

TABLE OF CONTENTS

Section 1. Introduction

Section 2. Program Administration

- 2.1 Office of the Vice President for Financial Affairs
- 2.2 UAB Institutional Biosafety Committee
- 2.3 The Department of Occupational Health & Safety
 - 2.3.1 Biosafety Division
 - 2.3.2 Biosafety Officer
- 2.4 Deans/Department Chairs/Directors
- 2.5 Principal Investigators/Laboratory Directors
- 2.6 Laboratory Staff
- 2.7 Liability Considerations
- 2.8 Incidents of Non-compliance

Section 3. Project Registration

- 3.1 New Project Registration
- 3.2 Renewals
- 3.3 Modifications of previously registered projects
- 3.4 IBC/Biosafety Approval
- 3.5 Appeal Process

Section 4. Principles of Biosafety

- 4.1 Containment
 - 4.1.1 Primary Containment (Safety Equipment)
 - 4.1.2 Secondary Containment (Facility Design)
- 4.2 Basic Laboratory Safety
- 4.3 Biosafety Levels – in brief

Section 5. Biohazards and Potentially Infectious Materials

- 5.1 Definitions
- 5.2 Potentially Infectious Materials Use
 - 5.2.1 Microbes
 - 5.2.2 Human Blood, Blood Products, Body Fluids and Tissues
 - 5.2.3 Tissue/Cell Culture
- 5.3 Animal Use
 - 5.3.1 Minimum Biosafety Guidelines
 - 5.3.2 Infected Animals
 - 5.3.3 Use of Non-human Primates
- 5.4 Recombinant DNA/RNA Use
 - 5.4.1 In the laboratory
 - 5.4.2 Human Gene Transfer (Therapy)
 - 5.4.3 Transgenic Animals
 - 5.4.4 Transgenic Plants
- 5.5 Restricted Research Activities
 - 5.5.1 Select Agents
 - 5.5.2 Attenuated Strains of Material on the Select Agents List
 - 5.5.3 Non-viable Agents on the Select Agents List
 - 5.5.4 Select Agent Toxin Exclusions
 - 5.5.5 Select Agents in Clinical or Diagnostic Samples

- 5.5.6 Requesting Exemptions from the Select Agent Regulation
- 5.5.7 Denial, Revocation, or Suspension of Registration
- 5.6 Prohibited Research Activities

Section 6. Biosafety Containment Levels

- 6.1 Laboratory Biosafety Level 1 (BSL-1)
- 6.2 Laboratory Biosafety Level 2 (BSL-2)
- 6.3 Laboratory Biosafety Level 3 (BSL-3)
- 6.4 Laboratory Biosafety Level 4 (BSL-4)
- 6.5 Animal Biosafety Level 1 (ABSL-1)
- 6.6 Animal Biosafety Level 2 (ABSL-2)
- 6.7 Animal Biosafety Level 3 (ABSL-3)
- 6.8 Animal Biosafety Level 4 (ABSL-4)

Section 7. Biological Agents and Biohazard Classification

- 7.1 Risk Group 1 (RG1)
- 7.2 Risk Group 2 (RG2)
- 7.3 Risk Group 3 (RG3)
- 7.4 Risk Group 4 (RG4)
- 7.5 Restricted Animal Pathogens

Section 8. Administrative Controls

- 8.1 Labels and Signs
- 8.2 Laboratory Safety Plan (Standard Operating Procedures)
- 8.3 Medical Surveillance
- 8.4 Training
- 8.5 Audits & Site Visits
- 8.6 Visitors/Minors in the lab

Section 9. Engineering Controls

- 9.1 Biological Safety Cabinets
- 9.2 Personal Protective Equipment
- 9.3 Centrifuges
- 9.4 Autoclaves
- 9.5 Other Safety Equipment

Section 10. Work Practices

- 10.1 Prudent Practices, Housekeeping, Hygiene
- 10.2 Universal Precautions
- 10.3 Syringes and Needles
- 10.4 Use of Biological Safety Cabinets
- 10.5 Blenders, Ultrasonic Disrupters, and Grinders
- 10.6 Laundry
- 10.7 Decontamination Procedures
- 10.8 Tuberculosis and the Workplace – Respiratory Fit Testing

Section 11. Management of Biohazardous Materials

- 11.1 Medical Waste Management
- 11.2 Storage
- 11.3 Recordkeeping
- 11.4 Laboratory Security

Section 12. Transportation of Biologic & Infectious Substances

- 12.1 Within UAB
- 12.2 Shipments From UAB
- 12.3 Import and Export of Biological Materials
- 12.4 Select Agent Transfer

Section 13. Emergency Response

- 13.1 Needlesticks and Exposures to Human Blood, Body Fluids, and Tissues
- 13.2 Other Personal Injury
- 13.3 Spill Response
- 13.4 Other Emergencies

APPENDICES

- A. UAB Biosafety Committee
- B. UAB Employee Occupational Health Program
- C. Exposure Control Plan Template
- D. DOT Guide for Shipping Infectious Substances
- E. Properties of Common Disinfectants
- F.
- G. Project Registration
- H. Registration for Recombinant DNA/RNA Research
- I. Select Agent Program Registration
- J. UAB Medical Waste Management Plan
- K. Herpesvirus Simiae (Herpes B) Guidelines
- L. Guidelines for Work with Vaccinia Vectors
- M. Guidelines for Work with Adenoviral Vectors

REFERENCES

McCunney, Robert J. ed. *Medical Center Occupational Health and Safety*. Philadelphia, Pa; Lippencott Williams & Wilkins, 1999.

Fleming, Diane O. and Hunt, D. L., ed. *Biological Safety Principles and Practices - Third Edition*. Washington, DC; ASM Press, 2000.

