and training requirements. For more information and to register for any courses, please visit the UAB Campus Learning System.

Table 10.1. 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**

11.0 UAB EMPLOYEE HEALTH PROGRAM

The UAB Employee Health is designed 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 Renewal Form” is due unless the employee’s job changes or work exposures change, then an “Enrollment Renewal Form” is required. Some employees may require a clinical examination and vaccinations.

11.1 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 Environmental 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
- Individuals from private companies conducting work at UAB
- Visiting Scientists

11.2 ENROLLMENT

The 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 risk assessment notification that 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 Renewal Form is due, unless the employee's job changes or work exposures change, then an updated Enrollment Renewal 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

11.3 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.

11.4 ADDITIONAL SERVICES

Hearing Conservation Program
The purpose of the UAB Hearing Conservation Program is to help protect UAB employees from hearing loss due to occupational noise exposure. Although UAB attempts to control noise exposures on campus, certain operations and workstations may expose faculty and staff to significant noise levels. All personnel who are regularly exposed to occupational noise levels at or exceeding an 8-hour time-weighted average of 85 dBA will be included in the Hearing Conservation Program.
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 Physician, employees may be fit tested for a respirator. For more information about UAB Employee Health and Forms please click here

11.5 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. Costs associated with routine vaccination and/or screening will be covered by the UAB Employee Health Program. 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 UAB employees, vaccinations and screenings will be offered based upon job duties and medical history outlined in the UAB Employee Health Enrollment Form and 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 11.1. 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

12.0 APPENDICES

Updated: November 20th, 2023

UAB Biosafety Program

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

THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM

UAB Biosafety Manual Appendices 12.1

Appendix 3.1
Agent Specific Safety Plan Template

AGENT-SPECIFIC DATA & SAFETY PLAN

BIOLOGICAL AGENT(S):_____

PHYSICAL PROPERTIES:	
MORPHOLOGY (PARTICLE/GENOME)	
STRAINS/VARIANTS (DESCRIBE)	

AGENT RISK FACTORS:					
RISK GROUP LEVEL		☐ RG-1	☐ RG-2	☐ RG-3	
HOST/VECTOR RANGE					
INFECTIOUS DOSE					
MEDICAL OPTIONS		Prophylaxis	Vaccines	Treatments	Surveillance
SEVERITY OF DISEASE	UNTREATED:	☐ Mild	☐ Moderate	☐ Severe	☐ Lethal
	TREATED:	☐ Mild	☐ Moderate	☐ Severe	☐ Lethal
NATURAL MODES OF TRANSMISSION					
POTENTIAL LABORATORY EXPOSURE ROUTES: SOURCE OF EXPOSURE:		☐ Mucosal membranes	☐ Parenteral inoculation or animal bite	☐ Ingestion	☐ Inhalation (droplet/aerosol)
ENVIRONMENTAL STABILITY		☐ Hours	☐ Days	☐ Weeks	☐ Months
GENETIC MODIFICATIONS (DOES THE MODIFICATION (S) ALTER ANY RISK FACTORS?)					
REGIONAL PREVALENCE		☐ Indigenous	☐ Emerging	☐ Exotic	

PROCEDURAL RISK FACTORS:			
ANIMAL MODELS -METHOD OF EXPOSURE -PRODUCTIVE INFECTION?	AEROSOL-PRODUCING PROCEDURES	SHARPS USED	AGENT VOLUME/CONCENTRATION
CULTURE/PROPAGATION METHODS			

DESCRIBE OTHER PROCEDURES THAT MAY POSE A RISK	

CONTAINMENT REQUIREMENTS:

	BIOSAFETY LEVEL	ADDITIONAL CONSIDERATIONS (SPECIAL PRACTICES, SAFETY EQUIPMENT, AND FACILITY SAFEGUARDS NEEDED)
LAB BSL1-3		
ANIMAL FACILITIES ABSL1-3		
POSTED SIGNAGE		
PPE REQUIRED		
DISINFECTANTS & INACTIVATION	**DISINFECTANTS (CONTACT TIME):**	**METHOD OF INACTIVATION**
REQUIRED SAFETY TRAINING	**Required OH&S Safety Courses:** * Training Matrix and Decision Tree: **http://www.uab.edu/ohs/training** ***Classes are on** The UAB Learning System: **http://www.uab.edu/learningsystem**	**Investigator or Lab Provided Training:**

EXPOSURE AND INCIDENT RESPONSE PROCEDURES:

MUCOSAL MEMBRANES	Flush eyes, mouth or nose at eyewash station for 15 minutes	
DERMAL	wash area with soap and water for 15 minutes	
SYMPTOMS		
INCUBATION PERIOD		
MEDICAL RESPONSE	**Treatment for Exposures:** **SEE CURRENT FLOWCHART**	**LIFE THREATENING INJURIES** • Campus phone : dial 911 • Outside line: 934-3535 **TO SEEK MEDICAL ATTENTION AFTER HOURS** • Report to the UAB Emergency Department
SPILL RESPONSE	**Small Spills:** Notify others working in the lab (post sign at entrance). Allow aerosols to settle. Don appropriate PPE. Cover area of the spill with paper towels and apply an EPA approved disinfectant, working from the perimeter towards the center. Allow appropriate contact time before disposal and cleanup of spill materials. Report incident to Biosafety representative at biosafety@uab.edu	
	Large Spills: For assistance, contact Biosafety via EH&S On-Call (205) 917-4766.	
REPORTING	1. Whether or not you're seeking medical attention, ALL incidents are reported to the lab supervisor. **Supervisor Name:** **Emergency contact number:**	

	2. Supervisors report ALL incidents to UAB BSO at biosafety@uab.edu
	3. Supervisors should also report all injuries/exposures requiring medical treatment to HR **PLEASE SEE INSTRUCTIONS AND FORMS FOR ON-THE-JOB-INJURY** **FOR MEDICAL CLAIM COVERAGE, YOU MUST FILL OUT:** 1) An OJI Application for Benefits form, 2) A RELEASE OF INFORMATION FORM, 3.) The Trend tracker Incident Report ***An incident/accident must be reported verbally by the employee to the employee's supervisor as soon as possible but no later than two calendar days following the incident/accident or following the onset of the illness or disease. Your failure to report an incident within two working days may jeopardize your On--the--Job Injury Program benefits.

ADDITIONAL REFERENCES:	
BMBL 6TH EDITION	Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition
CANADIAN MSDS	Pathogen Safety Data Sheets
CDC	https://www.cdc.gov
ABSA	https://my.absa.org/Riskgroups

SAFETY TRAINING DOCUMENTATION:

BY SIGNING BELOW, I VERIFY THAT I HAVE COMPLETED AND UNDERSTAND ALL OF THE SAFETY TRAINING REQUIRED FOR THE PROCEDURES AND WORK WITH THE AGENT LISTED ABOVE

NAME	SIGNATURE	DATE

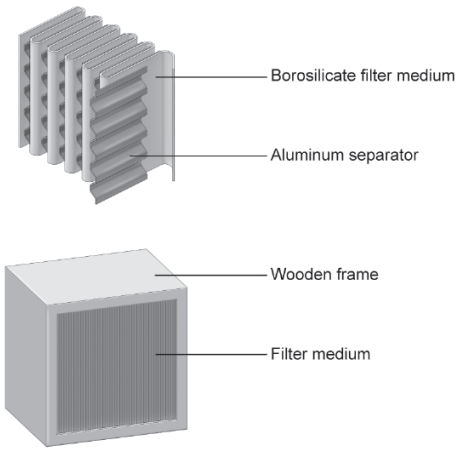
UAB Biosafety Manual Appendices 12.2

Appendix 3.2.a
Containment Devices (Engineering Controls)

Appendix 3.2.a: CONTAINMENT DEVICES (ENGINEERING CONTROLS)

Engineering controls are physical devices designed to isolate hazards and minimize the risk of exposure or release within the laboratory. Biosafety cabinets (BSCs), centrifuge safety cups, and safe needle devices are among the more common engineering controls used for work with infectious agents.

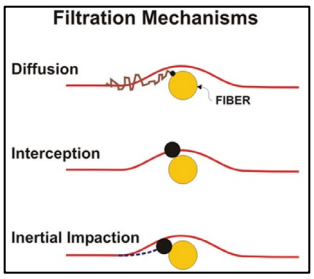
A) Biosafety Cabinets



BSCs are primary containment devices that utilize mechanical air filtration and directional airflow to protect personnel and the environment from exposure/release of the materials being worked with (product) in the cabinet. Most BSCs also protect the product itself, by reducing the risk of cross-contamination of samples or contamination from outside air. At UAB, BSCs are required for work with any RG2 agent, if the work is reasonably anticipated to generate aerosols or droplets. To aid in the understanding and appropriate use of BSCs, an extensive overview of available models, mechanisms, and applications are included below. For more detailed information, refer to Appendix A of the BMBL 6, or call EH&S.

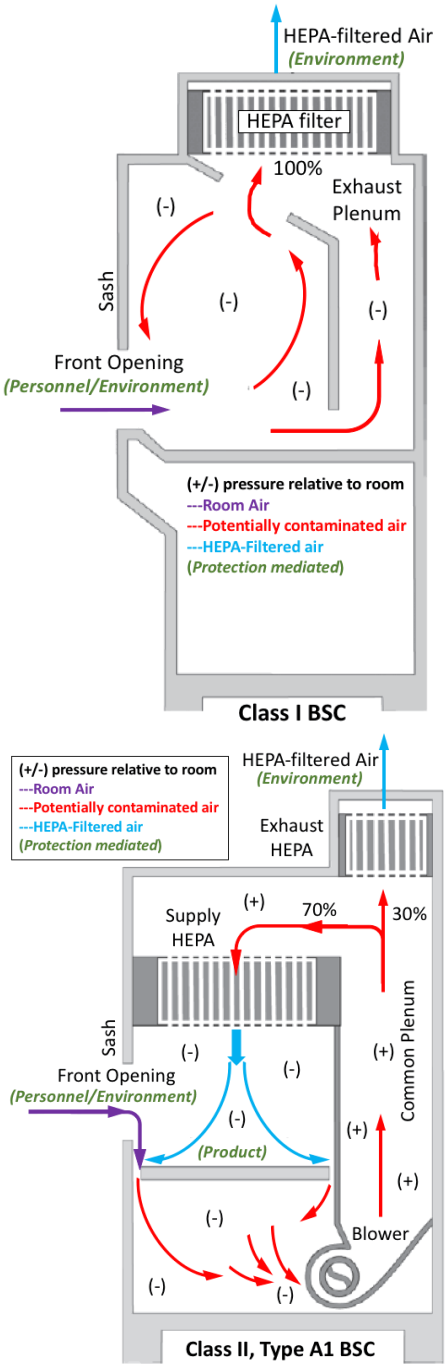
Components of a Biosafety Cabinet:

- **High Efficiency Particulate Air (HEPA) filters:** BSCs rely on specialized HEPA air filters to mediate their protective functions. HEPA filters are defined by their ability to remove 0.3 μm particles at 99.97% efficiency. Other particle sizes are also efficiently removed by HEPA filtration, but the 0.3 μm sized particles are the most difficult to exclude and thereby serve as the metric for defining a "HEPA filter." HEPA filters are typically constructed of pleated mats of randomly arranged borosilicate fibers that are coated with a water-repellant binder. The pore size between these fibers is typically much greater than 0.3 μm, so filtration is achieved through interception, impaction, and diffusion. The filter fiber diameter, thickness of the filter, and the face velocity all directly affect the efficiency of these mechanical filtration mechanisms.
    - **Interception:** is the process by which particles passing within a certain distance of a fiber are sequestered from the air through adherence
    - **Impaction:** larger particles are unable to avoid contact with the filter media and are sequestered by impaction with a fiber.
    - **Diffusion:** describes the movement of much smaller particles, which are affected by gas molecules, resulting in a disordered path through the medium and an increased likelihood of interception or impaction.



- **Directional airflow:** mechanical blowers and pressure differentials drive the directional movement of air currents in a BSC. The front grill of the BSC draws in a mixture of room air and potentially contaminated air from the work surface. This establishes an air "curtain" that prevents aerosols generated in the cabinet from exiting through the front opening. In some BSCs, supply

air is drawn from both the room and from recirculation from the front and rear grills. This supply air passes through a HEPA filter above the cabinet work surface and moves downward before splitting horizontally to the front and rear grills. This laminar airflow serves to protect the product from contamination. Any air leaving a BSC must first pass through a HEPA filter before being exhausted, which serves to protect the environment, if exhausted outdoors, or both personnel and the environment, if exhaust air is recirculated into the laboratory. Different BSCs offer varying degrees of personnel, environmental, and product protection, and are categorized based on the position of the HEPA filter(s), airflow patterns and velocities, and exhaust/recirculation routes.

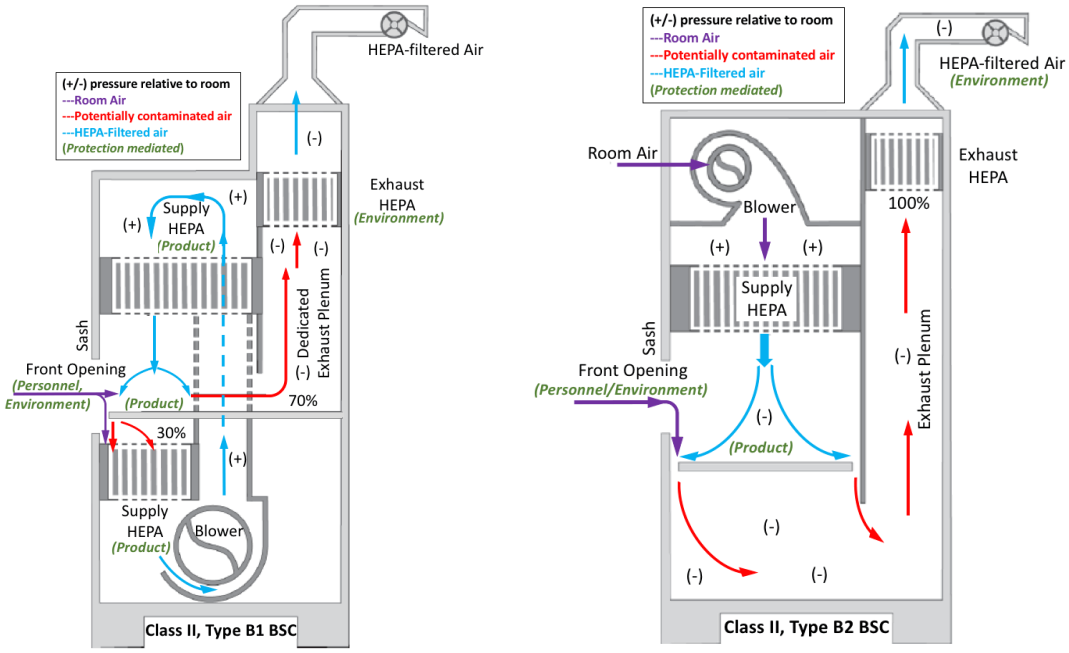


Class/Types of BSCs

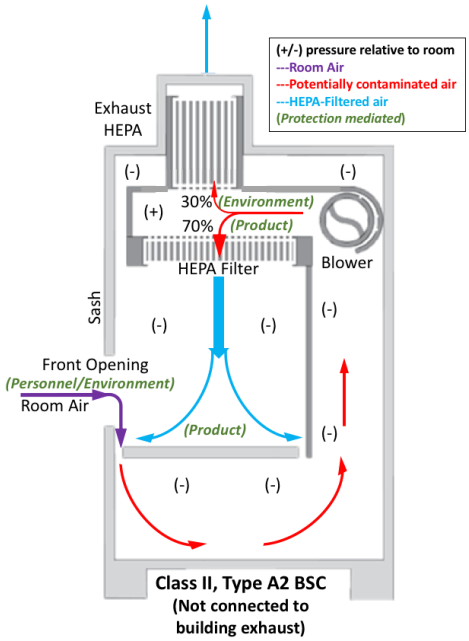
Class I BSCs: Class I BSCs protect the environment and personnel but offer **no product protection**. Environmental protection is achieved through HEPA filtration of exhaust air and personnel protection is achieved by the inward directional movement of unfiltered air through the work opening. These devices are typically used to enclose equipment that has the potential to generate aerosols.

Class II (Types A1, A2, B1, and B2) BSCs: Class II BSCs offer personnel, environmental, and product protection. Personnel protection is achieved by the inward flow of unfiltered air into the front grill. Product protection is achieved by the downward and split-directional laminar flow of HEPA-filtered air into front and rear grills, and environmental protection is achieved via HEPA filtration of air recirculated into the Laboratory (Types A1 and A2 BSCs), discharged via a canopy or thimble connection to the building exhaust (Types A1 and A2 BSCs), or hard ducted exhaust (Types B1 and B2 BSCs).

- **Class II, Type A1:** These BSCs have two HEPA filters, with 70% of air recirculated through the supply HEPA filter back into the BSC work zone, and the remaining 30% of air passed through an exhaust HEPA filter, to be recirculated into the laboratory. Due to potential buildup of toxic vapors from air recirculated into the lab and cabinet, volatile toxic chemicals are not to be used in these BSCs.
- **Class II, Type B1:** The design of these cabinets allows for small quantities of hazardous chemicals to be used. This is due to the fact that 70% of the air flowing downward to the work surface exits through the rear grill and is discharged from the building. The remaining 30%, as well as external room air, is drawn through the front grill and passes through a supply HEPA filter before it is returns across the work surface. Since the air entering the back grill is exhausted, hazardous chemical work should be conducted toward the rear of the cabinet.



- **Class II, Type B2:** These cabinets do not recirculate; all air is exhausted after passing through a HEPA filter. Supply air is drawn through the front grill, HEPA filtered, and passed across the work surface. Volatile chemicals can only be used if the vapors are compatible with the filter medium. Since the exhaust is hard ducted to the building exhaust, the cabinet will become positively pressured if the building exhaust fails. Interlocks are used to shutoff the supply blower when building exhaust rates are insufficient, and flow meters are used to warn users of a failure.
- **Class II, Type A2 (formerly A/B3):** Compared to Class II/A1 BSCs, which may have positively-pressured, biologically contaminated plenums, the plenums of these BSCs are under negative pressure to room or surrounding cabinet envelop, adding additional personnel protection in the event of a leak.