Richmond, JY & McKinney, RW ed. *Biosafety in Microbiological and Biomedical Laboratories – 4th Edition*. Washington, DC; U.S. Government Printing Office, 1999.

National Research Council. *Occupational Health and Safety in the Care and Use of Research Animals*. Washington, DC; National Academy Press, 1997.

Wood, M. & M. W. Smith, ed. *Health and Safety in Laboratory Animal Facilities*. London, England; The Royal Society of Medicine Press, 1999.

Podolsky, M.L. & Victor S. Lukas, ed. *The Care and Feeding of an IACUC*. Washington, DC; CRC Press, 1999.

Silverman, J et. al., ed. *The IACUC Handbook*. Washington, DC; CRC Press, 2000.

Mahy, B.W. & Hillar O. Kangro, ed. *Virology Methods Manual*. New York, NY; Harcourt Brace & Company, Publishers; Academic Press, 1996.

Cokendolpher, J. C. and Jill F. Haukos. *The Practical Application of Disinfection and Sterilization in Health Care Facilities*. Chicago, IL; American Hospital Association, 1996.

Rutala, William, A. ed. *Chemical Germicides in Health Care – International Symposium, May 1994*. Washington, DC; Association for Professionals in Infection Control and Epidemiology, Inc., 1995.

National Research Council. *Laboratory Design, Construction and Renovation*. Washington, DC; National Academy Press, 2000.

Other FORMS

- Hepatitis B Vaccine Declination Form
- Importation Permits
 - Animal Pathogens and Vectors
 - Cell Cultures
 - Human Pathogens and Vectors
 - Pathogens and Disease Vectors for Plants
- Laboratory Safety Audit Form
- Tb Mask (N-95) Medical Questionnaire
- UAB Accident/Incident Report Form

1. INTRODUCTION

The University of Alabama at Birmingham has gained recognition as a center of excellence for teaching, medical services, and research programs. This is a highly commendable achievement and one that could not have been realized without the continued support and dedication of faculty, staff members, and employees. Similar unfailing cooperation and support is necessary for the institution to be equally successful in its development of a comprehensive occupational health and safety program for protection of university personnel, students, and the community. An important part of this program is concerned with safety in research studies and safe disposal of laboratory and medical wastes.

The purpose of this manual is to describe the operation of the biological safety program and to provide guidelines for all university personnel for the safe operation of laboratories and performance of experiments involving biological agents. While many of the requirements mentioned herein have long been recognized by prudent members of the scientific community as essential when conducting research with hazardous or potentially hazardous biological materials, certain of them constitute recommendations and specific provisions promulgated by local, state, and federal government agencies, and by national accrediting organizations dedicated to the upgrading of research facilities and practices. The amalgamation and inclusion of these many safety requirements and guidelines in this manual signifies that the University of Alabama at Birmingham accepts, agrees to abide by, and to enforce them as they apply to research studies performed on University premises.

For the benefit of persons desiring to review in greater depth the safety recommendations, guidelines and regulations promulgated by the various government agencies and scientific organizations, the original published sources are listed under REFERENCES at the back of the manual or accessed from the OH&S web site at www.healthsafe.uab.edu.

Faculty and staff members are urged to carefully review Section 2 of this manual that deals briefly with the subject of liability in laboratory studies.

2. PROGRAM ADMINISTRATION

The policies, rules, and procedures set forth in the UAB Safety Manuals have a single, straightforward purpose: to promote a safe environment for the protection of University of Alabama at Birmingham employees, students, visitors, our community as well as UAB property. In order for these rules and procedures to be effective, it is important to have a structured administrative format in place that defines the roles and responsibilities of each person or administrative office.

2.1 Office of the Vice President for Research

The Office of the Vice President for Research and the Office of the Vice President for Financial Affairs share responsibility for the implementation of campus safety programs at UAB. The Vice President for Research has responsibility for ensuring that research is conducted in full conformity with the provisions of the safety manuals and all federal, state, and local regulations. All University research units with responsibility for any aspect of biohazards or potentially infectious materials must coordinate their activities through the UAB Department of Occupational Health & Safety, which has a dual reporting line to the Vice President for Research Safety and the Vice President for Financial Affairs.

The University and its administrative officers are ultimately responsible for:

- Promoting the importance of safety in all activities
- Supporting 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
- Assigning responsibility for the program components to appropriate individuals, task forces or committees and identifying and implementing clear lines of authority
- Providing facilities that meet University requirements for working with hazardous materials

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 UAB Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) is one of several safety committees with membership appointed by the UAB President. The IBC is responsible for assessing risk(s) and potential environmental impacts associated with campus activities involving biological and chemical agents and making recommendations for safe conduct of such activities. It is important for faculty and staff members to understand that 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.

IBC responsibilities are outlined in [Appendix A](#).

2.3 The [Department of Occupational Health & Safety](#)

The safe operations and activities of UAB are vital to its very existence. Whether the activity is teaching, conducting research or delivering health care, it must be done in a way that is as error free as possible, is top quality and is a final product that is acceptable to those receiving it and to the surrounding community.

The Department of Occupational Health and Safety is functionally organized into the following program operational units (alphabetically listed):

- Asbestos Abatement
- Biological Safety
- Chemical Safety
- Education and Training
- General Safety
- Hazardous Waste Management
- Hospital and Clinic Safety
- Information Technology
- Radiological Health and Safety

Program area reporting is through the Assistant Vice President for Occupational Health and Safety to the Associate Vice President for Facilities and the Vice President for Research.

In an effort to minimize requirements and to make sure fairness is upheld, the University has established several safety committees that set UAB policies regarding the acquisition, use, handling and final disposal of potentially hazardous materials. These policies are set forth in the form of "safety manuals" and represent a summation of regulatory requirements and agreements as to how these activities will be conducted at UAB. All health and safety manuals are signed and therefore endorsed by the President and in many cases are part of the licensing application and agreement with the regulatory agency.

There are currently four major health and safety committees:

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

Membership for all committees is composed of researchers and/or faculty, UAB administrators and OH&S staff. 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).

2.3.1 Biosafety Division

The Biosafety Division fosters safe Biosafety practices and compliance through implementation of policies, guidelines, or regulations set forth by University Administration, the Institutional Biosafety Committee, and regulatory and granting agencies.

The Biosafety Division, under the direction of the Director of Biosafety, is responsible for implementing and overseeing the technical aspects of the campus Biological Safety Program and includes the following services:

- Provides advice to faculty and staff on Biosafety matters.
- Reviews Project Registration including Recombinant DNA/RNA Registration, performs laboratory audits, and prepares recommendations for 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.

- Certifies biosafety cabinets, fume hoods, and clean air benches; performs other laboratory ventilation evaluations.
- Provides biological safety education and training aids and develops educational and training programs.
- Provides consultation for shipping infectious agents.
- Assists in coordinating and implementing the UAB Medical Waste Management Plan and conducts related training.
- Coordinates the Select Agent Program for biological agents.
- 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 OH&S staff to further promote a University-wide safety environment.

2.3.2 The Biosafety Officer's (BSO) duties include, but are not necessarily limited to, providing technical advice to the IBC and researchers on laboratory containment and safety procedures, overseeing periodic inspections to ensure that laboratory standards are maintained, and developing guidelines for handling spills and personnel contamination. The BSO reviews and approves Biosafety Level 1 project registrations, exempt recombinant DNA/RNA projects, projects involving the use of material of human origin, and serves as a member of the Institutional Biosafety Committee.

2.4 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 in 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 OH&S with the name of the designated laboratory safety coordinator for their respective units.

2.5 Principal Investigators / Laboratory Directors

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:

- Develop and implement written laboratory specific biosafety and security procedures (Laboratory Safety Plan) consistent with the nature of current and planned research

activities; develop emergency plans for handling hazardous spills and potential exposure events.

- Ensure that all laboratory personnel, including other faculty members, understand and comply with the Laboratory Safety Plan.
- Ensure that all laboratory personnel, maintenance personnel, and visitors who may be exposed to any biohazard are informed in advance of their potential risk and of the behavior required to minimize that risk.
- Register projects with OH&S and IBC that involve the use of recombinant DNA/RNA, microbial agents or products, human blood or body fluids, human gene transfer, human or non-human primate primary cell/tissue culture, the introduction of any of the above material into animals; register projects that require a letter of approval to the granting or funding agency; register projects that require signature of the University Safety Officer; register projects that involve the use, possession, or transfer of any quantity of agent listed on the select agent list.
- Delay initiation or modification of biohazardous materials use that requires Institutional Biosafety Committee approval (e.g., Biosafety Level 2 or greater containment required or non-exempt recombinant DNA/RNA work) until that work, or the proposed modification has been approved by the IBC and has met all other requirements of the Biosafety Manual.
- Ensure that any research project, that requires review or approval before initiation by institutional safety officials or committees in order to comply with the NIH Guidelines or any other funding agency requirements, be reviewed and approved before seeking or obtaining agency approval. Allow 4-6 weeks for IBC review.
- Assure that personnel working with biohazardous materials are aware of the hazards and proficient in the practices and techniques required for the safe handling of such materials. All training must be documented with records retained for a minimum of 3 years post employment or longer if required by laboratory specific regulatory or accrediting bodies.
- Assure that permits required by the United States Department of Agriculture (USDA) and/or the United States Public Health Service (USPHS) for work with animal or plant pathogens are obtained.
- Follow importation, exportation, and interstate shipping requirements for biological material. Obtain permits as indicated.
- Immediately report to the BSO all significant violations of the policies and procedures and all significant research-related accidents (spills, needle-sticks, exposures, injuries, etc.) that result in overt or potential exposure to infectious materials. (See the UAB On-the-job-injury policy.)
- Create and foster an environment in the laboratory that encourages open discussion of biosafety issues, problems and violations of procedure.

2.6 Laboratory Staff

For the purposes of this discussion, whoever works in the laboratory in a technical (rather than purely administrative) capacity is defined as laboratory staff; this includes faculty members, students, interns, visiting scholars or volunteers.

Laboratory staff members 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:

- Conscientiously follow lab-specific biosafety and security practices and procedures.
- Be familiar with protocols and organisms used in the laboratory regardless of whether or not he/she works directly with them.
- 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.

2.7 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 persons 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 on an [Accident/Incident Report Form](#) according to instructions provided on the form.

2.8 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 OH&S personnel or project review by the IBC. In most cases, these can readily be resolved through consultation by the PI or laboratory director with the Research Safety Coordinator’s staff, OH&S, and/or IBC. When more serious incidents arise, the IBC will review the incident, and based upon this review, which will include consultation

with the responsible investigator and/or laboratory director, will recommend corrective action to include the following:

- 2.8.1** 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.
- 2.8.2** 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.
- 2.8.3** 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.
- 2.8.4** 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.
- 2.8.5** 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.
- 2.8.6** 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.
- 2.8.7** 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.
- 2.8.8** 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.
- 2.8.9** The enforcement of safety measures instituted within a laboratory will ultimately rest with the PI/LD. Documented results of laboratory monitoring by OH&S will assist in determining the success of the program.
- 2.8.10** 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.

4. PRINCIPLES OF BIOSAFETY

4.1 Containment

The basic and only purpose of containment in a laboratory setting is to confine and reduce the exposure of research personnel, other university staff and students, and the surrounding community to potentially biohazardous agents. The risk assessment of the work to be done with a specific agent will determine the appropriate combination of practices and techniques, safety equipment, and facility design. For purposes of this manual the term "containment" is used to denote methods for controlling infectious agents in the laboratory areas where they are being used.