Types of Class II Biosafety Cabinets			Type A1	Type A2	Type B1	Type B2
Containment & Protection	Particulate Protection	Personnel	✓	✓	✓	✓
		Product	✓	✓	✓	✓
		Environment	✓	✓	✓	✓
	gas/vapor Protection	Personnel	X	If exhausted through facility	✓	✓
		Product	X	X	Reduces exposure	✓
		Environment	X	If exhausted through facility	Reduces exposure	If exhausted through facility
Airflow	Cabinet Face Velocity		≥75 FPM	≥100 FPM	≥100 FPM	≥100 FPM
	Nominal %	%Recirculated	70	70	30	0
		%Exhausted	30	30	70	100
Plenum	Biologically Contaminated plenum pressure		Pos. to room	Neg. to room or surrounded by neg. pressure	Neg. to room or surrounded by neg. pressure	Neg. to room or surrounded by neg. pressure
Exhaust Properties	Cabinet Exhaust Source		Common plenum	Common plenum	Exhaust plenum	Exhaust plenum
	Exhaust Destination	To room	✓	✓	X	X
		Vented outside	Optional	Optional	✓	✓
		Connection type	canopy	canopy	Hard ducted	Hard ducted

Proper Use of a BSC:

Pre-work checklist:

- Don (or put on) the appropriate PPE. The PPE should be determined by your protocol.
- If turned off after each use, decontaminate work surfaces exposed to room air
- Airflow and possible contamination will be lower if you do not have to move in and out. Therefore, load the supplies first.
- Turn the biosafety cabinet on and allow it to run for 5 minutes before use.
- Check the inward airflow by securely attaching a piece of tissue to the face hood. The tissue should be pulled in toward the cabinet.
- Make sure the sash is at the certification levels posted on the BSC.
- Adjust seat height so that the bottom edge of the sash is level with your underarms.

Working in the BSC:

- Always designate a clean side and a dirty side. Work from clean to dirty, and work on centerline of work surface. Note the location of discard trays and how other items are positioned to avoid compromising the airflow.
- Work on the approximate centerline. This is the recommended best location to maintain the integrity of proper airflow.
- Move slowly and deliberately into and out of the biosafety cabinet. Slow and deliberate movement has very little effect on the airflow, but rapid and sudden movements can disrupt the airflow dramatically causing issues with contamination.
- Avoid blocking the front grill. When front grill is blocked, airflow can be disrupted. Blocking the front grill also allows the room air to enter the biosafety cabinet.
- Place lab supplies and materials inside the biosafety cabinet. Place them in a location where the airflow is not disrupted.

Post-work Checklist:

- Disinfect all of the items to be removed from the cabinet
- Remove all waste products and place in appropriate receptacles
- Wipe down the interior of biosafety cabinet with an appropriate disinfectant
- Allow cabinet to run for 10 - 15 minutes before shutting off
- If you are using a UV light, make sure you still follow proper procedures. A UV light will not destroy all microbes, so an appropriate disinfectant must be used. UV lights should be wiped down at least once per week when the light is off.

BSC Care and Maintenance:

- **Decontamination:** Surface decontamination of a BSC is conducted using a disinfectant that is active against the agents being used. Chemical compatability with the stainless steel surfaces is also a concern. If corrosive disinfectants are used, the surfaces are typically rinsed with water following the appropriate contact time with the disinfectant. Full decontamination of a biosafety cabinet is not performed on a regular basis, as it typically requires paraformaldehyde gas or vaporized hydrogen peroxide (VHP) to ensure the HEPA filter is thoroughly disinfected and these chemicals pose their own exposure risks. BSCs that have only been used for product protection (i.e., no biohazardous work) do not need to be disinfected. A full decontamination is required for the following situations:

  • The BSC was used for work with biohazardous materials and it is being decomissioned or moved to the surplus warehouse
  • The BSC was used for work with biohazardous materials and repair work is needed that may expose service technicians

  BSCs are rarely a source of sample contamination unless the filter is not working properly (fails certification). Requests for in-house BSC decontamination services to address sample contamination issues will receive low priority until a consult with Biosafety has been conducted. Biosafety representatives will work with laboratories to ensure all other potential sources of contamination are addressed before recommending decontamination of a BSC (e.g., contaminated refrigerators, incubators, and waterbaths, or poor sterile technique).

  Certification: Class II biosafety cabinets are regulated by the National Sanitation Foundation (or NSF). The certification procedures listed here have been mandated by NSF and the NIH. Certification procedures assure the user that the protection factors of personnel, product, and environment are maintained by verifying that the down flow velocities, in-flow velocities, and HEPA filters are within specification. EH&S representatives are responsible for BSC certification across campus, upon request. Contact EH&S at biosafety@uab.edu to schedule an appointment or make inquiries.

  BSCs must be recertified:
  - After the unit has undergone repairs that necessitate re-certification
  - After a unit has been installed or relocated
  - At least annually thereafter

  The IBC may require work with specific agents (RG2 or higher) to only be conducted in a BSC. In this case, the BSC certification must be valid for active work to continue. If EH&S representatives find a BSC with an expired certification, the PI will be notified, and a sticker will be placed on the BSC indicating it is not to be used for personnel protection. Continued

use of an uncertified BSC for personnel and/or environmental protection is reportable to the IBC.

Animal cage change station:

Animal cage change stations are used to reduce animal allergen exposures to users, ARP staff during cage changes or normal animal husbandry practices. Animal cage change stations should not be used for cage changes and animal husbandry practices at ABSL-2 and higher (work with infectious agent or biological hazard or chemicals) due to an increased risk of exposure to users, ARP staff and maintenance personnel. Cage changing of infectious agent administered animals must be performed inside Biosafety cabinet. Follow Animal Use Safey Information (AUSI) guidelines recommended by Institutional Biosafety Committee. Animal cage change stations must be certified annually.

B) Centrifuge Safety

Many researchers are conscientious of the physical hazards associated with centrifugation, but fail to realize the potential risk of creating infectious aerosols. Engineering controls have been devised to accommodate centrifugation of infectious samples, but there are important safety processes to consider before, during, and after centrifugation, outlined below.

Before centrifugation

- Train all potential users on proper operating procedures, review the user manual.
- Use only rotors compatible with the centrifuge. Check the expiration date for ultracentrifuge rotors.
- Check rotors, bottles, and tubes for cracks/deformities before use.
- Clean and dry the rotor, tubes, and spindle after use.
- Examine O-rings and replace if worn, cracked, or missing.
- Never overfill centrifuge tubes (don't exceed 75% capacity).
- Always cap tubes before centrifugation.
- Always balance buckets, tubes, and rotors properly.
- Check that the rotor is seated on the drive correctly, close the lid on the centrifuge, and secure it.
- When using swinging bucket rotors, make sure that all of the bucket positions are filled and correctly hooked to move freely.

During centrifugation

- Keep the lid closed at all times during operation. Never open a centrifuge until the rotor has stopped.
- Do not exceed safe rotor speed.
- The operator should not leave the centrifuge until full operating speed is attained and the machine appears to be running safely without vibration.
- Stop the centrifuge immediately if an unusual condition (noise or vibration) begins and have user check load balances.

After centrifugation

- Allow the centrifuge to come to a complete stop before opening.
- Wear gloves to remove rotor and samples, see Glove Selection and Use.
- Check inside of centrifuge for possible spills and leaks, clean centrifuge and rotor thoroughly if necessary.
- Wash hands after removing gloves.

Centrifuging infectious materials or potentially-infectious samples

Safety procedures above, plus:

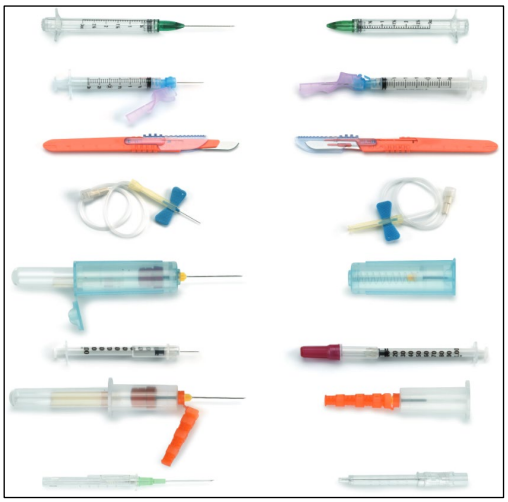
- Place a biohazard label on the centrifuge.
- Include centrifugation procedures and decontamination plans in lab SOPs.
- Always wear gloves when handling tubes or rotors.
- Avoid the use of celluloid tubes with biohazards. If celluloid tubes must be used, an appropriate chemical disinfectant must be used to decontaminate them.
- Always use sealed safety cups, safety buckets, or sealed rotors with O-ring as secondary containment, if available, or required by IBC.
- Fill centrifuge tubes, load into rotors, remove from rotors, and open tubes within a biological safety cabinet. Wipe exterior of tubes or bottles with appropriate chemical disinfectant prior to loading into rotor or bucket. Seal rotor or bucket, remove outer gloves, and transport to the centrifuge.
- If sealed safety cups are not used, wait at least 10 minutes after the run to allow aerosols to settle before opening the centrifuge. Check for possible spills or leaks. For spills of infectious materials, see Lab-specific Safety Plan for response procedures.
- Decontaminate centrifuge interior, safety cups or buckets, and rotors if tube breakage occurs. See Lab-specific Safety Plan for response procedures.

Centrifuge Maintenance

Moisture, chemicals, strong cleaning agents, and other substances can promote corrosion of centrifuge parts and cause centrifuge failure. The following are general maintenance recommendations:

- Follow manufacturer instructions for maintenance and cleaning.
- Keep the centrifuge clean and dry.
- Cleanup all non-infectious spills immediately. Lab-specific Safety Plan for response procedures.
- Decontaminate the rotor after use with biological materials.
- Never clean rotors and associated parts with abrasive wire brushes.
- Store the rotor upside down in a dry place, with lids or plugs removed, to prevent condensation.
- Remove adapters after use and inspect for corrosion.
- Inspect rotor regularly. Remove rotors from use that show any sign of defect, and report it to a manufacturer's representative for inspection.
- For high-speed rotors, maintain a log book to track the speed and spin time for each use, and discard rotors according to the manufacturer’s recommendations.

C) Engineering Controls for Sharps



“Sharps” is a broad term to describe any object capable of causing percutaneous injury, including but not limited to, needles, scalpels, microscope slides, capillary tubes, Pasteur pipettes, scissors, and broken glass or plasticware with sharp edges. Biomedically-contaminated sharps have the added infection and health risk to both the user and others who may come in contact with them before final disposal. Whenever possible, administrative policies should seek to eliminate or reduce the use of sharps (e.g., substitution of glassware with platicware). When sharps are required for infectious disease research, specialized devices that reduce the risk of percutaneous injury/exposure may be available. These engineering controls include needleless systems, retractable/self-sheathing needles or scalpel blades, and disposable scalpels.

The containers used for disposing of contaminated sharps are also a form of engineering control. Only approved sharps containers can be used for disposing of biomedical sharps waste. These containers must be:

- leak-proof
- non-breakable
- rigid
- puncture-resistant
- autoclavable
- chemically resistant, as required
- adequate to contain the sharp items
- labelled with the appropriate warning logo
- secured with a non-removable lid that does not allow access to the disposed material is preferred.
- disposed as biohazardous waste through UAB waste vendor.

Consult EH&S at biosafety@uab.edu if you have questions about sharps safety controls or disposal.

D) Aerosol Management Systems for Fluorescence Activated Cell Sorting (FACS)

Flow cytometers are the instruments that provide measures of the quantitative properties of single cells, one cell at a time. Cytometers can evaluate cell size and the fluorescence properties of cells by creating droplets. Based on the scatter and florescence properties, the populations of cells of interest, can be sorted into a sample receptacle by applying a charge to the droplets. Specimens analyzed through cell sorting core facilities can be broadly sourced and may contain known or unknown pathogens from human or animal sources. During the sorting process, pressurized liquid samples create droplets of cell suspension. These droplets are generated in large concentrations. Data suggests droplets are within the respirable size range and may be associated with infective pathogens. Based on these factors, safety procedures should be adopted in order to mitigate the risks of exposure to cell sorter operators and other laboratory workers.

Safety recommendations outlined in SECTION 3 PRINCIPLES OF BIOSAFETY: BSL2 (including all PPE, primary barriers, facility enhancements) should be followed for laboratories performing cell sorting. Since it is not possible to test cell lines for every possible human pathogen or to assert that they are pathogen-free, and due to the potential for aerosol exposure during cell sorting, human cell lines should be sorted using biosafety precautions appropriate for human blood and body fluids, i.e. BSL2. Ideally, flow cytometry and cell sorting equipment should be housed in an annually certified BSC. However, due to cost and BSC size limitations, alternative means of containment are often implemented for use with cell sorting devices.

Many devices utilize aerosol management systems, to aid in the containment of aerosols, by evacuating the sort collection chamber. These systems use vacuum attachments to rapidly evacuate aerosols through am ultra-low penetrating air filter (99.99% efficiency down to particles 0.1 microns in size) during routine sorting or analysis. Care should be taken to regularly check

vacuum lines, pumps, and filters. Loss or degradation of any component may result in a positively pressured sorting chamber and lead to a potential environmental (laboratory) release of aerosols.

Laboratory managers or PI's (including core facilities) should maintain containment devices according to manufacturer suggestions. Special attention should be paid to any indicated filter malfunctions or expirations. Annual safety audits may be conducted by EH&S at any core facility. Please contact EH&S Biosafety at biosafety@uab.edu for questions or assistance.

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Appendix 3.2.b
Laboratory Autoclaves Safety and Sustainability Guidelines

LABORATORY AUTOCLAVE: SAFETY and SUSTAINABILITY GUIDELINES

I TRAINING AND USAGE

1. All personnel in the laboratory should receive hands-on training before using an autoclave.
2. Each administrative unit should develop standard operating procedures for their autoclave uses and maintain a training record.
3. A log sheet should be maintained that captures the user, the program, and the purpose (reagent/instrument sterilization, or waste decontamination).
   a. If the autoclave is being used to sterilize waste, the procedures must be validated after 40 hours of run time. The log sheet is required to track this usage to ensure validations are being conducted.
4. Always use separate runs for clean and dirty items.
5. Anyone who generates, handles, or signs for removal of medical waste at UAB is required to complete **Medical Waste Management for Labs** (ID: E-7VR7VE) every three years (or if regulations change).

II ENERGY SAVING

1. Limit autoclave usage during regular hours. Try to avoid using autoclave during afterhours and weekends.
2. Keep a schedule of planned autoclave times so users can maximize the load of each run.
3. Avoid using longer times and higher temperatures than required.
4. Consult with Biosafety to determine if your waste requires autoclaving prior to Stericycle pick-up.

III AUTOCLAVING LIQUIDS and SOLIDS

1. Liquids should be sterilized using the liquid cycle. Dry loads such as lab ware and biohazard waste should be treated using the gravity cycle.
2. Do not overfill the bottle with more than 2/3rd of liquid. Always loosen the caps before loading to avoid shattering.
3. Wear appropriate personal protection equipment (PPE) such as heat resistant gloves, lab coat, safety glasses).
4. Check plastic materials to ensure that they are compatible with the autoclave. Instruments and surgical tools should be autoclaved in appropriate pouches, not biohazard bags.

IV CHEMICALS

1. Never autoclave flammable, combustible, reactive, corrosive, volatile, toxic, acids, bases, organic solvents or radioactive materials.
2. Unusual chemical smells and liquid leaks coming from autoclave should be immediately reported to responsible person mentioned on autoclave.

V BEFORE AND AFTER LOADING AUTOCLAVE

1. Before using the autoclave check for items left from the previous run.
2. Clearly label all materials with the date of autoclaving and any relevant information.
3. Use sterilization indicators on the containers to ensure steam sterilization is achieved.
4. Never place containers directly on the rack or autoclave floor. Always use secondary containers to capture spills. A small amount of water in the bottom of the secondary container helps for uniform heating, and it facilitates cleaning of solutions that overflow during the run.
5. Allow sufficient space between items to allow steam penetration. Make sure autoclave is full but do not overload.
6. Never attempt to open the door while the autoclave is in operation.
7. Always verify the door is secured before starting the cycle.
8. Make sure that jacket pressure gauge is reading 0 PSI before opening the door.
9. Open the door slowly and keep your head, face, and hands away from the door.
10. Never try to forcibly open the door of an autoclave. The autoclave door may not be opening because it has not yet fully depressurized or is still in the midst of a cycle. Attempting to open the autoclave door while it is hot and pressurized can result in severe injuries.
11. Wear Appropriate PPE while opening door.
12. If possible, put the autoclave in standby mode after removing items from the autoclave.

VI MAINTENANCE

1. Regular maintenance and calibration of the autoclave can ensure optimal performance and reduce energy consumption.
2. If the autoclave is not operating properly, post a sign to alert others not to use it, and notify the responsible person, as designated on the autoclave.

VII WASTE MANAGEMENT

1. Autoclaved waste should be discarded as per institutional guidelines. All Category A waste must be autoclaved before it is offered to Stericycle as “medical waste.”
2. If you need guidance, please Contact EH&S Biosafety if you are not familiar with those guidelines. biosafety@uab.edu

VIII ACCIDENT RESPONSE

1. Post Exposure/Injury Response Procedures near the autoclave.
2. Report accidents to supervisors immediately so proper medical attention and insurance coverage is assured. Report all injuries/exposures to Human Resources via the On-the-job-injury Program.

Autoclave Training Log Sheet

By signing below, I indicate that I have received proper training in how to safely handle the autoclave and I read and understand the autoclave safety information. I will adhere to the policy, hazards, requirements, safe work practices, and accident reporting outlined in the guidelines.

Building Name		**Room Number**	
Autoclave Name		**Autoclave Model**	

Training Date	Trainee	Trained by	Principal Investigator

Autoclave Training Log Sheet

Training Date	Trainee	Trained by	Principal Investigator

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

LAB SPECIFIC BISAFETY PLAN TEMPLATE FOR BSL-2

INCIDENT RESPONSE FOR THE _____LABORATORY

Hazard Communication

Risk Group 2 (RG2) infectious agents are used in this laboratory. RG2 agents are associated with disease that can cause infection of varying severity (rarely lethal). Host immunity is usually capable of controlling the infection and preventable or therapeutic interventions are often available. If you are immune compromised, you may be at greater risk for an infection if exposed.

Standard Microbiological Practices

1. Access to areas containing RG2 agents is limited or restricted by the Principal Investigator.
2. Persons must wash their hands after working with RG2 agents and before leaving the room where there are utilized.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in areas containing RG2 agents. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:
    - Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
    - Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
    - Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
    - Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.
6. Wear appropriate PPE while handling pathogen and perform all procedures to minimize the creation of splashes and/or aerosols.
7. Decontaminate work surfaces after completion of work and after any spill or splash of RG2 agents with appropriate disinfectant.
8. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport.

- Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
- Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.

9. A sign incorporating the universal biohazard symbol must be posted at the entrance to areas where RG2 agents are present. The sign must include the biosafety level, the name and phone number of the supervisor (or other responsible personnel). RG2 agent information should be posted in accordance with the institutional policy.
10. An effective integrated pest management program is required.
11. The supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur.
12. 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 (205-996-7817) to schedule a consult to determine what measures need to be taken to assure that they are adequately protected in the laboratory environment.

BSL–2 Containment:

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 facility include HIV, HBV, and HCV.

BSL-2 facilities require the same standard microbial practices as BSL-1 facilities, with enhanced measures due to the potential risk of human disease. Personnel working in BSL-2 areas are expected to take greater care to prevent exposures through percutaneous injury, ingestion, or mucous membranes. In addition to BSL-1 requirements, the following special practices are added for facilities designated as BSL-2:

Special Practices:

1. All persons entering the area must be advised of the potential hazards and meet specific entry/exit requirements. A "Biosafety Level 2" sign, with the biohazard symbol, the agents present, and the requirements for entry must be placed at each entrance.
2. Personnel must be provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory.
3. UAB dose not bank serum samples from at-risk personnel.
4. A facility-specific biosafety manual (this document) must be prepared and adopted as policy. The biosafety manual must be available and accessible.

- The supervisor must ensure that personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.

5. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
6. Equipment that may be exposed to RG2 agents should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.
7. Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
8. Equipment must be decontaminated before repair, maintenance, or removal from the area.
9. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the facility-specific biosafety manual. All such incidents must be reported to the supervisor. Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.
10. Animal and plants not associated with the work being performed must not be permitted in the areas where RG2 Agents are stored, dispensed, or administered.
11. All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a BSC or other physical containment devices.

Safety Equipment:

1. Properly maintained BSCs, other appropriate personal protective equipment, or other physical containment devices must be used whenever:
   - Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, infusion, and harvesting samples.
   - High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.
2. Appropriate personal protective equipment (PPE) must be worn (Specify PPE requirements):
   - ***Protective coats, gowns, smocks, or uniforms*** specified for use in the area must be worn while working with hazardous materials. Remove protective clothing before leaving the BSL-2 designated areas (e.g., cafeteria, library, and administrative offices). Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is recommended that protective clothing not be taken home.
   - ***Eye and face protection*** (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of RG2 AGENTS or other hazardous materials when these materials must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse.
   - ***Gloves*** must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Gloves must not be worn outside the BSL-2 designated area. In addition, BSL-2 facility workers should:
     - Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.

- Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the BSL-2 designated area.
- Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated waste. Hand washing protocols must be rigorously followed.

Facilities:

1. The facility doors should be self-closing and lockable, according to the institutional policies.
2. A sink and eyewash station should be readily available. The sink should be located near the exit.
3. The BSL-2 facility should be designed so that it can be easily cleaned and decontaminated.
   - *Carpets* and rugs are not permitted.
   - Furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
   - Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
   - Chairs used in RG2 agents work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
4. An autoclave or an alternative method of decontamination is available for proper disposals.
5. Biohazard warning signs should be placed on all equipment used for processing and storage of RG2 AGENTS samples.

Agent-Specific Safety Practices and Procedures:

Please include an Agent-Specific Safety Data Plan for each agent (or group of agents) requiring specific handling or response procedures (See example)

Incident Response Plan

1. Is there an SOP for cleanup and reporting (Disinfectant used, contact time, reporting contact numbers)?
2. Exposure Response: Is there an exposure response plan?

References:

1. SOP #
2. SOP #
3. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. National Institutes of Health.
4. Laboratory Biosafety Level Criteria, Biosafety in Microbiological and Biomedical Laboratories, Ed. 6th. Centers for Disease Control and Prevention and the National Institutes of Health.

ENVIRONMENTAL HEALTH AND SAFETY

AGENT-SPECIFIC SAFETY PLAN

BIOLOGICAL AGENT(S): HUMAN IMMUNODEFICIENCY VIRUS (HIV)

PHYSICAL PROPERTIES:	
MORPHOLOGY (PARTICLE/GENOME)	**Family: Retroviridae, Genus: Lentivirus. ssRNA, enveloped icosahedral nucleocapsid, of approximately 100 to 110 nm in diameter.**
STRAINS/VARIANTS (DESCRIBE)	**Strains: HIV-1 and HIV-2.**

AGENT RISK FACTORS:					
RISK GROUP LEVEL		☐ RG-1	☐ RG-2	☒ **RG-3**	
HOST/VECTOR RANGE					
INFECTIOUS DOSE					
MEDICAL OPTIONS		Prophylaxis **NA**	Vaccines **Experimental**	Treatments **Antiretroviral agents from 5 drug classes are currently available to treat HIV infection**	Surveillance **NA**
SEVERITY OF DISEASE	UNTREATED:	☐ Mild	☐ Moderate	☒ Severe	☐ Lethal
	TREATED:	☐ Mild	☒ Moderate	☐ Severe	☐ Lethal
NATURAL MODES OF TRANSMISSION		**Blood transfusion from an infected donor, needle sharing by infected injection-drug users, receptive anal intercourse, and percutaneous needle injuries.**			
POTENTIAL LABORATORY EXPOSURE ROUTES: SOURCE OF EXPOSURE:		☒ Mucosal membranes **Spills, Splashes, Contaminated gloves**	☒ Parenteral inoculation or animal bite **Needlesticks, Sharps, Exposures to open wounds**	☐ Ingestion **NA**	☐ Inhalation (droplet/aerosol) **NA**
ENVIRONMENTAL STABILITY		☐ Hours	☒ Days	☐ Weeks	☐ Months
GENETIC MODIFICATIONS (DOES THE MODIFICATION (S) ALTER ANY RISK FACTORS?)		**NA**			
REGIONAL PREVALENCE		☒ Indigenous	☐ Emerging	☐ Exotic	

PROCEDURAL RISK FACTORS:			
ANIMAL MODELS -METHOD OF EXPOSURE -PRODUCTIVE INFECTION?	AEROSOL-PRODUCING PROCEDURES	SHARPS USED	AGENT VOLUME/CONCENTRATION
	Pipetting, Sonicating, Centrifuging, Vortexing	**Needles, Scalpels**	
CULTURE/PROPAGATION METHODS	**Projects will not involve large volumes of concentrated stock.**		
DESCRIBE OTHER PROCEDURES THAT MAY POSE A RISK	**Other Bloodborne pathogens present in human tissues.**		

CONTAINMENT REQUIREMENTS:			
	BIOSAFETY LEVEL	ADDITIONAL CONSIDERATIONS (SPECIAL PRACTICES, SAFETY EQUIPMENT, AND FACILITY SAFEGUARDS NEEDED)	
LAB BSL1-3	**2**	**BSL3 PRACTICES AND PROCEDURES (DOUBLE GLOVES, EYE PROTECTION, AND LAB COAT OR CLOSED-FRONT GOWN**	
ANIMAL FACILITIES ABSL1-3	**NA**		
POSTED SIGNAGE	**RESTRICTED ACCESS: HIV, HUMAN TISSUES (BLOODBORNE PATHOGEN)**		
PPE REQUIRED			
DISINFECTANTS & INACTIVATION	DISINFECTANTS (CONTACT TIME): **FRESH 2% GLUTARALDEHYDE, 1% SODIUM HYPOCHLORITE**	METHOD OF INACTIVATION **HIV is inactivated by ultraviolet (UV) light, in close proximity; cell-free medium; pH higher or lower than 7.1; temperature higher than 60 C for at least 30 min.**	
REQUIRED SAFETY TRAINING	Required OH&S Safety Courses: **HS200, BIO301L, BIO303, BIO304, BIO500** * **Training Matrix and Decision Tree**: http://www.uab.edu/ohs/training *Classes are on **The UAB Learning System**: http://www.uab.edu/learningsystem	Investigator or Lab Provided Training: **Agent-specific training (this document) and supervisor attestation of proficiency**	

EXPOSURE AND INCIDENT RESPONSE PROCEDURES:	
MUCOSAL MEMBRANES	**Flush eyes, mouth or nose at eyewash station for 15 minutes**
DERMAL	**wash area with soap and water for 15 minutes**
SYMPTOMS	**DUE TO IMMUNODEFICIENCY, PATIENTS SUCCUMB TO VARIOUS FUNGI, PARASITES, BACTERIA, AND/OR VIRUSES AND ARE PRONE TO CERTAIN TUMORS**

INCUBATION PERIOD	**VARIABLE**	
MEDICAL RESPONSE	**Treatment for Exposures: See Flowchart** **SEE CURRENT FLOWCHART**	**LIFE THREATENING INJURIES** • Campus phone : dial 911 • Outside line: 934-3535 **TO SEEK MEDICAL ATTENTION AFTER HOURS** • Report to the UAB Emergency Department • Or call (205) 934-4011 and ask to have the Employee Health nurse on call paged
SPILL RESPONSE	**Small Spills:** Notify others working in the lab (post sign at entrance). Allow aerosols to settle. Don appropriate PPE. Cover area of the spill with paper towels and apply an EPA approved disinfectant, working from the perimeter towards the center. Allow appropriate contact time before disposal and cleanup of spill materials. Report incident to Biosafety **representative at biosafety@uab.edu**	
	Large Spills: For assistance, contact Biosafety via EH&S On-Call (205) 917-4766.	
REPORTING	**1.** Whether or not you're seeking medical attention, ALL incidents are reported to the lab supervisor **Supervisor's name:** **Emergency contact number**:_____)	
	2. Supervisors report ALL incidents to UAB Biosafety at **biosafety@uab.edu**	
	3. Supervisors should also report all injuries/exposures requiring medical treatment to HR PLEASE SEE INSTRUCTIONS AND FORMS FOR ON-THE-JOB-INJURY FOR MEDICAL CLAIM COVERAGE, YOU MUST FILL OUT: 1) An OJI Application for Benefits form, 2) A RELEASE OF INFORMATION FORM, 3.) The Trend tracker Incident Report ***An incident/accident must be reported verbally by the employee to the employee's supervisor as soon as possible but no later than two calendar days following the incident/accident or following the onset of the illness or disease. Your failure to report an incident within two working days may jeopardize your On--the--Job Injury Program benefits.	

ADDITIONAL REFERENCES:	
BMBL 6TH EDITION	Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition
CANADIAN MSDS	Pathogen Safety Data Sheets
CDC	https://www.cdc.gov
ABSA	https://my.absa.org/Riskgroups

SAFETY TRAINING DOCUMENTATION:

BY SIGNING BELOW, I VERIFY THAT I HAVE COMPLETED AND UNDERSTAND ALL OF THE SAFETY TRAINING REQUIRED FOR THE PROCEDURES AND WORK WITH THE AGENT LISTED ABOVE

NAME	SIGNATURE	DATE

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

Standard Operating Procedure (SOP) / Biosafety Protocol

Study Title:	
Principal Investigator:	
Investigational Product:	
Site:	

Table of Contents

Contents

1.0 Hazard Communication Statement

1.1 The Investigational Product:

Please provide a general description of the investigational product, including any genetic alterations:

1.2 Risk Associated with the Investigational Product:

Please provide a description of the risks associated with the investigational product, in regard to exposures to personnel or release into the environment:

2.0 Standard Biological Safety Practices

Investigators are recommended to follow prudent standard biological safety practices and precautions when handling infectious human specimens in clinical laboratories. The following precautions are adapted from the NIH and CDC publication, Biosafety in Microbiological and Biomedical Laboratories, 6th ed.,:

A) Good laboratory Practices:

1) Access to areas containing the investigational product is limited or restricted by the Principal Investigator.
2) Persons must wash their hands after working with potentially hazardous materials and before leaving the room where they are utilized.
3) Gloves should not be worn in hallways or common areas outside of laboratory designated for work.
4) Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in areas containing the investigational product. Food must be stored outside of these areas in cabinets or refrigerators designated and used for that purpose.
5) Mouth pipetting is prohibited; mechanical pipetting devices must be used.
6) Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:
    a) Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
    b) Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
    c) Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

d) Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.

7) Perform all procedures to minimize the creation of splashes and/or aerosols.

8) Work surfaces should be covered with absorbent sheets to collect splashes and drips to minimize the spread of contamination.

9) Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.

10) Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport:

a) Materials to be decontaminated outside of the immediate work area must be placed in a durable, leak proof container and secured for transport.

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

c) A sign incorporating the universal biohazard symbol must be posted at the entrance to the work area when infectious agents are present. Posted information must include: the biosafety level, supervisor's name (or other responsible personnel), telephone number, agent information should be posted in accordance with the institutional policy.

11) An effective integrated pest management program is required.

12) The supervisor must ensure that study personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Study personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all study personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

B. Special Practices (BSL2):

1) All persons entering the area containing the investigational product must be advised of the potential hazards and meet specific entry/exit requirements. BSL2 signage should be posted on laboratory door with information about the pathogen.

2) Study personnel must be provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present. For UAB campus employees, that surveillance is achieved through enrollment in Employee Health.

3) UAB currently does not collect and store serum samples from at-risk personnel involved in clinical trials.

4) A study specific biosafety manual (**this document**) must be prepared and adopted as policy. The biosafety manual must be available and accessible.

5) The supervisor must ensure that study personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.
6) Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
7) Potentially infectious substances should be labelled properly before storage.
8) Potentially infectious samples should be inactivated before moving out of facility for downstream processing.
9) Appropriate disinfectant to inactivate or decontaminate the biological agent should be prepared and used as per manufacturers recommendations.
10) Equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.
    a) Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
    b) Equipment must be decontaminated before repair, maintenance, or removal from the work area.
11) Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the biosafety manual. All such incidents must be reported to the supervisor. Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.
12) Animal and plants not associated with the work being performed must not be permitted in the work area.
13) All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a biosafety cabinet (BSC) or other physical containment devices.
14) Investigators are recommended to keep a hard copy of SOP's that are used to manipulate infectious agent in the laboratory.

C. Safety Equipment (Primary Barriers and Personal Protective Equipment):

1) Properly maintained BSCs, other appropriate personal protective equipment, or other physical containment devices must be used whenever:
    a) Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.
    b) High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.
2) Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. Remove protective clothing before leaving the work area. Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is recommended that laboratory clothing not be taken home.
3) Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the

microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated waste or decontaminated before reuse. Persons who wear contact lenses in should also wear eye protection.

4) Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the work area designated for infectious agents. In addition, BSL-2 workers should:
   a) Change gloves inside out when contaminated, glove integrity is compromised, or when otherwise necessary.
   b) Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the work area.
   c) Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated waste. Hand washing protocols must be rigorously followed.
5) Respiratory Protection: Investigators should wear N-95 respirator to prevent exposure to infectious agents if recommended by regulations. Personnel must be medically evaluated, fit-tested, and trained prior to using respiratory protection. Contact Employee Health for more information.

D. Facilities (Secondary Barriers) Intended for Use with Infectious Agents

1) Doors should be self-closing and have locks in accordance with the institutional policies.
2) Work areas involving the investigational product must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.
3) The work area should be designed so that it can be easily cleaned and decontaminated. Carpets and rugs are not permitted in areas utilized in conjunction with infectious agents.
4) Furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
   a) Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
   b) Chairs in conjunction with infectious agents must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
5) Windows that open to the exterior are not recommended. However, if windows exist that open to the exterior, they must be fitted with screens.
6) BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled areas, and other possible airflow disruptions.
7) Vacuum lines should be protected with liquid disinfectant traps.
8) An eyewash station should be readily available. If an eye wash is not available, compensate with use of eye protection such as safety glasses or goggles when utilizing infectious agents.

9) There are no specific requirements for ventilation systems. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the facility.

10) HEPA filtered exhaust air from a Class II BSC can be safely recirculation back into the facility if the cabinet is tested and certified at least annually and operated according to manufacturer ’s recommendations. BSCs can also be connected to the facility exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection. Provisions to assure proper safety cabinet performance and air system operation must be verified.

11) A method for decontaminating all wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

3.0 Safety Practices for Study Procedures

3.1 Receiving and storage:

Please describe how the IP will be stored:

- Building:
- Room:
- Fridge/Freezer/Cabinet:
- Primary containment (e.g., glass stoppered vials):
- Access Controls to IP (room / storage equipment):
- Signage: A biohazard placard will be displayed at the entrance to the rooms while the investigational product is stored, dispensed or administered. The placard will be provided by UAB Biosafety, if needed.
- PPE for unpacking:

3.2 Dispensing

The IP will be prepared and dispensed according to the protocol and Sponsor's instructions contained in the study Brochure and associated pharmacy SOPs.

Please describe how the IP will be dispensed:

- Building:
- Room:
- Signage: Biohazard (BSL-2)
- Describe dispensing methods:
  - PPE for dispensing
  - Biosafety Cabinet

3.3 Transport to Clinic Area

For transport, the IP will be packaged in a sealed, durable, leak-proof container with a biohazard label.

3.4 Administration

Please describe how the IP will be administered:

- Building:
- Room:
- Signage
- PPE for administration
- Signage: Biohazard (BSL-2)

3.5 Work Surface Disinfection

To disinfect surfaces, site specific procedures/protocols will be followed, or the surface will be wiped with a clean cloth dampened with an EPA-approved disinfectant/detergent or an approved germicidal wipe (such as 10% bleach).

Please describe the products used for routine surface disinfections, or in response to a spill:

Disinfectant used in pharmacy: _____ Contact time: _____
Disinfectant used in clinic: _____ Contact time: _____

3.6 Waste Disposal

The UAB Hospital Medical Waste Policy will be adhered to for all UAB-affiliated clinics. After the IP is administered, all contaminated items considered to be medical waste are stored in leak-proof red bags or sharps containers. Medical waste may also include unused IP. Sharps containers are disposable, leak-proof, and puncture resistance, and are located as near as feasible to all areas where contaminated needles and sharps are generated and may be found. The containers are red or labeled with biohazard symbol. Per UAB Biosafety policy, needles shall not be recapped, bent, sheared, broken, removed from disposable syringes or otherwise manipulated by hand prior to disposal.

Specify how the unused IP will be disposed:

Bags and containers of medical waste are closed prior to removal to prevent spillage during handling and transporting of waste. Disposal of all regulated waste is in accordance with State and Federal regulations. All hospital/clinical waste that has been designated for disposal in red bags will be collected by Stericycle and transported off site for processing.

Location for medical waste storage for Stericycle pick-up: _____

4.0 Incident Response Plan

Study personnel must be adequately trained to respond properly to potential incidents such as spills of the investigational product as well as occupational exposures (e.g. needle sticks) and environmental releases (spills outside the facility). Spills involving rDNA are of particular concern, not only from a safety standpoint, but from a regulatory standpoint. All spills shall be rectified, as discussed below, with the added procedure of reporting the incident to the Biosafety Officer (BSO).