4.1.1 Primary Containment (Safety equipment)

An important element in primary containment is the employment of **good microbiological techniques and practices** by the laboratory worker. Included in the practices are the wearing of personal protective devices such as face masks and gloves and the use of mechanical safety equipment such as biological safety cabinets.

4.1.2 Secondary Containment (Facility design)

This containment is concerned with the protection of the environment external to the laboratory from exposure to infectious materials through building design, proper air-movement systems, and operational practices.

4.2 Basic Laboratory Safety

All laboratory personnel are expected to be familiar with the following rules and to conduct their work in accordance with them:

- 4.2.1 Storage of food in refrigerators or freezers used for infectious materials, radioactive materials, and chemical carcinogens is not permitted. In addition, there shall be no eating, drinking, smoking, chewing of tobacco, application of cosmetics, shaving, brushing of teeth, or storage of food in areas where these biohazardous materials are used.
- 4.2.2 Outer street clothing (coats, hats, etc.) should not be kept in an area where accidental contamination with potentially hazardous material can occur.
- 4.2.3 Mechanical pipetting aids must be used when pipetting any biohazardous material. **Mouth pipetting is not permitted at any containment level.**
- 4.2.4 Hands should be washed immediately after completion of any procedure in which biohazardous material is used. Persons working with infectious material should be especially careful not to inadvertently touch the face or eyes with unwashed hands.
- 4.2.5 Long hair, beards, and loose-flapping clothing are potentially dangerous when working near open flames or moving (operating) laboratory equipment. Tying back hair or employment of hairnets should be encouraged in all laboratories.
- 4.2.6 Gloves are the most widely used form of personal protective equipment. They serve as a primary barrier between the hands and hazardous materials. **Gloves must be worn when one anticipates hand contact with blood, infectious and potentially infectious material.** Rubber (latex) or plastic (vinyl) gloves should be worn when working with an etiologic agent that may cause infection by

entry through minute skin abrasions. Vinyl and nylon single use disposable gloves should be replaced as soon as possible if contaminated, torn, punctured or damaged in any way. Never wash or attempt to decontaminate such gloves for reuse.

- 4.2.7** Avoid the use of hand lotions immediately before donning [latex gloves](#). Some lotions may break down the protective action of the gloves and increase permeability.
- 4.2.8** Protection to the eyes is a matter that should be given high priority in every laboratory. Signs bearing the legend "**EYE PROTECTION REQUIRED**" should be prominently displayed in every area where there is risk of eye exposure. Infection can occur through the conjunctiva if a pathogenic microorganism is splattered into the eye. Safety glasses or goggles must be available in every laboratory where spills or splashes of potentially infectious materials may occur and worn when necessary. The increased impact resistance of modern lens glass and plastic lenses provides wearers of corrective glasses a reasonable level of protection. Contact lenses provide little or no practical protection to the eyes. In fact, foreign material present on the surface of the eye often becomes trapped beneath the contact lens, and similarly entrapped caustic chemicals, irritating vapors, and infectious agents cannot be readily washed from the eye without removal of the lenses. **No person shall wear contact lenses while working in any BSL-3 containment level laboratory located on UAB premises.** Laboratory supervisors shall be responsible for the strict enforcement of rules regarding the wearing of safety glasses and use of protective glass or plastic shields.
- 4.2.9** Laboratories where infectious agents are used must have an emergency eye wash facility installed at a strategic location. The Speakman SE400 Model or equivalent is acceptable (see UAB General Safety Manual). Building Maintenance should be contacted for eyewash procurement and installation.
- 4.2.10** Avoid working alone in a building; do not work alone in a laboratory if procedures are hazardous or potentially hazardous (4.1.13 UAB Chemical Safety Manual).
- 4.2.11** Procedures or activities likely to produce aerosols of infectious material **must** be conducted in an annually certified biological safety cabinet. Centrifuges, sonicators, household type blenders, and shaking (aerating) equipment require special attention because they can disperse aerosols if not operated with proper precaution. Internal aerosols invariably are created in a closed centrifuge, sonicator tubes and in so-called leak-proof blenders during operation. At the end of the operating period, it is recommended that the containers be opened in a biological safety cabinet.
- 4.2.12** Disposable and reusable laboratory clothing (coats, gowns, etc.) overtly contaminated with infectious materials, or worn in **BSL-3** containment facilities or laboratories in which **Risk Group 3** etiologic agents are employed, **must** be decontaminated by steam sterilization (autoclaving) or other proven effective means before discarding or releasing to the laundry. In certain circumstances, the Institutional Biosafety Committee may recommend routine "decontamination" of laboratory clothing worn in certain **BSL-2** containment facilities or in laboratories where certain **Risk Group 2** etiologic agents are used. The PI or department/division is responsible for arranging and providing laundry services to clean reusable laboratory clothing.

- 4.2.13** All biohazardous materials **must** be placed in rigid, leak-proof, closed containers labeled with a "**BIOHAZARD**" symbol for intra-campus transport between buildings or from one laboratory to another located in the same building when public elevators or passageways are used (See Section 12).
- 4.2.14** Vacuum lines in laboratories must be protected from contamination with infectious materials by inserting a filter and overflow flask between the vacuum line and the infectious material (Table 2).
- 4.2.15** The use of water aspirators as a source of vacuum is strictly prohibited unless the water line is equipped with a recently inspected and functioning anti back-flow valve and the requirement given in Section 10 is followed.

4.3 Biosafety Levels – in brief

Four biosafety levels (BSLs) are described below which consist of combinations of laboratory practices and procedures, safety equipment, and laboratory facilities. The recommended biosafety level(s) for the organisms in Section 7 represent those conditions under which the agent ordinarily can be safely handled. (See Section 6 for specific recommendations for the levels of containment.)