4.1 Incident / Spill Response

Biohazard spills can potentially be a danger to human life. Therefore, taking the proper steps to contain and render the spill of harm is vital to preventing exposure. This section will discuss 3 types of spills.

1. Minor Spills Within the BSC (less than 10ml of infectious material)
2. Major Spills Within the BSC (more than 10ml of infectious material)
3. Spills Outside the BSC (any amount of infectious material)

MINOR SPILLS WITHIN THE BSC: If a spill occurs, while the BSC is running, double glove and decontaminate the spill with approved disinfectant (e.g. 10% bleach solution) allowing for a minimum 30-minute contact time. All absorbent material used to clean-up the spill will be discarded into a biohazard bag within the BSC and autoclaved.

MAJOR SPILLS WITHIN THE BSC: Aspirate the liquid using a pipette into a waste container within the BSC. Then follow the process of decontamination for minor spills. Contact EH&S Biosafety at biosafety@uab.edu for consultation or help with larger spills.

SPILLS OUTSIDE THE BSC (PRIMARY CONTAINMENT): Spills that occur outside primary containment are urgent, due to the risk of aerosols. Individuals are to notify all staff within the lab and evacuate immediately discarding contaminated PPE and/or clothes into a biohazard barrel (utilizing the emergency shower and eyewash station if necessary). Users will follow their incident response procedures and contact EHS for further instructions.

EXPOSURE RESPONSE: Incidents resulting in droplet exposure to mucous membranes (eyes, nose or mouth) or other areas of the body will be rinsed with water for 15 minutes using the appropriate washing station (e.g. lab sink, eyewash, safety shower). In the event of a stick and/or cut with contaminated sharps, personnel will wash the affected area with soap and water for 15 minutes.

4.2 Incident Reporting

All exposed (or potentially exposed) personnel will report the incident to the Principle Investigator (PI), Human Resources (OJI), and to the EH&S Biosafety Officer. Any exposures to human materials potentially contaminated with BBP should be followed up immediately to Employee Health. See “Table I Reporting Contacts,” below, and “Appendix I UAB Exposure Response Flowchart” at the end of this document for instructions and contact information.

Researchers must be made aware that all spills and accidents, even if relatively minor, require reporting. Any significant problems, violations, or any significant research-related accidents and illnesses must be also reported to the UAB Institutional Biosafety Committee (IBC) and the National Institutes of Health Office of Science Policy (NIH OSP) at NIHGuidelines@od.nih.gov within 30 days. Medical evaluation, surveillance, and treatment are provided, as appropriate, and written records are maintained. Spills and accidents which result in overt exposures to Risk group 2 or higher organisms, or organisms containing recombinant or synthetic DNA, must be immediately reported to the PI, the BSO, the IBC, and the OSP.

Table I. Reporting Contacts

Contact	Name	Primary	Secondary
Principal Investigator			
UAB EHS		205-934-2487	
UAB Biosafety Officer	Justin Roth	205-934-7488	205-276-5063
UAB Responsible Official	Brian LaGory	205-996-0119	
UAB Employee Health (Bloodborne pathogen exposures)	Needlestick Team	205-934-3411 Ask for “needlestick team”	

5.0 Training Guidelines

The standards for performing research involving genetic engineering or gene therapy are codified in *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines). NIH Guidelines are promulgated by the NIH Office of Science Policy (OSP) and call for oversight of genetic engineering and gene therapy research at the site level by Institutional Biosafety Committees (IBCs). NIH Guidelines places the responsibility for supervision of research personnel on the Principal Investigator. The PI is responsible for ensuring personnel are aware of the risks associated with the research as well as the pertinent safety practices for the safe conduct of research. The PI must ensure personnel have the appropriate training, personal protective equipment (PPE) and safety equipment. The PI is

responsible for ensuring research personnel are aware of how to respond to incidents such as exposures, spills or violations of NIH Guidelines and report them to the PI and the IBC.

Course Title:	Course ID in Campus LMS:	Frequency:
Basic Biosafety	ID: E-5VNQVM	Once
Bloodborne Pathogen Training	ID: E-E04XR0	Annually
Medical Waste Management for Labs	ID: E-7VR7VE	Every 3 yrs, or earlier, if regulations change
NIH Guidelines - Recombinant or Synthetic Nucleic Acid Molecules	ID: E-G0381J	Once
Shipping with Dry Ice	ID: E-P0WZ0J	Every 2 yrs, or earlier, if regulations change
Shipping Biological Substances, Category B • Includes Exempt Human Specimens	ID: E-E1LZV4	Every 2 yrs, or earlier, if regulations change
Shipping Infectious Substances, Category A	ID: E-71KDVJ	Every 2 yrs, or earlier, if regulations change

6.0 References

Provide any references cited in the safety protocol / SOP such as the study protocol, safety data sheets or medical journal articles.

Laboratory Biosafety Level Criteria, Biosafety in Microbiological and Biomedical Laboratories, Ed. 6th., Centers for Disease Control and Prevention and the National Institutes of Health

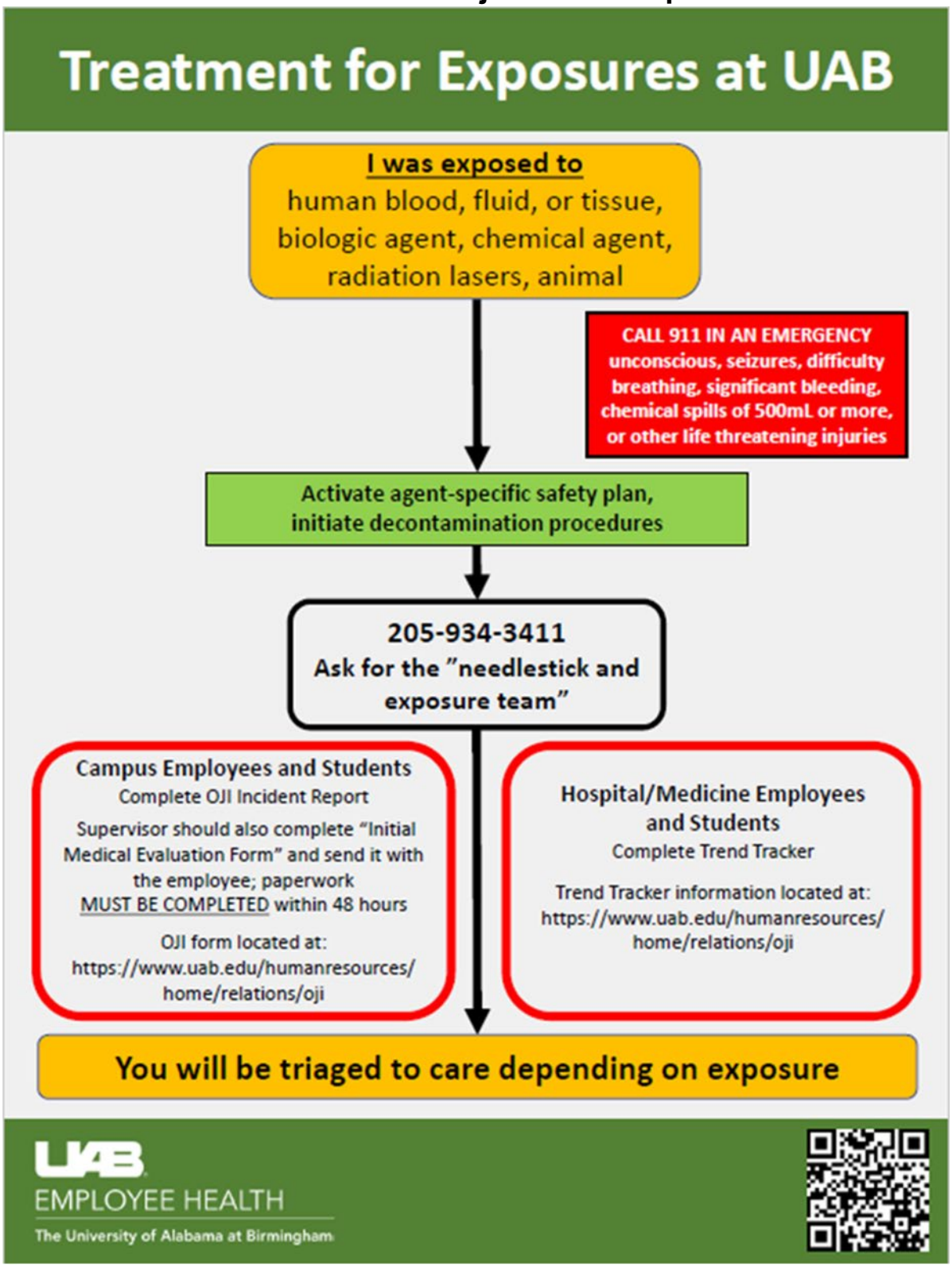
NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. National Institutes of Health

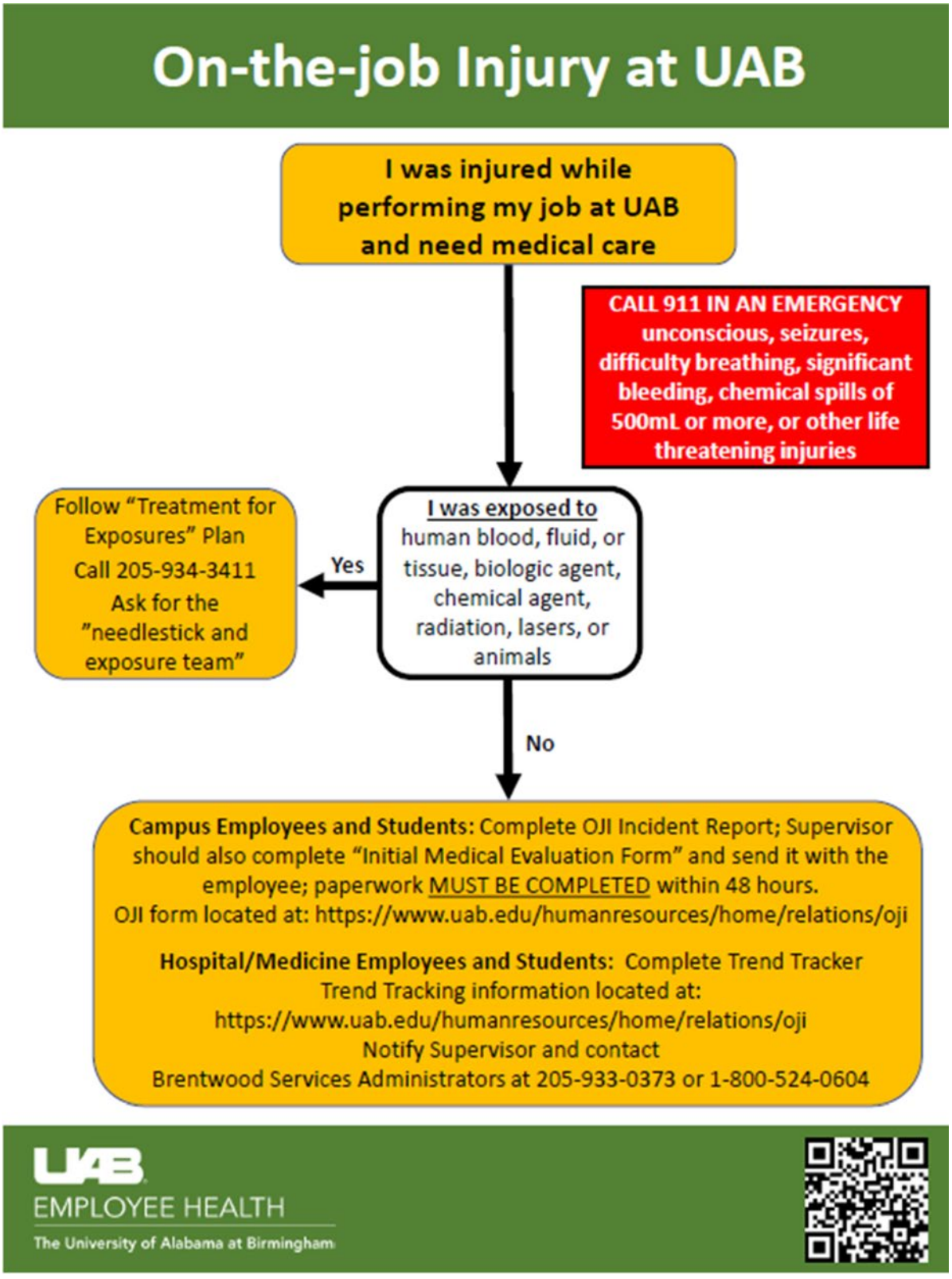
7.0 Signatures of Study Personnel

The study personnel signing below attest to having read the safety protocol, completed the listed training, and will follow the precautions described therein. This includes study personnel who handle, transport, administer or dispose of the investigational product.

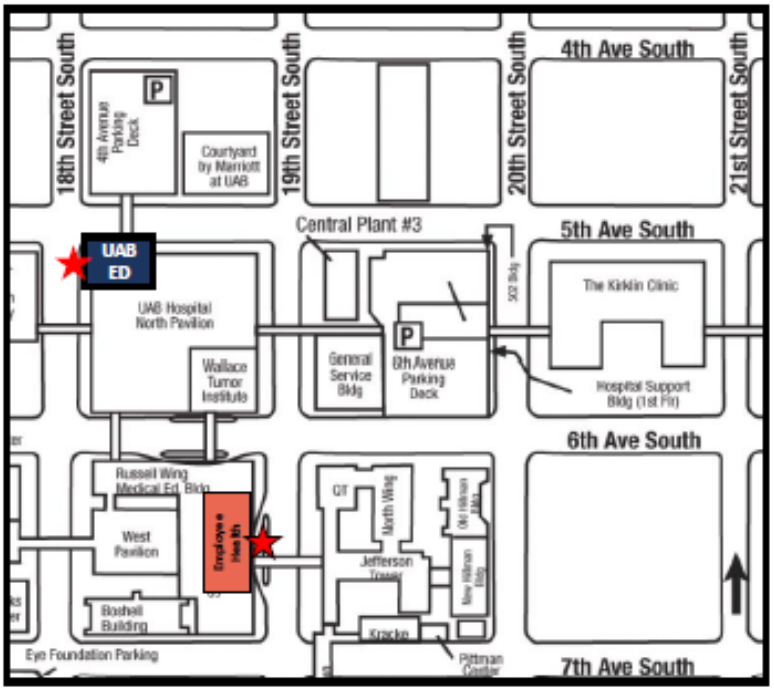
NAME	SIGNATURE	DATE

Treatment Providers for Injuries and Exposures at UAB




On-the-job Injury at UAB
I was injured while performing my job at UAB and need medical care
CALL 911 IN AN EMERGENCY unconscious, seizures, difficulty breathing, significant bleeding, chemical spills of 500mL or more, or other life threatening injuries
I was exposed to human blood, fluid, or tissue, biologic agent, chemical agent, radiation, lasers, or animals
Yes
Follow "Treatment for Exposures" Plan
Call 205-934-3411
Ask for the "needlestick and exposure team"
No
Campus Employees and Students: Complete OJI Incident Report; Supervisor should also complete "Initial Medical Evaluation Form" and send it with the employee; paperwork MUST BE COMPLETED within 48 hours.
OJI form located at: https://www.uab.edu/humanresources/home/relations/oji
Hospital/Medicine Employees and Students: Complete Trend Tracker
Trend Tracking information located at:
https://www.uab.edu/humanresources/home/relations/oji
Notify Supervisor and contact
Brentwood Services Administrators at 205-933-0373 or 1-800-524-0604
UAB
EMPLOYEE HEALTH
The University of Alabama at Birmingham

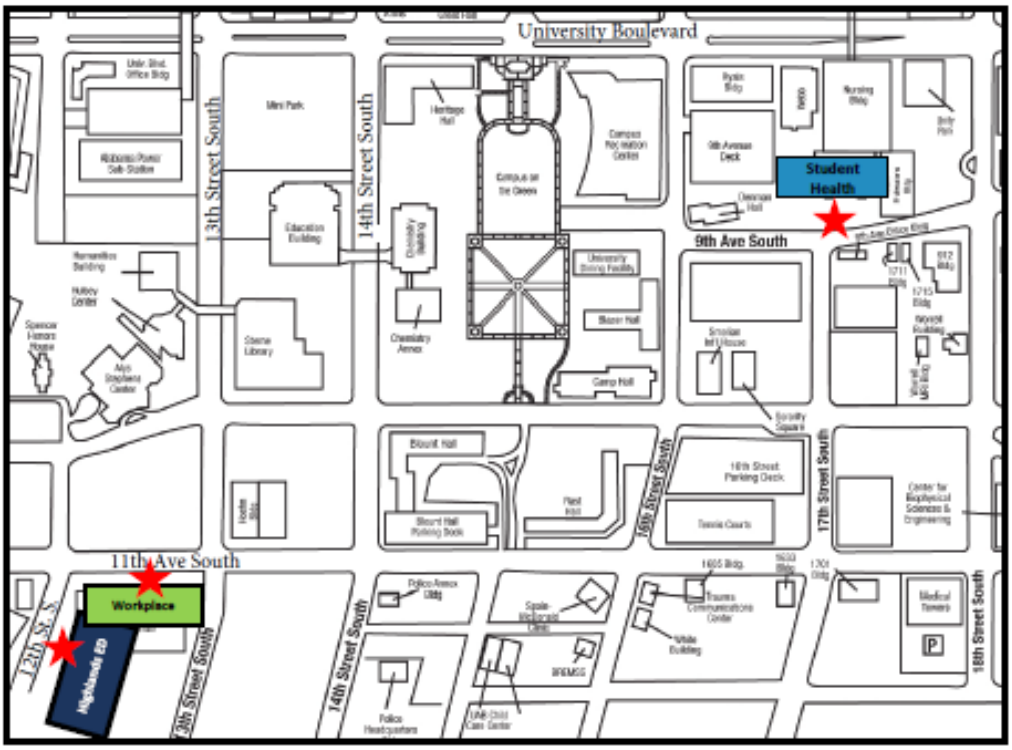
Treatment Provider Locations for Injuries and Exposures at UAB



University ED:
Highlands ED: 1201 11th Ave S
*enter on 12th St S
(205)934-3411

Employee Health:
Spain Wallace SW123
620 19th St. S.
6:30am-5pm: (205)934-3675

Rapid Response Team:
(after hours/weekends)
(205)934-4011
Ask for Employee Health nurse on call



Highlands ED:
Highlands ED: 1201 11th Ave S
*enter on 12th St S
(205)934-3411

Workplace Clinic:
1201 11th Ave S
7:30am-4pm
(205)930-7007

Student Health
1714 9th Ave S
M-F, 8am-5pm (205)934-3580
After hours: (205)934-3411
Ask for on-call provider

BIOHAZARD

BSL-2 LABORATORY

AGENTS IN USE:
ENTRY REQUIREMENTS:

Appendix 3.4
ASM Guidelines for Biosafety for Teaching Laboratories (Undergraduate Micro Laboratories)

Refer link below:

[ASM Guidelines for Biosafety in Teaching Laboratories | ASM.org]

Appendix 3.5
Appendix to the Guidelines for Biosafety in Teaching Laboratories
(Undergraduate Micro Laboratories)

Refer link below:

https://asm.org/ASM/media/Education/Biosafety-Guidelines-Appendix.pdf

UAB Biosafety Manual Appendices 12.8

Appendix 4.1.a
Exposure Control Plan Template for Researchers

EXPOSURE CONTROL PLAN TEMPLATE FOR RESEARCHERS

PURPOSE:

The purpose of this Exposure Control Plan is to identify hazards and describe ways to minimize the risks of laboratory exposure to human blood or other potentially infectious materials, in compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) and the Respiratory Protection Standard (29 CFR 1910.134).