- 4.3.1** Biosafety Level 1 (BSL-1) practices, safety equipment, and facility design and construction are appropriate for work done with defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy adult humans. BSL-1 represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a sink for handwashing.
- 4.3.2** Biosafety Level 2 (BSL-2) practices, safety equipment, and facility design and construction are appropriate for work done with moderate-risk agents that are present in the community and associated with human disease of varying severity. With good microbiological techniques, these agents can be used safely in activities conducted on the open bench, provided splashes or aerosol productions are unlikely. All BSL-2 laboratories must prepare a safety plan and register projects/grants with UAB OH&S.
- 4.3.3** Biosafety Level 3 (BSL-3) practices, safety equipment, and facility design and construction are appropriate for work done with indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection. BSL-3 places more emphasis on primary and secondary barriers to protect personnel in surrounding labs, the community and the environment from exposure to potentially infectious aerosols. All BSL-3 laboratories must prepare a laboratory specific safety plan and register projects/grants with UAB OH&S. The Institutional Biosafety Committee/OH&S may require monthly activity reports for all work conducted in BSL-3 facilities.
- 4.3.4** Biosafety Level 4 (BSL-4) practices, safety equipment and facility design is appropriate for work with dangerous and exotic agents that pose a high individual risk or life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy. **NO BSL-4 work is permitted at UAB.**

Animal Biosafety Levels – four biosafety levels are also recommended for activities involving infectious disease work with experimental animals. These four combinations of practices, safety equipment, and facilities are designed ABSL-1, 2, 3, and 4, and provide

increasing levels of protection to personnel and the environment. **NO ABSL-4 work is permitted at UAB.**

- 4.3.4** Animal Biosafety Level 1 (ABSL-1) practices, safety equipment, and facility design and construction are appropriate for work done with defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy adult humans. ABSL-1 represents a basic level of containment that relies on standard practices and procedures approved by the Animal Resources Program and Institutional Animal Care and Use Committee in conjunction with the Institutional Biosafety Committee.
- 4.3.5** Animal Biosafety Level 2 (ABSL-2) involves practices for work with agents associated with human disease. ABSL-2 builds upon the practices, procedures, containment equipment, and facility requirements of ABSL-1. All PIs must prepare a specific animal room safety plan and register projects/grants with UAB OH&S.
- 4.3.6** Animal Biosafety Level 3 (ABSL-3) involves practices for work with indigenous or exotic agents that present the potential of aerosol transmission and of causing serious or potentially lethal disease. ABSL-3 builds upon the practices, procedures, containment equipment, and facility requirements of ABSL-1 and ABSL-2. All PIs must prepare a specific animal room safety plan and register projects/grants with UAB OH&S.
- 4.3.7** Animal Biosafety Level 4 (BSL-4) practices, safety equipment and facility design is appropriate for work with dangerous and exotic agents that pose a high individual risk or life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy. **NO BSL-4 work is permitted at UAB.**

5.5 Restricted Research Activities

5.5.1 Select Agents

At UAB possession, receipt, use, storage, transfer, and disposal of select agents is authorized by permit only and coordinated through the University's Responsible Official (RO).

In response to the mandates of "The Antiterrorism and Effective Death Penalty Act of 1996", additional shipping and handling requirements were placed on facilities that transferred or received a list of agents deemed agents of mass destruction. As of April 15, 1997, commercial suppliers of "Select agents" as well as government agencies, universities, research institutions, individuals and private companies seeking to transfer or obtain regulated "select agents" are required to register with the *Centers for Disease Control and Prevention* (CDC) as a registered facility.

On December 13, 2002 the Department of Health and Human Services and the Department of Agriculture published interim rules governing the way select agents and toxins are to be managed within the United States. The final rule published March 1, 2005 implements provisions of the Public Health and Security and Bioterrorism Preparedness and Response Act of 2002 and was designed to protect public health and safety, animal and plant health, and animal and plant products. [Click here](#) to access the most recent select agent rules and regulations.

The list of HHS and USDA [select agents](#) and related FAQs are available on the respective website as well as the [UAB OH&S](#) website.

UAB Occupational Health & Safety serves as the facilitator and provides University oversight (Responsible Official) required by the regulation. The Responsible Official (RO) is a presidential appointment currently held by the Assistant Vice President for Occupational Health and Safety. An Alternate RO (ARO) has been also appointed to act on the ROs behalf when needed. All possession, use, transfer, and disposal of select agents **must** be coordinated through the Responsible Official or the Alternate Responsible Official.

Research involving select agents must be reviewed by the Institutional Biosafety and/or Chemical Safety Committee before initiation to provide time for amending the UAB facility (entity) registration with the appropriate federal groups.

5.5.1.1 Principal investigators who use, transfer, store, or dispose of select agents must register the project (Appendix G and/or H) and obtain a permit for use from UAB Occupational Health & Safety **before** material may be received, used, transferred or disposed.

5.5.1.2 Complete UAB Form ASA to apply for permit. Allow three to four weeks for application processing, information gathering, and review by UAB Safety Committee(s) and federal regulatory agencies (HHS or USDA). During this time the applicant may be invited to meet with the appropriate UAB Safety Committee representatives to discuss details of the permit and vice versa. Upon review and approval by the appropriate Safety Committee(s), a permit of use and permit system procedures will be issued to the principal investigator (permit holder).

5.5.1.3 PIs, employees, and labs must conform to all requirements of 42 CFR 73, 7 CFR 121, and/or 9 CFR 331, USA PATRIOT Act of 2001, and any other applicable rules and regulations before permits will be issued.