RESPONSIBILITIES:

I, _____, as the Principal Investigator/Laboratory Director, recognize my responsibility to implement and monitor this exposure control plan.

The PI, Manager, and/or Supervisor will ensure that employees receive information and specific training on the laboratory procedures and techniques to be followed as well as information included in this document as required by the Bloodborne Pathogens Standard. **Documented training must occur prior to the start of work with human or primate specimens, and at least annually thereafter and when new or modified tasks or procedures affect a worker's occupational exposure.** Records must be maintained by the PI or the department for at least 3 years.

SCOPE:

Each laboratory working with material of human origin must include an exposure control plan in the lab's safety manual. This manual should be available to for all employees who may have occupational exposure to human bloodborne pathogens.

The following plan may serve as a guide, but each lab should customize their plan to identify the specific BBP exposure hazards present in their work setting.

The PI or designee must review and update this plan annually or whenever the exposure risks or personnel at risk for exposure significantly change. Each Dean, Department Chair, or supervisor is responsible for implementation of this plan.

DEFINITIONS:

- **Bloodborne Pathogens** – disease-causing organisms carried in the blood, and include organisms like HBV, HIV, HCV, malaria, Creutzfeld-Jacob agent, human T-lymphotropic virus type 1 and others.
- **Other Potentially Infectious Materials (OPIM)** – refers to semen or vaginal secretions; cerebrospinal, synovial, pleural, peritoneal, pericardial, or amniotic fluids, or tissue. saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids. Any unfixed tissue or organ (other than intact skin) from a human (living or dead) is considered OPIM. HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV- containing culture medium or other solutions and blood, organs, or other tissues from experimental animals infected with HIV or HBV are also included.

- **Universal Precautions (UP)** – an approach to infection control in which all human blood and certain human body fluids (OPIM) are treated as if they are known to be infectious. Although the BBP standard incorporates UP, the infection control community has adopted Standard Precautions to account for other infectious body fluids (e.g., urine, saliva, feces, vomit, breast milk).
- **Standard Precautions** – is an approach to infection control. According to the concept of Standard Precautions, all human blood and body fluids (except sweat) are treated as if known to be infectious. Wearing proper PPE is one such precaution.
- **Exposure Incident** – means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.
- **Regulated Medical Waste** – any liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious material – including liquid, semi-liquid, or solid material.
- **Engineering Controls –** controls that isolate or remove the bloodborne pathogens hazard from the workplace (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered injury protections and needless systems)
- **Sharps with Engineered Sharps Injury Protections –** a non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.
- **Needleless Systems** – a device that does not use needles for the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; the administration of medication or fluids; or any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

EXPOSURE DETERMINIATION:

The Principal Investigator, laboratory supervisor and/or designated laboratory safety officer will identify laboratory employees and procedures in the laboratory that present the possibility of occupational exposure to bloodborne pathogens and/or OPIM. This determination is based on the risk of performing each procedure without the use of personal protective equipment.

The material used in this laboratory that may be associated with potential exposure to human or bloodborne pathogens include the items checked below:

☐ Human or primate blood, serum, plasma, blood products, components or cells

☐ Other potentially infectious materials (OPIM) which include: human or primate body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid visibly

contaminated with blood, and all body fluids where it is difficult to differentiate between fluids.

- ☐ Any unfixed human or primate tissue or organ (other than intact skin).
- ☐ Cell, tissue or organ cultures containing HIV; culture medium or other solutions containing HIV, HBV, HCV; blood, organs or other tissues from experimental animals infected with HIV, HBV, or HCV.
- ☐ Contact with non-human primates
- ☐ Other(s), specify:

The job classifications in which laboratory employees may have occupational exposure to human pathogens in this work setting include the classifications checked below:

- ☐ Professor
- ☐ Postdoctoral Researcher
- ☐ Med Technologist/Technician
- ☐ Research Scientist
- ☐ Laboratory Assistant
- ☐ Graduate Student
- ☐ Undergraduate Student
- ☐ Other (specify):

The tasks and procedures used in this work setting that may pose risk of exposure to human or primate bloodborne pathogens may include: venipuncture of humans (including co-workers or students) or primates; injections using primate or human specimens, use of needles with human or primate specimens; preparing, dissecting, cutting, or otherwise handling human or primate tissue; pipetting, mixing, or vortexing human or primate blood, or OPIM; centrifuging human or primate blood, or OPIM; handling tubes or other containers of human or primate blood, or OPIM; handling contaminated sharps or other contaminated waste; cleaning up spills of human or primate blood or OPIM; preparing or handling primary human or primate cell cultures; working or caring for non-human primates.

LABORATORY REQUIREMENTS:

Each laboratory where human or primate blood or OPIM is used must prepare an Exposure Control Plan. Standard precautions and Biosafety Level 2 practices and procedures (see Biosafety in Microbiological and Biomedical Laboratories BMBL 6th Edition) will be followed to minimize exposure to bloodborne pathogens.

Engineering and Work Practice Controls

- **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.
- **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.
- The laboratory should be maintained in a clean and sanitary condition. At a minimum, benches and biosafety cabinets are cleaned at the end of the day and after any spill using the appropriate disinfectant(s).
- Employees must be made aware of signs and symptoms of latex sensitivity and provided with prevention strategies.
- Hands are washed after removing gloves, before exiting the lab, and before eating, drinking, smoking, handling contact lenses or other activities that may result in hand contact to a mucous membrane.
- Only approved sharps containers are to be used for sharps disposal (see UAB Medical Waste Management Plan).
- Needles shall not be recapped, removed from disposable syringes, purposefully bent or otherwise manipulated. When there is no alternative for recapping or removal of needles, the recapping or removal will be accomplished by a mechanical device (e.g. a needle block or holder). Mechanical devices will be disinfected as they become contaminated.
- Sharps disposal containers are inspected and maintained or replaced by every _____, or whenever necessary to prevent overfilling.
- Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leakproof on sides and bottoms, and labeled or color-coded appropriately.
- Protected needle devices or safety needle systems will be evaluated and used whenever possible. Disposal containers (bags, sharps containers, red barrels, etc.) are required to be closed during transport. If there is a chance of leakage, an additional labeled container will be used.
- The specific engineering controls and work practice controls used in this lab are listed below:

- This facility identifies the need for changes in engineering control and work practices through:

Personal Protective Equipment

- Personal protective equipment (PPE) and clothing is used in the laboratory to minimize or eliminate exposure to human bloodborne pathogens. The PI or department is responsible for supplying personal protective equipment and clothing and arranging for replacement or cleaning, as needed. Appropriate gloves are to be worn when exposure to blood or OPIM is probable. PPE must be replaced frequently and immediately if they become contaminated or damaged in any way.
- 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.
- PPE training is provided by_____. This includes instructions on the type of PPE to use for distinct tasks, and how to use, care, and dispose of PPE used for the tasks or procedures the employees will perform.
- The types of PPE available to employees are as follows:

- PPE locations:
- The person responsible for ordering and distribution of PPE is:
- PPE must be removed after it becomes contaminated, and before leaving the work area.
- Lab members must wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated materials or surfaces; replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised. Never wash or decontaminate disposable gloves for reuse. Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth. Remove immediately or as soon as feasible any garment contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface.

- The procedure for handling used PPE is as follows:

- Laboratories using high volumes or concentrations of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), or Hepatitis C Virus (HCV) must follow additional safety practices and procedures according to their laboratory specific safety manual.

UAB EMPLOYEE HEALTH PROGRAM:

The PI or department is responsible for arranging for Employee Health services **before an exposure** event occurs.

Hepatitis B Vaccination: The PI/Manager will ensure that all persons in the laboratory/unit area who were determined to have occupational exposure to human bloodborne pathogens are offered Hepatitis B vaccination within ten days of starting work with human or primate specimens. The PI or department must maintain documentation of 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. Hepatitis B Vaccination Declaration/Declination Forms are available by request to UAB Employee Health at ehocchealth@uab.edu.

Post-Exposure Evaluation and Follow-up: See the "UAB Exposure Response Plans" flow chart on the last page of this document for broad exposure response procedures.

A bloodborne pathogen exposure event is any situation, such as a spill, splash, needlestick, ingestion, or accident in which you have direct, unprotected contact with human or primate blood or OPIM. If this happens immediately flush the body part with water for 15 minutes, notify your PI or supervisor, **and contact the Employee Health Needlestick Team. Timing is of the essence, as treatment may only be effective if received within hours of an exposure.**

- **Needlestick Team: (205) 934-3411**

If an exposure to material of primate origin occurs: Follow your lab's agent specific plan for potential exposure to Herpes B virus. (Attach plan, if applicable)

Prior to receiving treatment for an exposure, an UAB On-The-Job-Injury Initial Medical Evaluation Authorization form may be required. In all cases, an Incident Report Form must be completed. Your supervisor/colleagues can help to fill out OJI forms, and ensure spilled materials are contained and decontaminated. Additional information on UAB Instructions and Forms for OJI can be found on the UAB HR website.

Every individual handling material with potential bloodborne pathogens has the responsibility to report any exposure to these materials to their supervisor and the PI/Manager.

The PI/Manager is responsible for reporting the incident to UAB Employee Health (**205) 996-7817.** Employee Health will investigate the circumstances surrounding the exposure, and work with the PI/Manager to modify work practices and/or develop additional prevention strategies.

RESOURCES/REFERENCES

1. Centers for Disease Control and Prevention. Recommendations for prevention of HIV transmission in health-care settings. *MMWR* 1987; 369 (suppl no 2S).
2. McCunney, Robert J. ed. *Medical Center Occupational Health and Safety*. Philadelphia, PA: Lippencott Williams & Wilkins, 1999.
3. Risk and Management of Bloodborne Infections in Health Care Workers. Clin. Micro. Rev. July 2000.
4. UAB Medical Waste Management Plan, Appendix J, UAB Biosafety Manual 3rd Edition, Oct 2023.
5. US Department of Labor/Occupational Safety and Health Administration. 1991. Occupational exposure to bloodborne pathogens; final rule. 29 CFR part 1910.1030. *Federal Register*, 56:64175-64182.
6. US Department of Health and Human Services/Department of Labor. Respiratory Protective Devices; final rule, 1995. 42CFR Part 84. *Federal Register,* 60:30336-30404.
7. US Department of Labor/Occupational Safety and Health Administration. 2006. Respiratory Protection 29 CFR 1910.134.
8. US Department of Health and Human Services, National Institute for Occupational Health and Safety *Latex Allergy* A Prevention Guide, 1999. DHHS (NIOSH) Publication No. 98-113.
9. For more information about the Bloodborne Pathogens Standard, the written Exposure Control Plan, and the Respiratory Protection Standard or for assistance in compliance, please contact your supervisor or PI or call EH&S Biosafety at biosafety@uab.edu. Copies of the standards and guidelines are available from the EH&S website.

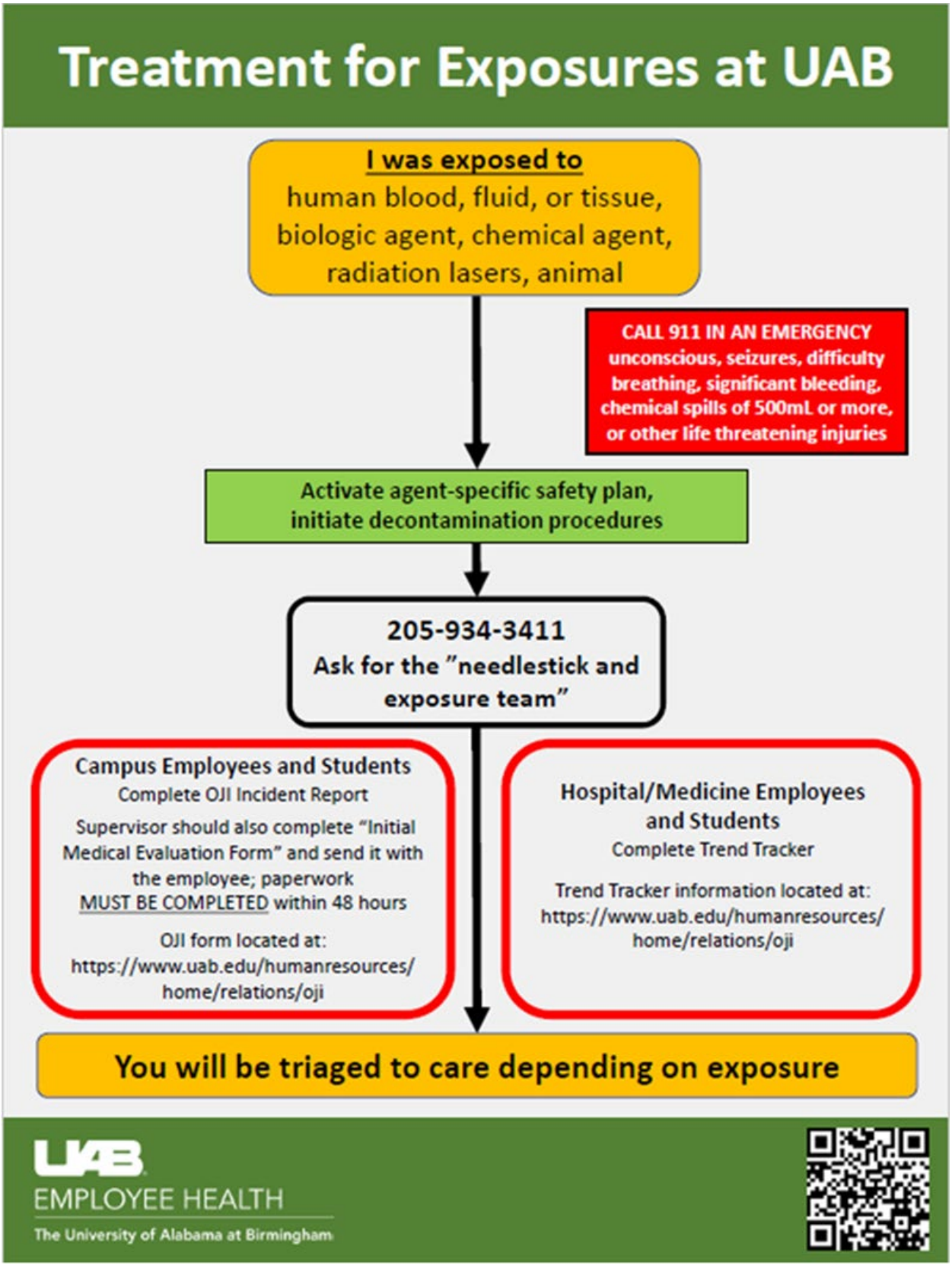
REVIEW SCHEDULE:

This plan was implemented by:

Name of PI, Manager, Supervisor:	
Date:	

Use the table below to track required annual reviews or edits of this document.

Reviewed (Yes or No)	**Updated** (Yes or No)	**Date**	**PI, Manager or Supervisor Signature**


Treatment for Exposures at UAB
I was exposed to
human blood, fluid, or tissue, biologic agent, chemical agent, radiation lasers, animal
CALL 911 IN AN EMERGENCY
unconscious, seizures, difficulty breathing, significant bleeding, chemical spills of 500mL or more, or other life threatening injuries
Activate agent-specific safety plan, initiate decontamination procedures
205-934-3411
Ask for the "needlestick and exposure team"
Campus Employees and Students
Complete OJI Incident Report
Supervisor should also complete "Initial Medical Evaluation Form" and send it with the employee; paperwork MUST BE COMPLETED within 48 hours
OJI form located at:
https://www.uab.edu/humanresources/home/relations/oji
Hospital/Medicine Employees and Students
Complete Trend Tracker
Trend Tracker information located at:
https://www.uab.edu/humanresources/home/relations/oji
You will be triaged to care depending on exposure
UAB
EMPLOYEE HEALTH
The University of Alabama at Birmingham

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

EXPOSURE CONTROL PLAN TEMPLATE FOR UAB ENVIRONMENTAL SERVICES and MAINTENANCE

PURPOSE

The purpose of this Exposure Control Plan (ECP) is to communicate the risks associated with exposure to human blood or other potentially infectious materials, to identify personnel who may be at risk for such exposures, to provide an explanation of controls in place to mitigate exposure risk, and to provide response and reporting procedures in the event of an exposure. In doing so, this document also ensures compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) and the Respiratory Protection Standard (29 CFR 1910.134).

RESPONSIBILITIES

I, _____, as the Department/Unit Director or safety authority, recognize my responsibility to implement and monitor this exposure control plan.

The manager, and/or supervisor will ensure that employees receive information and specific training on the department's procedures and techniques to be followed as well as information included in this document as required by the Bloodborne Pathogens Standard. **Documented training must occur prior to the start of work with human or primate specimens, and at least annually thereafter and when new or modified tasks or procedures affect a worker's occupational exposure.** Records must be maintained by the department/Unit for at least 3 years.

SCOPE

Each Department/Unit deemed to have employees who are at risk for bloodborne pathogen (BBP) exposure must include an ECP in their safety documents. This manual should be available to for all employees who may have occupational exposure to human bloodborne pathogens.

The following plan may serve as a guide, but each Department/Unit should customize their ECP to identify the specific BBP exposure hazards present in their work setting.

A Department/Unit designee is responsible for implementation and review of this plan, updating it annually, or whenever the exposure risks, or personnel at risk for exposure, significantly change.

DEFINITIONS

- **Bloodborne Pathogens** – disease-causing organisms carried in the blood, including Hepatitis B Virus (HBV), Hepatitis C Virus, Human Immunodeficiency Virus (HIV), human T-lymphotropic virus type 1 (HTLV-1), and others.
- **Other Potentially Infectious Materials (OPIM)** – refers to semen or vaginal secretions; cerebrospinal, synovial, pleural, peritoneal, pericardial, or amniotic fluids or tissue, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids. Any unfixed tissue or organ (other than intact skin) from a human (living or dead) is considered OPIM. HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV- containing culture medium or other solutions and blood, organs, or other tissues from experimental animals infected with HIV or HBV are also included.
- **Universal Precautions (UP)** – an approach to infection control in which all human blood and certain human body fluids (OPIM) are treated as if they are known to be infectious. Although the BBP standard incorporates UP, the infection control community has adopted Standard Precautions to account for other infectious body fluids (e.g., urine, saliva, feces, vomit, breast milk).

- **Standard Precautions** – is an approach to infection control. According to the concept of Standard Precautions, all human blood and body fluids (except sweat) are treated as if known to be infectious. Wearing proper PPE is one such standard.
- **Exposure Incident** – means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.
- **Regulated Medical Waste** – any liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious material – including liquid, semi-liquid, or solid material.
- **Engineering Controls –** controls that isolate or remove the bloodborne pathogen hazard from the workplace (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered injury protections and needless systems)
- **Sharps with Engineered Sharps Injury Protections –** a non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.
- **Needleless Systems** – a device that does not use needles for the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; the administration of medication or fluids; or any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

EXPOSURE DETERMINIATION

The supervisor or designated safety officer will identify employees and situations/procedures in the workplace that present the possibility of an occupational exposure to bloodborne pathogens and/or OPIM. This determination is based on the risk that would be anticipated in performing work-related tasks without the use of personal protective equipment.

The material/items that may be associated with potential exposure to human or bloodborne pathogens include the following:

- ☐ Exhaust duct servicing laboratories and clinics
- ☐ Drains servicing laboratories and/or research buildings
- ☐ Medical waste in laboratories and/or research buildings
- ☐ Contaminated sharps or surfaces in laboratories, clinics, and restrooms
- ☐ Other (specify):

The job classifications within UAB EVS (Environmental Services)/Maintenance considered to have an occupational exposure risk to human pathogens or OPIM include:

- ☐ Plumbers
- ☐ HVAC mechanics EVS
- ☐ staff
- ☐ Other (specify):

The tasks and procedures used in this work setting that may pose risk of exposure to human or primate bloodborne pathogens may include:

- ☐ Plumbing services in drains/leaks originating in laboratories and clinics
- ☐ Repairing HVAC exhaust in UAB research and clinics
- ☐ Miscellaneous sanitation services in laboratories, clinics, public corridors, and restrooms(
- ☐ Other (specify):

CONTAINMENT CONTROLS

The methods, practices, procedures, facilities, and equipment used to safely manage biohazardous materials. The purpose of **containment** is to reduce or eliminate exposure of people or the environment to potentially hazardous agents.

Engineering Controls

The engineering controls EVS and Maintenance encounter in laboratories and clinics involve building controls, used to achieve directional airflow, and specialized devices researchers and clinicians use to contain infectious aerosols, like biosafety cabinets. Other than HVAC mechanics, maintenance and EVS staff should just be aware of the role engineering controls play in containment control.

Workplace Practices

- **Attention to signage:** Laboratory-specific requirements for entry are posted at the door. If in doubt, call the responsible person listed as the laboratory contact at the entrance. Infectious aerosols should not be a risk you encounter when making entry into a properly functioning laboratory. In this regard, the primary risk is through contact with contaminated surfaces. Due to the nature of BBP transmission requirements, that would require a splash or transfer to an open wound or mucous membrane, or a skin puncture from a contaminated object.
- **Hand washing:** Hands are washed after removing gloves, before exiting the area, and before eating, drinking, smoking, handling contact lenses or other activities that may result in hand contact to a mucous membrane.
- **Sharps:** Needles shall not be recapped, removed from disposable syringes, purposefully bent or otherwise manipulated. When there is no alternative for recapping or removal of needles, the recapping or removal will be accomplished by a mechanical device (e.g. a needle block or holder). Mechanical devices will be disinfected as they become contaminated.

- **Sharps Containers:** Only approved sharps containers are to be used for sharps disposal (see UAB Medical Waste Management Plan).Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leakproof on sides and bottoms, and labeled or color-coded appropriately.

Personal Protective Equipment

- Personal protective equipment (PPE) and clothing is used by the department to minimize or eliminate exposure to human bloodborne pathogens. The supervisor or department is responsible for supplying personal protective equipment and arranging for replacement or cleaning, as needed. Appropriate gloves are to be worn when exposure to blood or OPIM is probable. PPE must be replaced frequently and immediately if they become contaminated or damaged in any way.

- PPE is typically used in conjunction with engineering controls, but it can also serve as a primary barrier in specific cases. The department's safety manual should define the safety equipment needed for specific procedures or agents, including the PPE required for response.

- PPE training is provided by_____. This includes instructions on the type of PPE to use for distinct tasks, and how to use, care, and dispose of PPE used for the tasks or procedures the employees will perform.

- The types of PPE available to employees are as follows:

- PPE locations: _____

- The person responsible for ordering and distribution of PPE is: _____

- PPE must be removed after it becomes contaminated and before leaving the work area.

- UAB employees must wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated materials or surfaces; replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised. Never wash or decontaminate disposable gloves for reuse. Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth. Remove immediately or as soon as feasible any garment contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface.

- When making entry into a laboratory, EVS and Maintenance may request laboratory staff to provide gloves. Unless visibly contaminated, gloves should be discarded in the normal trash, and hands should be washed just prior to exiting the laboratory.

- For consults regarding the type of PPE appropriate for the scope of work, contact Biosafety team at biosafety@uab.edu

EMPLOYEE HEALTH PROGRAM

The supervisor or department is responsible for arranging for Employee Health medicine services **before an exposure** event occurs.

Hepatitis B Vaccination: The Supervisor will ensure that all persons determined to have occupational exposure to human bloodborne pathogens are offered Hepatitis B vaccination within ten days of starting work. 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. Hepatitis B Vaccination Declaration/Declination Forms are available by request to Employee Health at ehocchealth@uab.edu.

Post-Exposure Evaluation and Follow-up: See the "UAB Exposure Response Plans" flow chart on the last page of this document for broad exposure response procedures.

A bloodborne pathogen exposure event is any situation, such as a spill, splash, needlestick, ingestion, or accident in which you have direct, unprotected contact with human or primate blood or OPIM. If this happens immediately flush the body part with water for 15 minutes, notify your manager or supervisor, **and contact the Employee Health Needlestick Team. Timing is of the essence, as treatment may only be effective if received within hours of an exposure.**

- **Needlestick Team:** (205) 934-3411

Prior to receiving treatment for an exposure, an UAB On-The-Job-Injury Initial Medical Evaluation Authorization Form may be required. In all cases, an Incident Report Form must be completed. Your supervisor/colleagues can help to fill out OJI forms, and ensure spilled materials are contained and decontaminated. Additional information on UAB Instructions and Forms for OJI can be found on the UAB HR website.

Every individual handling material with potential bloodborne pathogens has the responsibility to report any exposure to these materials to their supervisor.

The Supervisor should report the incident to UAB Biosafety at Biosafety@uab.edu. Biosafety representatives will investigate the circumstances surrounding the exposure, and work with the staff to modify work practices and/or develop additional prevention strategies.

RESOURCES/REFERENCES

1. Centers for Disease Control and Prevention. Recommendations for prevention of HIV transmission in health-care settings. *MMWR* 1987; 369 (suppl no 2S).

2. McCunney, Robert J. ed. *Medical Center Occupational Health and Safety*. Philadelphia, PA: Lippencott Williams & Wilkins, 1999.

3. Risk and Management of Bloodborne Infections in Health Care Workers. Clin. Micro. Rev. July 2000.

4. UAB Medical Waste Management Plan, Appendix J, UAB Biosafety Manual 3rd Edition, Oct 2023.

5. US Department of Labor/Occupational Safety and Health Administration. 1991. Occupational exposure to bloodborne pathogens; final rule. 29CFR part 1910.1030. *Federal Register*, 56:64175-64182.

6. US Department of Health and Human Services/Department of Labor. Respiratory Protective Devices; final rule, 1995. 42CFR Part 84 . *Federal Register,* 60:30336-30404.

7. US Department of Labor/Occupational Safety and Health Administration. 2006. Respiratory Protection 29 CFR 1910.134.

8. US Department of Health and Human Services, National Institute for Occupational Health and Safety *Latex Allergy* A Prevention Guide, 1999. DHHS (NIOSH) Publication No. 98-113.

9. For more information about the Bloodborne Pathogens Standard, the written Exposure Control Plan, and the Respiratory Protection Standard or for assistance in compliance, please contact your supervisor or call EH&S Biosafety at biosafety@uab.edu. Copies of the standards and guidelines are available from the EH&S website.

EH&S CONTACTS

Please contact us at EH&S for any questions, concerns, or advice for keeping your team safe. Our team is listed below:

Specialty	Contact Name	Email
Biosafety	Justin Roth, PhD	jcroth@uab.edu
	Brian LaGory	blagory@uab.edu
Employee Health	Julie Allen, CRNP	juallen@uab.edu
	Kathy Jo Baker	kjbaker@uab.edu
Research Safety	Julie Gray	grayj@uab.edu
Medical/Biohazardous Waste	Julie Gray	grayj@uab.edu

REVIEW SCHEDULE

This plan was implemented by:

Name of PI, Manager, Supervisor:	
Date:	

Use the table below to track required annual reviews or edits of this document.

Reviewed (Yes or No)	**Edited** (Yes or No)	**Date**	**Manager or Supervisor Signature**

UAB Biosafety Manual Appendices 12.10

Appendix 4.1.c
Exposure Control Plan Template for Police Department

EXPOSURE CONTROL PLAN TEMPLATE FOR UAB POLICE DEPARTMENT

PURPOSE

The purpose of this Exposure Control Plan (ECP) is to communicate the risks associated with exposure to human blood or other potentially infectious materials, to identify personnel who may be at risk for such exposures, to provide an explanation of controls in place to mitigate exposure risk, and to provide response and reporting procedures in the event of an exposure. In doing so, this document also ensures compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) and the Respiratory Protection Standard (29 CFR 1910.134).

RESPONSIBILITIES

I,_____, as the Department/Unit Director or safety authority, recognize my responsibility to implement and monitor this exposure control plan.

The Manager, and/or Supervisor will ensure that employees receive information and specific training on the department's procedures and techniques to be followed as well as information included in this document as required by the Bloodborne Pathogens Standard. **Documented training must occur prior to the start of work with human or primate specimens, and at least annually thereafter and when new or modified tasks or procedures affect a worker's occupational exposure.** Records must be maintained by the department/Unit for at least 3 years.

SCOPE

Each Department/Unit deemed to have employees who are at risk for bloodborne pathogen (BBP) exposure must include an ECP in their safety documents. This manual should be available to for all employees who may have occupational exposure to human bloodborne pathogens.

The following plan may serve as a guide, but each Department/Unit should customize their ECP to identify the specific BBP exposure hazards present in their work setting.

A Department/Unit designee is responsible for implementation and review of this plan, updating it annually, or whenever the exposure risks, or personnel at risk for exposure, significantly change.

DEFINITIONS

- **Bloodborne Pathogens** – disease-causing organisms carried in the blood, including Hepatitis B Virus (HBV), Hepatitis C Virus, Human Immunodeficiency Virus (HIV), human T-lymphotropic virus type 1 (HTLV-1), and others.
- **Other Potentially Infectious Materials (OPIM)** – refers to semen or vaginal secretions; cerebrospinal, synovial, pleural, peritoneal, pericardial, or amniotic fluids, or tissue. saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids. Any unfixed tissue or organ (other than intact skin) from a human (living or dead) is considered OPIM. HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV- containing culture medium or other solutions and blood, organs, or other tissues from experimental animals infected with HIV or HBV are also included.
- **Universal Precautions (UP)** – an approach to infection control in which all human blood and certain human body fluids (OPIM) are treated as if they are known to be infectious. Although the BBP standard incorporates UP, the infection control community has adopted Standard Precautions to

account for other infectious body fluids (e.g., urine, saliva, feces, vomit, breast milk).

Standard Precautions – is an approach to infection control. According to the concept of Standard Precautions, all human blood and body fluids (except sweat) are treated as if known to be infectious. Wearing proper PPE is one such precaution.

- **Exposure Incident** – means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.
- **Regulated Medical Waste** – any liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious material – including liquid, semi-liquid, or solid material.
- **Engineering Controls –** controls that isolate or remove the bloodborne pathogen hazard from the workplace (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered injury protections and needless systems)
- **Sharps with Engineered Sharps Injury Protections –** a non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.
- **Needleless Systems** – a device that does not use needles for the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; the administration of medication or fluids; or any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

EXPOSURE DETERMINIATION

The supervisor or designated safety officer will identify employees and situations/procedures in the workplace that present the possibility of an occupational exposure to bloodborne pathogens and/or OPIM. This determination is based on the risk that would be anticipated in performing work-related tasks without the use of personal protective equipment.

The material/items that may be associated with potential exposure to human or bloodborne pathogens include the following:

- ☐ Human blood or OPIM spilled in UAB research or clinical areas
- ☐ Human blood or OPIM released and present during response to an accident/incident,
- ☐ Human blood or OPIM released during apprehension or rescue of subjects in the community
- ☐ Exposure to contaminated sharps (e.g., used needles and syringes associate with drug paraphernalia or medical waste)
- ☐ Other (specify):

The job classifications within UABPD considered to have an occupational exposure risk to human pathogens or OPIM include:

The tasks and procedures used in this work setting that may pose risk of exposure to human or primate bloodborne pathogens may include:

- ☐ Apprehension of suspects requiring physical altercations.
- ☐ Frisking/pat-downs of suspects harboring contaminated sharps.
- ☐ Life-preserving medical interventions.
- ☐ Responding to spills or incidents in medical research laboratories.

CONTAINMENT CONTROLS

The methods, practices, procedures, facilities, and equipment used to safely manage biohazardous materials. The purpose of **containment** is to reduce or eliminate exposure of people or the environment to potentially hazardous agents.

Engineering Controls

Since the duties that put police officers at risk for BBP exposure primarily entail field work, the facility-specific controls officers encounter will primarily exist in laboratories they may enter in response to a call. In this regard, officers should be aware of the role engineering controls play in containment control.

Workplace Practices

- **Attention to signage:** Laboratory-specific requirements for entry are posted at the door. If in doubt, call the responsible person listed as the laboratory contact at the entrance. Infectious aerosols should not be a risk you encounter when making entry into a properly-functioning laboratory. In this regard, the primary risk is through contact with contaminated surfaces. Due to the nature of BBP transmission requirements, that would require a splash or transfer to an open wound or mucous membrane, or a skin puncture from a contaminated object.
- **Hand washing:** Hands are washed after removing gloves, before exiting the area, and before eating, drinking, smoking, handling contact lenses or other activities that may result in hand contact to a mucous membrane.
- **Sharps:** Needles shall not be recapped, removed from disposable syringes, purposefully bent or otherwise manipulated. When there is no alternative for recapping or removal of needles, the recapping or removal will be accomplished by a mechanical device (e.g. a needle block or holder). Mechanical devices will be disinfected as they become contaminated.

- **Sharps Containers:** Only approved sharps containers are to be used for sharps disposal (see UAB Medical Waste Management Plan).Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leakproof on sides and bottoms, and labeled or color-coded appropriately.

- **Personal Protective Equipment**
  Personal protective equipment (PPE) and clothing is used by the department to minimize or eliminate exposure to human bloodborne pathogens. The supervisor or department is responsible for supplying personal protective equipment and arranging for replacement or cleaning, as needed. Appropriate gloves are to be worn when exposure to blood or OPIM is probable. PPE must be replaced frequently and immediately if they become contaminated or damaged in any way.

- PPE is typically used in conjunction with engineering controls, but it can also serve as a primary barrier in specific cases. The department's safety manual should define the safety equipment needed for specific procedures or agents, including the PPE required for response.

- PPE training is provided by_____. This includes instructions on the type of PPE to use for distinct tasks, and how to use, care, and dispose of PPE used for the tasks or procedures the employees will perform.

- The types of PPE available to employees are as follows:

- PPE locations: _____

The person responsible for ordering and distribution of PPE is: _____

- PPE must be removed after it becomes contaminated, and before leaving the work area.

- UAB employees must wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated materials or surfaces; replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised. Never wash or decontaminate disposable gloves for reuse. Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth. Remove immediately or as soon as feasible any garment contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface.

- When making entry into a laboratory, officers may request laboratory staff to provide gloves. Unless visibly contaminated, gloves should be discarded in the normal trash, and hands should be washed just prior to exiting the laboratory.

EMPLOYEE HEALTH PROGRAM

The supervisor or department is responsible for arranging for Employee Health medicine services **before an exposure** event occurs.

Hepatitis B Vaccination: The Supervisor will ensure that all persons determined to have occupational exposure to human bloodborne pathogens are offered Hepatitis B vaccination within ten days of starting work. 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. Hepatitis B Vaccination Declaration/Declination Forms are available by request to Employee Health at ehocchealth@uab.edu.

Post-Exposure Evaluation and Follow-up: See the "UAB Exposure Response Plans" flow chart on the last page of this document for broad exposure response procedures.

A bloodborne pathogen exposure event is any situation, such as a spill, splash, needlestick, ingestion, or accident in which you have direct, unprotected contact with human or primate blood or OPIM. If this happens immediately flush the body part with water for 15 minutes, notify your manager or supervisor, **and contact the Employee Health Needlestick and Exposure Team. Timing is of the essence, as treatment may only be effective if received within hours of an exposure.**

- **Needlestick and Exposure Team: (205) 934-3411**

Prior to receiving treatment for an exposure, an UAB On-The-Job-Injury Initial Medical Evaluation Authorization Form may be required. In all cases, an Incident Report Form must be completed. Your supervisor/colleagues can help to fill out OJI forms, and ensure spilled materials are contained and decontaminated. Additional information on UAB Instructions and Forms for OJI can be found on the UAB HR website.
Every individual handling material with potential bloodborne pathogens has the responsibility to report any exposure to these materials to their supervisor.

The Supervisor should report the incident to UAB Biosafety (Biosafety@uab.edu). Biosafety team members will investigate the circumstances surrounding the exposure, and work with the staff to modify work practices and/or develop additional prevention strategies.

RESOURCES/REFERENCES

1. Centers for Disease Control and Prevention. Recommendations for prevention of HIV transmission in health-care settings. *MMWR* 1987; 369 (suppl no 2S).

2. McCunney, Robert J. ed. *Medical Center Occupational Health and Safety*. Philadelphia, PA: Lippencott Williams & Wilkins, 1999.