5.5.1.4 "Restricted persons" as defined by 18 U.S.C. 175(b) may not possess, ship, transport or receive select agents. Specific, limited access approval may be requested by the RO from HHS/USDA on a case-by-case basis.

5.5.1.5 Training sessions are conducted by UAB Occupational Health & Safety for all active select agent program participants at permit time with updates at least annually.

5.5.2 Attenuated strains of material on the select agents list

Certain strains of biological agents exempt from federal regulations qualify for additional security due to the high profile of the agent or implications of use that may be associated with them. Therefore, at UAB, facilities receiving, storing, using, or have in their possession attenuated strains of select agents approved for human or animal vaccination purposes by FDA or other recognized national or international organization and used for research purposes or administered in a manner other than as originally intended by the manufacturer and not already regulated by the select agent regulations, must follow the additional practices and procedures as described below:

5.5.2.1 Notify UAB Biosafety and the Institutional Biosafety Committee of intent to obtain and use the agent by completing a Request for Exemption (SA Ex-B) and a Project Registration form (Appendix G and/or H). Material may not be obtained or used until written IBC approval is granted.

5.5.2.2 Control access to areas where agents are stored and used. If the lab is left unattended, lock it.

5.5.2.3 Agents must be stored in a lockable storage box or refrigerator/freezer, when not in use. Access to the agents must be strictly controlled.

5.5.2.4 An up to date inventory must be maintained and available to UAB Biosafety upon request.

5.5.2.5 A list of persons with access to the agent must be maintained and available to UAB Biosafety upon request. Only authorized persons may have access to the agent.

5.5.2.5 Know who is in the laboratory. Only authorized persons should have access to the laboratory. UAB identification badges should be visibly worn.

5.5.2.6 Agents that are resistant to disinfectants or that persist in the environment (i.e. spores) require that strict adherence to cleanliness be followed. Aerosol generating activities must be confined to annually certified biosafety cabinets or other closed systems to reduce agent dispersal. Laboratory waste associated with the agent must be autoclaved on-site and arrangements made through UAB Biosafety and the HMF for final treatment by incineration. Animal carcasses must be double bagged and arrangements made through UAB Biosafety and the HMF for final treatment by incineration.

5.5.3 Non-viable agents on the select agents list

5.5.3.1 Laboratories receiving or in possession of non-viable select agents must maintain documentation confirming the non-viable status of each batch of such agents. Documentation may include statement of non-viability from the source

company, PI or institution, or in-house testing results. Documentation must be available to OH&S during site visits or upon request.

5.5.3.2 Notify UAB Biosafety of intent to obtain and use the non-viable agent by completing a Request for Exemption (SA Ex-B) and a Project Registration form (Appendix G and/or H).

5.5.3.3 Fixed tissues that bear or contain select agents are currently not subject to select agent regulations

5.5.3.4 Non-viable select agents are currently not subject to select agent regulations.

5.5.4 Select agent toxin exclusions

5.5.4.1 Principal Investigators who possess one of the select agent toxins and wish to apply for a toxin exclusion from the select agent regulation must complete the UAB Form SA-ExT and a Project Registration form (Appendix G and/or H).

5.5.4.2 If the total aggregate amount of a select agent toxin (purified form in combination with impure forms) under the control of a principal investigator does not, at any time, exceed the following amounts, that toxin will not be subject to select agent regulations. **Inventory and disposal/destruction record of toxin(s) must be maintained by PI to confirm quantities do not exceed exclusion limits.**

Abrin	≤ 100 mg
Botulinum neurotoxin	≤ 0.5 mg
<i>Clostridium perfringens</i> epsilon toxin	≤ 100 mg
Conotoxins	≤ 100 mg
Diacetoxyscirpenol (DAS)	≤ 1,000 mg
Ricin	≤ 100 mg
Saxitoxin	≤ 100 mg
Shigatoxin	≤ 100 mg
Shiga-like ribosome inactivating proteins	≤ 100 mg
Staphylococcal enterotoxins	≤ 5 mg
Tetrodotoxin	≤ 100 mg
T-2 toxin	≤ 1,000 mg

5.5.4.3 Inventory and waste disposal records must be made available to UAB OH&S upon request.

5.5.5 Select agents in clinical or diagnostic samples

Clinical and diagnostic laboratories are exempt from the select agent regulations **if all of the following apply:**

5.5.5.1 The select agents involved in the laboratory activities are contained in diagnostic specimens or in isolates from specimens presented for diagnosis, verification, or proficiency testing; **and**

5.5.5.2 Upon identification of a select agent as the result of diagnosis or verification, the Laboratory Director/Manager or designee immediately reports to the UAB RO any of the following: HHS SAs Ebola viruses, Lassa fever virus, Marburg virus, South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito) Variola major (Smallpox virus), Variola minor (Alastrim), *Yersinia pestis*; Overlap agents *Bacillus anthracis*, Botulinum neurotoxins, *Brucella melitensis*, *Francisella tularensis*, Hendra virus, Nipah virus, Rift Valley fever

virus, or Venezuelan equine encephalitis virus and/or any select agent listed on the USDA/APHIS list of animal agents and toxins; **and**

- 5.5.5.3** After the diagnosis, verification, or proficiency testing the lab must have written approval from the UAB RO to either transfer the specimens or isolates containing a select agent to a facility eligible for receiving them under this part, or destroy them on-site by autoclaving, incineration, or by a sterilization or neutralization process sufficient to cause inactivation;
- 5.5.5.4** The lab transfers or destroys those select agents used for diagnosis or testing within seven days after identification, unless directed otherwise by the Federal Bureau of Investigation or other law enforcement entity after the UAB RO has consulted with the HHS Secretary; **and**
- 5.5.5.5** The lab transfers or destroys those select agents used for proficiency testing within 90 days after receipt; **and**
- 5.5.5.6** The lab submits to the UAB RO a record of the identification and transfer or destruction on the APHIS/CDC Form 4 – Report of the Identification of a Select Biological Agent or Toxin in a Clinical or Diagnostic Laboratory which will be submitted to APHIS/CDC within seven calendar days after identification.
- 5.5.5.7** The UAB RO/ARO will file reports with CDC/HHS and/or APHIS/USDA as appropriate upon notification from said laboratory. **Lab staff and PIs do not file directly with APHIS/CDC.**

5.5.6 Requesting Exemptions from the Select Agent Regulation

The HHS Secretary or the USDA Administrator may grant case-by-case exemptions to individuals or entities upon showing of good cause that the exemption is consistent with protecting animal or plant health, animal or plant products, or regulation of the type and/or form of the agent is not necessary to protect public health and safety.