3. Risk and Management of Bloodborne Infections in Health Care Workers. Clin. Micro. Rev. July 2000.

4. UAB Medical Waste Management Plan, Appendix J, UAB Biosafety Manual 3rd Edition, Oct 2023.

5. US Department of Labor/Occupational Safety and Health Administration. 1991. Occupational exposure to bloodborne pathogens; final rule. 29CFR part 1910.1030. *Federal Register*, 56:64175-64182.

6. US Department of Health and Human Services/Department of Labor. Respiratory Protective Devices; final rule, 1995. 42CFR Part 84 . *Federal Register,* 60:30336-30404.

7. US Department of Labor/Occupational Safety and Health Administration. 2006. Respiratory Protection 29 CFR 1910.134.

8. US Department of Health and Human Services, National Institute for Occupational Health and Safety *Latex Allergy* A Prevention Guide, 1999. DHHS (NIOSH) Publication No. 98-113.

9. For more information about the Bloodborne Pathogens Standard, the written Exposure Control Plan, and the Respiratory Protection Standard or for assistance in compliance, please contact your supervisor or call EH&S Biosafety at 4-2487. Copies of the standards and guidelines are available from the EH&S website.

EH&S CONTACTS

Please contact us at EH&S for any questions, concerns, or advice for keeping your team safe. Our team is listed below:

Specialty	Contact Name	Email
Biosafety	Justin Roth, PhD	jcroth@uab.edu
	Brian LaGory	blagory@uab.edu
Employee Health	Julie Allen, CRNP	juallen@uab.edu
	Kathy Jo Baker	kjbaker@uab.edu
Research Safety	Julie Gray	grayj@uab.edu
Medical/Biohazardous Waste	Julie Gray	grayj@uab.edu

REVIEW SCHEDULE

This plan was implemented by:

Name of Manager or Supervisor:	
Date:	

Use the table below to track required annual reviews or edits of this document.

Reviewed (Yes or No)	**Updated** (Yes or No)	**Date**	**Manager or Supervisor Signature**

UAB Biosafety Manual Appendices 12.11

Appendix 4.2
UAB Campus Medical Waste Management Plan

UAB Campus Medical Waste Management Plan

PURPOSE: To set forth guidelines for the safe management of medical waste throughout the University of Alabama at Birmingham (UAB) campus.

SCOPE: This plan is intended to support non-clinical campus operations-including, but not limited to-teaching and research activities that generate medical waste, as defined by the Alabama Department of Environmental Management (ADEM), the Department of Transportation (DoT), and UAB policy, below. Medical waste shall be properly managed from the points of origin to the ultimate disposal.

ASSOCIATED INFORMATION:

I. **Definitions** per the Alabama Department of Environmental Management Land Division 17-Medical Waste Program, Chapter 335-17-1, Medical Waste (ADEM), 49 CFR 173.134 Hazardous Materials Regulations and UAB policy:

Medical waste shall be interpreted to mean:

A. **Animal Waste:** Carcasses and body parts, regulated bulk blood and body fluids, and surgical waste 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, blood, and body parts 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.

B. **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 clinical and research laboratories.

Note: 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. **For all research studies at UAB**, any material contaminated with human blood and/or body fluids is treated as medical waste.

C. **Microbiological Waste:** Discarded cultures and stocks of human infectious agents and associated microbiologicals **that do not qualify as Category A waste material**; 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.

IMPORTANT: Infectious waste containing (or contaminated with) viable Class A infectious organisms must be inactivated prior to disposal as Medical Waste. **See Table below** for agents listed as Category A. If an autoclave is used to inactivate waste the autoclave must be validated after every 40 hours of use (a log must be present to track use).

Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicated (3.6.2.2.2.1)		
	All Material	**CULTURES ONLY**
Crimean-Congo haemorrhagic fever virus	X	
Ebola virus	X	
Flexal virus	X	
Guanarito virus	X	
Hantaan virus	X	
Hantavirus causing hemorrhagic fever	X	
Hendra virus	X	
Kyasanur Forest disease virus	X	
Junin virus	X	
Lassa virus	X	
Machupo virus	X	
Marburg virus	X	
Monkeypox virus	X	
Nipah virus	X	
Omsk haemorrhagic fever virus	X	
Sabia virus	X	
Variola virus	X	
African swine fever virus		X
Avian paramyxovirus Type 1–Velogenic Newcastle disease virus		X
Bacillus anthracis		X
Brucella abortus		X
Brucella melitensis		X
Brucella suis		X
Burkholderia mallei–Pseudomonas mallei–Glanders		X
Burkholderia pseudomallei/Pseudomonas pseudomallei		X
Chlamydia psittaci–avian strains		X
Classical swine fever virus		X
Clostridium botulinum		X
Coccidioides immitis		X
Coxiella burnetii		X
Dengue virus		X
Eastern equine encephalitis virus		X
Escherichia coli, verotoxigenic		X
Foot and mouth disease virus		X
Francisella tularensis		X
Goatpox virus		X

CONTINUED from previous page	All Material	CULTURES ONLY
Hepatitis B virus		X
Herpes B virus		X
Highly pathogenic avian influenza virus		X
Human immunodeficiency virus		X
Japanese Encephalitis virus		X
Lumpy skin disease virus		X
Mycobacterium tuberculosis		X
Mycoplasma mycoides–Contagious bovine pleuropneumonia		X
Peste des petits ruminants virus		X
Poliovirus		X
Rabies virus		X
Rickettsia prowazekii		X
Rickettsia rickettsii		X
Rift Valley fever virus		X
Rinderpest virus		X
Russian spring-summer encephalitis virus		X
Sheep-pox virus		X
Shigella dysenteriae type 1		X
Swine vesicular disease virus		X
Tick-borne encephalitis virus		X
Venezuelan equine encephalitis virus		X
Vesicular stomatitis virus		X
West Nile virus		X
Yellow fever virus		X
Yersinia pestis		X
*CULTURE ONLY = agents that are considered Category A as cultures only (i.e., only when they are intentionally propagated). Note: Pathogens not listed may also be considered “Category A” if they are capable of causing permanent disability or life-threatening disease in otherwise healthy humans or animals. If there is any doubt as to whether or not a substance meets the criteria it must be considered “Category A.”		

D. **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.

E. **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.

F. **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.

Note: These items are to be placed directly into designated and approved sharps containers located as close to the work area as possible. After they are full and properly closed, they are packaged for disposal by UAB's medical waste contractor.

Other glass items that are not contaminated with blood or body fluids or other hazardous materials are to be discarded in rigid, puncture-resistant containers which are labeled "glass only" or "broken glass only" as appropriate. These containers will be removed from the facility by environmental services and disposed of in the landfill.

G. **Surgical Waste:** All materials discarded from surgical procedures which are contaminated with human bulk blood, blood components, or body fluids, included but not limited to disposable gowns, dressings, sponges, lavage tubes, drainage sets, underpads, and surgical gloves.

H. **Recombinant Waste:** All material contaminated with recombinant or synthetic nucleic acid molecules.

I. **Medical Waste Storage Areas:** Defined per ADEM Admin Code R. 335-17-.02(23) as *the containment of medical waste at the generating facility or some alternative place for a temporary or extended period of time at the end of which the waste is treated or stored elsewhere. Placing waste in a container at the point of generation such as a patient's room, operating room, a laboratory, or a designated room within a research area (staging area) would not be considered as a "storage area" under this code.*

II. Education and Training

A. An education program designed to provide information about the types of medical waste encountered in the workplace and identify appropriate procedures, personal protective equipment, and precautions used for handling and disposing of medical waste in accordance with UAB, the Alabama Department of Environmental Management and the US Department of Transportation requirements is available through the UAB Department of Environmental Health & Safety to all employees who manage or have contact with medical waste. This training must be renewed every 3 years. Visit UAB Campus Leaning to access training.

Training Required for any contact with medical waste:

- **Basic Biosafety Training (ID: E-5VNQVM):** How to conduct a biological risk assessment for safe work with infectious organisms
- **Medical Waste Management for Labs (ID: E-7VR7VE):** How to properly dispose of medical waste at UAB
- **Bloodborne Pathogen Training (ID: E-E04XRO):** Bloodborne Pathogen (BBP) Standard awareness and annual refresher training (if medical waste involves contact with BBP).

B. Consultation and response to questions regarding medical waste issues will be provided on request by contacting UAB Biosafety at biosafety@uab.edu.

III. Coordination and Implementation of Medical Waste Management

A. The UAB Medical Waste Management Plan is designed to be in compliance with local, state, and federal regulations. The UAB Biosafety Program, operating in the Department of Environmental Health & Safety reviews and revises the plan yearly, and as regulations and guidelines mandate.

B. Updates to this plan are periodically reviewed and endorsed by the UAB IBC.

C. The UAB Biosafety Manager Coordinated Medical Waste Accounts and Pickup Sites and serves as a liaison between UAB campus medical waste generators and Stericycle.

IV. References:

- Alabama Department of Environmental Management Land Division-Solid Waste Program, Division 17, Code 335-17, January 2012.
- US Department of Transportation Hazardous Materials Regulation 49 CFR 173.134.
- CDC, National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories. 6th Ed. Washington, DC: US Department of Health and Human Services, Public Health Service, CDC; DHHS publication no. (CDC) 2007.

UAB Biosafety Manual Appendices 12.12

Appendix 4.3
UAB Exposure Response Plans

Treatment for Exposures at UAB

I was exposed to
human blood, fluid, or tissue, biologic agent, chemical agent, radiation lasers, animal

CALL 911 IN AN EMERGENCY
unconscious, seizures, difficulty breathing, significant bleeding, chemical spills of 500mL or more, or other life threatening injuries

Activate agent-specific safety plan, initiate decontamination procedures

205-934-3411
Ask for the "needlestick and exposure team"

Campus Employees and Students
Complete OJI Incident Report

Supervisor should also complete "Initial Medical Evaluation Form" and send it with the employee; paperwork MUST BE COMPLETED within 48 hours

OJI form located at:
https://www.uab.edu/humanresources/home/relations/oji

Hospital/Medicine Employees and Students
Complete Trend Tracker

Trend Tracker information located at:
https://www.uab.edu/humanresources/home/relations/oji

You will be triaged to care depending on exposure

UAB EMPLOYEE HEALTH
The University of Alabama at Birmingham

On-the-job Injury at UAB

I was injured while performing my job at UAB and need medical care

CALL 911 IN AN EMERGENCY
unconscious, seizures, difficulty breathing, significant bleeding, chemical spills of 500mL or more, or other life threatening injuries

I was exposed to
human blood, fluid, or tissue, biologic agent, chemical agent, radiation, lasers, or animals

Yes

Follow "Treatment for Exposures" Plan
Call 205-934-3411
Ask for the "needlestick and exposure team"

No

Campus Employees and Students: Complete OJI Incident Report; Supervisor should also complete "Initial Medical Evaluation Form" and send it with the employee; paperwork MUST BE COMPLETED within 48 hours.
OJI form located at: https://www.uab.edu/humanresources/home/relations/oji

Hospital/Medicine Employees and Students: Complete Trend Tracker
Trend Tracking information located at:
https://www.uab.edu/humanresources/home/relations/oji
Notify Supervisor and contact
Brentwood Services Administrators at 205-933-0373 or 1-800-524-0604

UAB EMPLOYEE HEALTH
The University of Alabama at Birmingham

UAB Biosafety Manual Appendices 12.13

Appendix 5.1
Example Select Toxin SOP – Diphtheria Toxin

Example Select Toxin SOP - Diphtheria Toxin

Laboratory Information		
Title of the Project:	Date:	Lab location:
PI: Dr. Doe	Contact Info:	Date of review:

Emergency Procedures

(Describe what procedures should be followed in the event of an emergency including phone # floor plan, exits, location of emergency equipment like eyewash/safety shower, fire extinguisher etc.)

Exposure First Aid Procedures:

- **For all UAB Emergencies, call UAB Police (UAB PD) by dialing 911 from a campus phone, or 934-3535 froma mobile phone**. **The UAB Emergency Department (ED) is located at 1801 6th Avenue South, Birmingham, AL 35233**
- For oral (mouth) exposure, or if DT has been swallowed and the person is conscious, wash out mouth withwater while another worker calls UAB PD.
- For inhalation exposure, move person to fresh air.
- For contact exposure to the eye, flush eye with copious amounts of water for at least 15 minutes and callUAB Police
- For dermal exposure, rinse area with copious amounts of water for at least 15 minutes, remove anycontaminated clothing. Call UAB PD or go directly to the Emergency Department (ED).
- Needlesticks are a medical emergency and all work should be halted. Another person should secure thetoxin while the injured person washes and obtains treatment. Call UAB PD, or go directly to ED.

Hazardous materials and equipment

(List items used. Include chemical name, common name and abbreviation)

Diptheria Toxin (DT)

Signs and Symptoms of Exposure

(Describe the specific signs and symptoms of an exposure to the chemical such as visual cues or odors)

There have been reports of rapid onset of local pain after percutaneous exposure to diphtheria toxin and such an occurrence would indicate a significant exposure. Further symptoms include: skin irritation, respiratory irritation, fever and headache. Do not breathe dust, fume or vapors of

DT powder or solutions. DT may cause death if ingested. Onset of symptoms following significant diphtheria toxin exposure would typically have onsetdelayed by days to weeks and are due to the inhibition of protein synthesis. The Emergency Department (ED) shall assess the severity of the exposure and take appropriate actions.

Potential Hazard(s)

(Describe the potential hazards associated with the chemicals or the procedure.) Examples include:

DT is an exotoxin that inhibits eukaryotic protein synthesis by ADP-ribosylating an enlongation factor needed to translocate the ribosome along mRNA. DT exposure can be extremely toxic at very low levels. Allcontact should be avoided.

Routes of Exposure

(Potential routes of exposure such as inhalation, injection, skin/eye contact)

Routes: Ingestion, inhalation, absorption, percutaneous

Symptoms: Skin irritation, respiratory irritation, fever and headache. Do not breathe dust, fume or vapors of DTpowder or solutions. DT may cause death if ingested.

Exposure Limit

(As applicable, list the Permissible Exposure Limit (PEL) or Threshold Limit Value (TLV) of the chemical(s) if known)

LD50 = 0.1 ug/kg

Quantity/Concentration Hazards

(As applicable, describe if the quantity/concentration of the chemical(s) used increases the risk ofexposure to the chemical.)

If possible do not work with powder form of diphtheria toxin (DT). If necessary purchase pre-weighed or pre- diluted DT in the least quantity possible to perform work. [Vials of DT will be purchased in pre-weighed powder form and then reconstituted in a [fume hood/glove box/biological safety cabinet (BSC)]. Weighing the toxin is not necessary as reconstitution will occur in the purchased vial and then aliquoted into vials with caps.]

Engineering Controls

(As applicable, describe the engineering controls used for the procedure) Examples:

- Use fume hoods, BSCs, or glove boxes for all toxin work
- Bench paper, pads, plastic-backed paper should be used for work surfaces inside containment devices
- Special ventilation: work areas should be under negative pressure to surrounding areas
- vacuum lines should be HEPA filtered
- Safe sharp devices: Be extremely cautious using needles with DT. Follow the written procedures for safeuse of sharps, and practice doing a "dry run" with less hazardous materials as needed. A sharps containermust be in the immediate vicinity for safe sharps disposal. Use a syringe holder to secure syringe. Contact Biosafety for consultation at 205-917-4766 or email biosafety@uab.edu.
- Other safety devices used: centrifuge safety cups or sealed rotors when centrifuging toxin-containing materials.

Personal Protective Equipment (PPE)

(Refer SDS or other sources/consult EH&S)

- Double Gloves (Nitrile)
- Lab Coats, Suits, Aprons (long sleeves)
- Safety Glasses, Goggles, Faceshields
- N95 Respirators may be required, depending on procedure

Work Practice Controls

(As applicable, describe work practice controls used for the procedure) Examples:

- All preparation of DT will be performed over plastic backed absorbent pads.
- If possible do not work with powder form of diphtheria toxin (DT). If necessary purchase pre-weighed orpre-diluted DT in the least quantity possible to perform work. [Vials of DT will be purchased in pre- weighed powder form and then reconstituted in a [fume hood/glove box/biological safety cabinet (BSC)].Weighing the toxin is not necessary as reconstitution will occur in the purchased vial and then aliquotedinto vials with caps.]
- Vaccine is available for diphtheria, and must be offered every ten years. If persons working with DT arenot current with their immunizations, contact Occupational Medicine
- Reconstitution, dilution and administration of the toxin will be performed only in a *[fume hood/glovebox/BSC]* while wearing PPE.
- Designate specific area for toxin work
- Housekeeping: Decontamination of all work surfaces and materials after procedures are complete
- Two people should be present during high-risk procedures.
- Restricted access during work with toxins.
- Special signage: "Toxins in Use. Authorized Personnel Only"

- Hand wash
- DO NOT RECAP needles. Never leave exposed needle tip in work area.
- Animals will be anesthetized or placed into a restraining apparatus before procedures using DT are performed. Once the animal has been properly fitted into the restraining apparatus, the syringe will be loaded just prior to injection.

Monitoring

(As applicable, describe any monitoring needed for the procedure) Examples:

- N/A

Cleanup/Decontamination Procedures

(Describe the process for cleaning the work area during and after the procedure.)

Work space surfaces must be wiped down with 1% NaOCl or 10% bleach daily, during the length of the experiment. To prevent corrosion of metal surfaces rinse with water after using chlorine-based chemicals. Absorbent pads will be replaced daily. The used and contaminated absorbent pads, PPE, etc. will be placed in a biohazard bag and autoclaved. Note that some disinfecting agents may not deactivate DT.

Storage Procedures

(Describe how and where the chemical will be safely stored

Example: Reviewing expiration dates on peroxide formers

- Unused DT will be kept in its original container or aliquoted into labeled vials that are tightly closed and stored at -20ºC. The original DT container or vials containing aliquots, will be stored inside a labeled, leak-spill-proof secondary container.
- Store DT in a secure location.

Transportation Procedures

(If the chemical will be transported on campus, describe procedure)

- Transport DT in secondary, sealed, labeled non-breakable containers.

Waste Disposal Procedures

(*Description of how waste will be disposed)*

- Any waste DT will be chemically decontaminated or autoclaved before disposal.
- Chemical decontamination/neutralization with 1% NaOCl or 10% bleach for 30 min.

- If in-lab decontamination/autoclaving is not possible for some DT waste, it should be manifested as chemical waste.

Spills or Releases

(Provide specific instructions on what personnel should do in the event of a spill or gas release. Includelocation of spill kits.)

If you are not trained or comfortable cleaning up a spill, call 205-917-4766 or email biosafety@uab.edu for assistance. If it is an emergency (risk of exposure to others such as an on-going DT release) call UAB Police by dialing 911 from a campus phone or 934-3535 from a mobile phone

- **Liquid spills**: To be cleaned by properly protected and trained personnel. Personnel cleaning up a liquid spill will wear a lab coat/gown, goggles, and two pairs of nitrile gloves. Cover spill with absorbent paper towels and apply 1% sodium hypochlorite (NaOCl) (or 10% bleach), starting at the perimeter and working towards the center, allowing 30 min. contact time to deactivate DT before clean up. Clean the spill area with 1% NaOCl (or 10% bleach) allowing 30 min. contact time, then soap and water. The decontaminated spill waste will be double bagged and disposed of in regular trash.

- **Powder spills inside of [*fume hood/glove box/BSC]***: To be cleaned by properly protected and trained personnel. Personnel cleaning up a powder spill will wear a lab coat/gown, goggles, and two pairs of nitrile gloves. Gently cover powder spill with dampened absorbent paper towels to avoid raising dust. Apply 1% NaOCl (or10% bleach), starting at the perimeter and working towards the center, allowing 30 min. contact time to deactivate DT before clean up. Clean the spill area with 1% NaOCl (or 10% bleach) allowing 30 min. contact time, then soap and water. The decontaminated spill waste will be double bagged and disposed of in regular trash. Wash hands thoroughly after completing any spill clean up.
- **Powder spills outside of a *[fume hood/glove box/BSC]***: Remove all personnel from the room and restrict access. A spill cleanup professional will need to manage the spill since it requires respiratory protection.
  As soon as possible report the spill by notifying EH&S (EH&S business hours 205-917-4766, outside business hours call UAB PD; tell them that a spill has occurred, and you need to contact a UAB EH&S Director On Call. Be prepared to provide the following information:
  - Name and phone number of knowledgeable person that can be contacted: _____
  - Name of chemical, concentration and amount spilled
  - Number of injured, if any
  - Location of spill

  This information can also be used in reporting to the Emergency Department after potential exposures.

Fire

(Provide specific instructions on what personnel should do in the event of a fire)

N/A

Occupational Medicine Requirements

(Describe any Occupational Medicine requirements necessary that are associated with the procedure Examples include medical evaluation, and respiratory fit testing)

Contact Occupational Medicine for information on DT vaccines.

Safety Data Sheets (SDS)

(Describe how personnel will access SDS in the lab. Include a copy of the SDS with this SOP)

Ensure the toxin Material Safety Data Sheet/Safety Data Sheet (MSDS/SDS) is available to staff at all times

Training Requirements

(Describe what training personnel must complete before using chemical/procedure. This training should be documented)

The PI is responsible for ensuring training on toxin-specific hazards and standard operating procedures (SOP) is carried out and documented for all laboratory personnel prior to the start of work. The training must include but is not limited to appropriate workplace practices and procedure-specific activities involving toxins, personal protective equipment, the health and physical hazards of the toxin, signs and symptoms associated with exposure, and emergency response procedures. All training must be documented and maintained by the PI.

Review of Procedure

(Describe the frequency for reviewing the SOP document)

Per PI policies

Protocol

Description of how to safely perform the experiment or operation.

Training Documentation	
Training Acknowledgement: I have read, asked questions, and understand the hazards of and safeworking procedures for the activity/materials described herein.	
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:

UAB Biosafety Manual Appendices 12.14

Appendix 5.2
Select Toxin SOP Template

Select Toxin SOP Template

Laboratory Information		
Title of the Project:	Date:	Lab location:
PI: Dr.	Contact Info:	Date of review:

Emergency Procedures
Describe what procedures should be followed in the event of an emergency including phone # floor plan, exits, location of emergency equipment like eyewash/safety shower, fire extinguisher etc.

Hazardous materials and equipment
(List items used. Include chemical name, common name and abbreviation)

Signs and Symptoms of Exposure
(Describe the specific signs and symptoms of an exposure to the chemical such as visual cues or odors)

Potential Hazard(s)
(Describe the potential hazards associated with the chemicals or the procedure.) Examples include:

Routes of Exposure
(Potential routes of exposure such as inhalation, injection, skin/eye contact)

Exposure Limit
(As applicable, list the Permissible Exposure Limit (PEL) or Threshold Limit Value (TLV) of the chemical(s) if known)

Quantity/Concentration Hazards
(As applicable, describe if the quantity/concentration of the chemical(s) used increases the risk ofexposure to the chemical.)

Engineering Controls

(As applicable, describe the engineering controls used for the procedure) Examples:

- *Use of fume hoods or glove boxes*
- *Special ventilation*
- *HEPA filtered vacuum lines*
- *Temperature control*
- *Bench paper, pads, plastic-backed paper*
- *Special signage*
- *Safe sharp devices*
- *Other safety devices used*

Personal Protective Equipment (PPE)

(Refer SDS or other sources/consult EH&S)

- *Gloves (what type)*
- *Lab Coats, Suits, Aprons*
- *Safety Glasses, Goggles, Face shields*
- *Respirators, Hearing Protection*
- *Special Equipment (such as blast shields)*
- *Other PPE*

Work Practice Controls

(As applicable, describe work practice controls used for the procedure) Examples:

- *Designated areas (for highly toxic chemicals)*
- *Requirement of two people*
- *Restricting access*
- *Hand wash*
- *Housekeeping*

Monitoring

(As applicable, describe any monitoring needed for the procedure) Examples:

- *Personnel exposure monitoring*
- *Gas/spill release monitoring*

Cleanup/Decontamination Procedures

(Describe the process for cleaning the work area during and after the procedure.)

Storage Procedures

(Describe how and where the chemical will be safely stored

Example: Reviewing expiration dates on peroxide formers

Transportation Procedures

(If the chemical will be transported on campus, describe procedure)

Waste Disposal Procedures

(*Description of how waste will be disposed)*

Examples:

- *Animals: include bedding, cages and carcasses*
- *Chemicals*
- *Radioactive*
- *Sharps*

Spills or Releases

(Provide specific instructions on what personnel should do in the event of a spill or gas release. Includelocation of spill kits.)

Fire

(Provide specific instructions on what personnel should do in the event of a fire)

Exposures

(Provide specific instructions on what personnel should do in the event of an exposure)

First Aid: (If first aid for exposure is available, describe procedure. If not, describe what steps should personnel take if injured.)

Occupational Medicine Requirements
(Describe any Occupational Medicine requirements necessary that are associated with the procedure Examples include medical evaluation, and respiratory fit testing)

Safety Data Sheets (SDS)
(Describe how personnel will access SDS in the lab. Include a copy of the SDS with this SOP)

Training Requirements
(Describe what training personnel must complete before using chemical/procedure. This training should be documented)

Review of Procedure
(Describe the frequency for reviewing the SOP document)

Protocol
Description of how to safely perform the experiment or operation.

Training Documentation	
Training Acknowledgement: I have read, asked questions, and understand the hazards of and safeworking procedures for the activity/materials described herein.	
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:
Name:	Date:

UAB Biosafety Manual Appendices 12.15

Appendix 5.3
Destruction of Select Agent Form

Contact biosafety@uab.edu for this Form

UAB Biosafety Manual Appendices 12.16

Appendix 5.4
Risk Group 3 Agent Transfer Request Form

Contact biosafety@uab.edu for this Form

UAB Biosafety Manual Appendices 12.17

Appendix 5.5
Select Toxin Exemption Checklist

Exemption Checklist for Use of Select Toxins

The following form should be submitted and approved prior to purchasing or obtaining Select Toxins. This is a PDF fill-able form. Answer all items completely, save a copy for your file, and send to the UAB Responsible Official (RO), Brian LaGory at blagory@uab.edu or biosafety@uab.edu

SECTION 1 –APPLICANT INFORMATION			
Last Name (PI/Applicant):	First Name:	Title:	Email address:
Campus Address – Building:	Room:		Phone:
Department:	Division:		
TOXIN USE IS LIMITED TO THE FOLLOWING:			
Lab Building(s):	Room(s):		

SECTION 2 – DOCUMENTED USERS, TRAINING, and SECURITY

Instructions: Check the appropriate box in the left hand column to certify completion of laboratory safety, training, and security in regards to possessing exempt quantities of select agent toxins.

Approved Users/Training:

☐ PI has approved and verified current list of users with access to toxins.

General Safety:

☐ Appropriate procedures are in place to ensure safe handling, storage, and disposal of Toxins, (i.e. Standard Operating Procedures SOP's). Please attach any relevant SOPs with submission of this document.

☐ All approved users have documented toxin-specific safety training and have demonstrated proficiency on relevant SOPs

Storage/Physical Security Measures:

☐ All Select Agent toxin containers are labeled properly and are securely stored within the laboratory.

SECTION 3 – SELECT TOXINS and QUANTITIES USED

Instructions: Please check all toxins in use, and the current quantity in inventory. See the current list of select toxins and exempt quantities. Any theft, loss, or release of a select toxin, regardless of the quantity, must be immediately reported to the RO/ARO.

Select Toxin	Current quantity on hand (for all toxin forms) mg	Exempt quantity mg	
☐ Abrin		≤ 1000 mg	Exemption applies if the aggregate amount (purified and impure forms) under the control of a PI does not, at any time, exceed the amount specified in the exempt column, documentation of due diligence is maintained for transfers and **Inventory of toxin(s) must be maintained by PI (at least 3 years) to confirm quantities do not exceed exemption limits.**
☐ Botulinum neurotoxins		≤ 1 mg	
☐ Conotoxins		≤ 100 mg	
☐ Diacetoxyscirpenol (DAS)		≤ 10,000 mg	
☐ Ricin		≤ 1000 mg	
☐ Saxitoxin		≤ 500 mg	
☐ Staphlococcal enterotoxins		≤ 100 mg (all subtypes combined)	
☐ Tetrodotoxin		≤ 500 mg	
☐ T-2 toxin		≤ 10,000 mg	

I am obtaining _____ mg of _____ from _____ on _____
(Select Agent Toxin) (Vendor/Collaborator) (Date)

SECTION 4 – EXEMPTION REQUEST and ATTESTATION

Instructions: Check all boxes, sign, and date

☐ I would like to request an exemption from the select agent regulations to use the material indicated above, and

☐ **I will NOT transfer** this material to any other location without prior written approval from the UAB RO/ARO for Select Agents for each transfer.

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 42 CFR 73, 9 CFR 121, or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of PI _____ Date _____

For EH&S Use Only: Applicant is approved to maintain exempt quantities of the listed toxin(s) in the lab location(s) listed above

by: _____ on: _____

UAB Biosafety Manual Appendices 12.18

Appendix 8.1
Guidance for Transport and Shipping of COVID-19+ / SARS-CoV-2 Patient Samples at UAB

Guidance for Transport and Shipping of COVID-19+/ SARS-CoV-2 Patient Samples at UAB

Shipping COVID-19/SARS-CoV-2 patient samples for commercial shipment off UAB property

- COVID-19+ patient specimens should be shipped as UN3373, “Biological Substance, Category B”.
- Viral cultures or isolates of SARS-CoV-2 **must** be shipped as Category A, UN2814, “infectious substance, affecting humans”.

Transport of COVID-19/SARS-CoV-2 patient samples on UAB Property

If COVID-19+ patient specimens must be moved to a new on-campus destination and cannot be moved on foot or by professional courier, there are several options:

- **EH&S Support Facility** – Email: biosafety@uab.edu for more information on having EH&S move your patient samples.
- **UAB Vehicles or Personal vehicles -** Individuals using a UAB or personal vehicle to move patient samples must abide by the *UAB Vehicle Safety Management Program* and complete *Bloodborne Pathogens and Category B/ UN3373 IATA shipping training.*
- **DO NOT** move patient samples using cabs, Birmingham city buses, Lyft, Uber, Blazer shuttles, etc.

Packaging of COVID-19/SARS-CoV-2 patient samples for transport on UAB Property

Transport of COVID-19+/SARS-CoV-2 patient samples 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. Unless transport is between sites within a contiguous space (see Table 7.1), packaging of potentially infectious samples for hand transport on campus should resemble the packaging required for shipment. 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 7.1. 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.

Description	Containers	Labels
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, and tertiary[3]	Agent-specific info on primary, Biohazard label on secondary, Emergency contact info on tertiary

[1]**primary container:** 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 sufficient material to absorb the entire volume of the sample(s) [3]**tertiary container:** a rigid outer container sufficient to maintain containment if the shipment is dropped.

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Appendix 9.1
Spill Cleanup Cue Cards

ut cue cards and post in a highly visible work area

SPILLS INSIDE THE BIOSAFETY CABINET

1. Make sure the cabinet continues to operate. Wait 5 min. to allow aerosols to be pulled through the HEPA filter.
2. Decontaminate the surfaces within the cabinet wearing protective clothing. Gently cover the spill with absorbent paper towels and apply the appropriate disinfectant starting at the perimeter and working towards the center.
   * Note: Examine drain pan for contents of the spill. Disinfect if needed.
3. Discard soaked paper towels in a biohazard bag. Wipe up residual fluids. Wipe down surfaces with 70% EtOH, discarding towels in a biohazard bag.

SPILLS OUTSIDE THE BIOSAFETY CABINET

Small Spill (<10 mL, localized to small area)

1. Alert personnel in the vicinity.
2. Check for contaminated clothing, including shoes. Decontaminate if necessary.
3. Evacuate the room. Close door. Discard potentially contaminated PPE, remove and decon any contaminated clothing. Wash hands.
4. Notify PI. Wait for 20 minutes to allow for room air exchanges to clear aerosols through room exhaust.
5. Don fresh PPE: lab coat or gown, gloves, mask, eye protection.
6. Cover spill with paper towels.
7. Soak paper towels with the appropriate disinfectant, from perimeter toward the center.
8. Allow 20 min. of contact time. Work can continue during contact time.
9. Discarded towels go in biohazard bags. Pick up sharps with tongs & place in sharps container.
10. Wipe down spill area one final time with appropriate disinfectant.

SPILLS OUTSIDE THE BSC

Major Spill (>10 mL, localized to small area)

1. Alert personnel in the vicinity.
2. Check for contaminated clothing, including shoes. Decontaminate if necessary.
3. Evacuate the room. Close door. Discard potentially contaminated PPE and remove any contaminated clothing. Wash hands thoroughly.
4. Post warning sign: “DO NOT ENTER: Biological spill!”
5. Wait 20 min. Meanwhile, notify PI and a Biosafety Officer/Specialist (934-2487).
6. If assistance is needed, discuss with Biosafety Officer.
7. Don fresh PPE: lab coat or gown, gloves, mask, eye protection.
8. Re-enter the room, cover spill with paper towels.
9. Soak paper towels with appropriate disinfectant, from perimeter toward the center.
10. Allow 20 min. of contact time. Work can continue during contact time.
11. Discarded towels go in biohazard bags. Pick up sharps with tongs & place in sharps container.
12. Wipe down spill area one final time with appropriate disinfectant.
13. With PI, write up a report and submit to the Biosafety Officer.

SPILLS INSIDE AN INCUBATOR

Decontaminate water pan via autoclave.

1. Alert personnel in the vicinity.
2. Evacuate the room. Close door. Discard potentially contaminated PPE and remove any contaminated clothing. Wash hands thoroughly.
3. Notify PI.
4. Don fresh PPE: lab coat or gown, gloves, mask, eye protection.
5. Cover spill with paper towels.
6. Soak paper towels with appropriate disinfectant, from perimeter toward the center.
7. Allow 20 min. of contact time.
8. Discarded towels go in biohazard bags. Pick up sharps with tongs & place in sharps container.
9. Wipe down spill area one final time with appropriate disinfectant.

SPILLS INSIDE A CENTRIFUGE

1. Open lid of centrifuge slowly.
2. If there has been no breach of containment, spray rotor with 70% EtOH.
3. If inside of rotor is contaminated, decontaminate in the BSC. As a precautionary measure, decontaminate the centrifuge chamber.
4. If rotor buckets are damaged, close centrifuge lid.
5. Alert personnel in the vicinity. Evacuate room.
7. Wait 30 min. Meanwhile, notify PI and a Biosafety Officer/Specialist (934-2487).
8. If assistance is needed, discuss with Biosafety Officer.
9. Open lid slowly and add paper towels.
10. Spray walls of chamber and rotor with 70% EtOH.
11. Close centrifuge lid for 20 min. contact time.
12. Finish centrifuge clean-up as for major spill outside the BSC. Transport rotor to BSC.
13. Open and decontaminate rotor/buckets in the BSC.
14. With PI, write up a report and submit to Biosafety Officer

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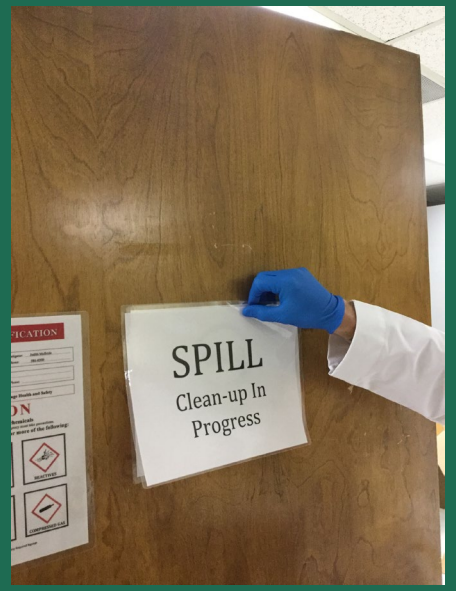
Appendix 9.2
Spill Cleanup Procedures

1

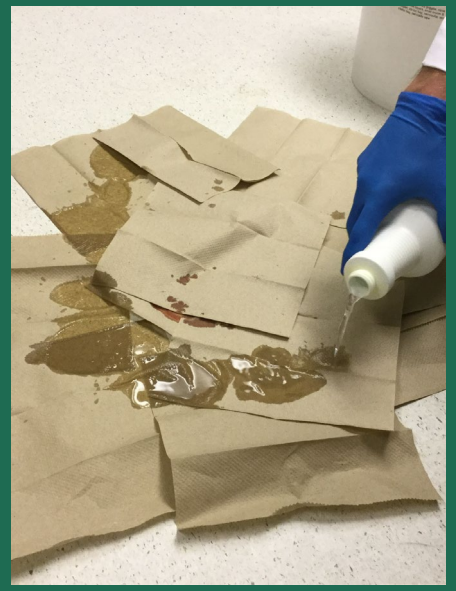


Post sign on lab door and alert others

2

Assess spill size and retrieve spill kit

3



Cover with paper towels and soak

4

Soak with disinfectant for appropriate time

5

Clean up with tongs

6

Place all clean up material in red bag

7

Dispose of material as medical waste

8

Discard gloves and wash hands