To apply for an exemption not covered under the toxin exclusion:

- 5.5.6.1** Submit to the UAB RO a completed APHIS/CDC Form 5 - Request for Exemption of Select Biological Agents and Toxins for Public Health or Agricultural Emergency or Investigational/Experimental Product.
- 5.5.6.2** Until such time as the RO receives notification or denial of exemption from APHIS/CDC, the agent must be considered regulated and handled as such.

5.5.7 Denial, Revocation, or Suspension of Registration

CDC and APHIS may deny, revoke, or suspend any or all activities of an individual PI and/or the entire institution if they identify issues of failure to comply with the select agent regulations. The causes for this type of action may include, but are not limited to:

- 5.5.7.1** There are repeated violations of the containment or security requirements
- 5.5.7.2** Possession, receipt, use, or transfer of a select agent by a “restricted person” has not been disclosed

5.5.7.3 An authorized user has undisclosed involvement with an organization that engages in domestic or international terrorism or intentional crimes of violence

5.5.7.4 The HHS Secretary or USDA Administrator determines that such action is necessary to protect human health and public security, animal or plant health, or animal or plant products.

7. Biological Agents and Biohazard Classification

Classification of Microorganisms on the Basis of Risk

Risk group classifications are most often used in the academic health center research environment as a way to categorize infectious agents based on their relative risk. [The NIH Guidelines](#) also use risk groups as an aid in risk assessment.

7.1 Risk Group 1

This group includes all bacterial, fungal, parasitic, and viral agents generally not associated with disease in healthy adult humans and not listed in the higher risk groups. Included in this group are:

Parainfluenza virus type 3, SF4 strain
Influenza virus strains A/PR8/34 and A/WS/33
Newcastle Disease virus strains licensed for vaccine use in the United States
Adeno-Associated virus serotypes 1-4 (when free of adenoviruses and Herpes simplex virus types 1 & 2)
Escherichia coli K12 and similar strains

as well as the following Low-Risk Oncogenic Viruses:

Adenovirus 7-Simian virus 40 (Ad7-SV40)
Avian leukosis virus
Bovine leukemia virus
Bovine papilloma virus
Chick-embryo-lethal orphan (CELO) virus or fowl adenovirus-1
Dog sarcoma virus
Guinea pig herpes virus
Lucke (Frog) virus
Hamster leukemia virus
Marek's disease virus
Mason-Pfizer monkey virus
Mouse mammary tumor virus
Murine leukemia virus
Murine sarcoma virus
Polyoma virus
Rat leukemia virus
Rous sarcoma virus
Shope fibroma virus
Shope papilloma virus
Simian virus 40 (SV-40)

7.2 Risk Group 2

This group includes agents of moderate potential hazard to personnel and the environment and may be associated with human disease. Included in this group are:

7.2.1 Bacterial Agents (including Chlamydia and Rickettsia)

Acinetobacter calcoaceticus
Actinobacillus - all species
Actinomyces species
Aeromonas hydrophila
Amycolata autotrophica

Arizona hinshawii - all serotypes (*Salmonella enterica* - subspecies *arizonae*)
Bacillus anthracis
Bordetella - all species
Borrelia recurrentis, *B. vincenti*, *B. burgdorferi*
Campylobacter fetus, *C. coli*, *C. jejuni*
Chlamydia psittaci, *C. trachomatis*, *C. pneumoniae*
Clostridium botulinum, *Cl. chauvoei*, *Cl. haemolyticus*, *Cl. histolyticum*, *Cl. novyi*,
Cl. septicum, *Cl. tetani*
Corynebacterium diphtheriae, *C. equi*, *C. haemolyticum*, *C. pseudotuberculosis*,
Cl. renale
Dermatophilus congolensis
Edwardsiella tarda
Erysipelothrix insidiosa
Escherichia coli - all enteropathogenic, enterotoxigenic, enteroinvasive, strains
bearing K1 antigen including 0157:H7
Fusobacterium necrophorum
Haemophilus ducreyi, *H. influenzae*
Helicobacter pylori
Klebsiella - all species including *K. oxytoca*
Legionella pneumophila
Leptospira interrogans - all serotypes
Listeria - all species
Moraxella - all species
Mycobacterium - all species (including *M. bovis* BCG vaccine strain) **except**
those listed in Risk Group 3
Mycoplasma - all species **except** *Mycoplasma mycoides* and *Mycoplasma*
agalactiae which are restricted animal pathogens in Risk Group 5
Neisseria gonorrhoeae, *N. meningitidis*
Nocardia asteroides, *N. brasiliensis*, *N. otitidiscaviarum*, *N. transvalensis*
Pasteurella - all species **except** *Pasteurella multocida* type B and other virulent
strains in Risk Group 3
Rhodococcus equi
Rochalimaea quintana, *R. vinsonii* - (*Bartonella*)
Salmonella - all species and serotypes
Shigella - all species and serotypes
Sphaerophorus necrophorus
Staphylococcus aureus
Streptobacillus moniliformis
Streptococcus pneumoniae, *S. pyogenes*, and *viridans streptococcus*
Treponema pallidum, *T. pertenue*, *T. carateum*
Vibrio cholerae, *V. parahemolyticus*, *V. vulnificus*
Vole rickettsia
Yersenia enterocolitica

7.2.2 Fungal Agents

Blastomyces dermatitidis
Cladosporium bantianum, *C. trichoides*
Cryptococcus neoformans
Dactylaria galopava (*Oochroconis galloparvum*)
Epidermophyton - pathogenic species
Exophiala (Wangiella) dermatitidis
Fonsecaea pedrosoi
Microsporum - pathogenic species
Paracoccidioides brasiliensis
Penicillium marneffeii

Sporothrix schenckii
Trichophyton - pathogenic species

7.2.3 Parasitic Agents

Ancylostoma human hookworms including *A. duodenale*, *A. ceylanicum*
Ascaris lumbricoides suum and other *Ascaris* species
Babesia divergens, *B. microti*, and other *Babesia* species
Coccidia species
Cryptosporidium parum and other *Cryptosporidium* species
Cystisercus cellulosa
Echinococcus granulosis, *E. vogeli*, *E. multilocularis*
Entamoeba histolytica
Enterobius species
Fasciola gigantica, *F. hepatica*, and other *Fasciola* species
Giardia lamblia and other *Giardia* species
Heterophyes species
Hymenolepis diminuta, *H. nana*, and other *Hymenolepis* species
Isospora species
Leishmania braziliensis, *L. ethiopia*, *L. donovani*, *L. major*, *L. mexicana*, *L. peruviana*, *L. tropica*
Naegleria fowleri
Necator americanus and other *Necator* species
Plasmodium falciparum, *P. malariae*, *P. vivax*, *P. cynomologi*, *P. ovale*, and simian species
Sarcocystis sui hominis and other *Sarcocystis* species
Schistosoma haematobium, *S. japonicum*, *S. mansoni*, *S. intercalatum*, *S. mekongi*, and other *Schistosoma* species
Strongyloides stercoralis and other *Strongyloides* species
Taenia solium
Toxocara canis and other *Toxocara* species
Toxoplasma gondii and other *Toxoplasma* species.
Trichinella spiralis
Trypanosoma brucei brucei, *T. brucei gambiense*, *T. brucei rhodesiense*, *T. cruzi*, and and other *Trypanosoma* species
Wuchereria bancrofti

7.2.4 Viral Agents

Adenoviruses - human origin, all serotypes
Bebaru virus
Buffalopox virus
Bunyamwera virus
Cache Valley virus
California Encephalitis virus
Chikkungunya virus vaccine strain 131/25
Coronaviruses
Cowpox virus
Coxsackie A and B viruse
Creutzfeldt-Jakob Disease Agent
Cytomegalovirus - both human and murine strains
Dengue virus - all serotypes - no animal inoculations
Echoviruses - all serotypes
Encephalomyocarditis virus (EMC)
Epstein-Barr virus
Flanders virus

Hart Park virus
 Hazara virus
 Hepatitis viruses - types A,B,C,D,E, associated antigen material and any other
 bloodborne hepatitis viruses
 Herpes simplex virus - types 1 and 2
 Influenza A and B viruses - all strains except those listed in Risk Group 1
 Kunjin virus
 Kuru virus
 Langat virus
 Lymphocytic Choriomeningitis virus - non-neurotropic strains: neurotropic strains
 are in Risk Group 3
 Measles (rubeola) virus
 Mopeia virus
 Mumps virus
 O'nyong-nyong virus
 Orf virus
 Parainfluenza virus - all serotypes except those listed in Risk Group 1
 Parvovirus - animal origin
 Rabies virus - all laboratory strains; Rabies "street" virus is classified in Risk
 Group 3
 Reoviruses - all serotypes
 Respiratory Syncytial virus
 Rhinovirus - all serotypes
 Rift Valley Fever virus vaccine strain MP-12 only
 Ross River virus
 Rubella virus
 Simian viruses - all strains and serotypes except Herpes simiae virus (monkey B
 virus) and Marburg virus which are listed in Risk Group 4
 Sindbis virus
 Tanapox virus
 Tensaw virus
 Turlock virus
 Vaccinia virus
 Venezuelan Equine Encephalitis virus (vaccine strain TC-83)
 Vesicular stomatitis virus – laboratory adapted strains
 Yabapox virus
 Yellow fever virus (17D vaccine strain)

7.3 RISK GROUP 3

This Risk Group includes indigenous or exotic agents with potential for aerosol transmission. The resulting human disease may have serious or lethal consequences. Agents in this Risk Group include:

7.3.1 Bacterial Agents (including Rickettsia)

Bartonella -all species
Brucella abortus, *B. suis*, *B. melitensis*, *B. ovis*, *B. canis*, *B. neotomae*
Burkholderia (Pseudomonas) mallei, *B. pseudomallei*
Coxiella burnetii
Francisella tularensis
Mycobacterium tuberculosis, *M. bovis*, *M. avium*
Pasteurella multocida type B - and other virulent strains
Rickettsia prowazekii, *R. mooseri*, *R. akari*, *R. rickettsii*, *R. conorii*, *R. canada*,
R. siberica, *R. tsutsugamushi*, *R. australis*
Yersinia pestis

7.3.2 Fungal Agents

Coccidioides immitis
Histoplasma capsulatum
Histoplasma capsulatum var duboisii

7.3.3 Viral Agents

Dengue virus - all serotypes, when used for animal inoculation experiments
Eastern Equine Encephalomyelitis virus
Hantavirus - under some conditions may be considered for Risk Group 2
Human immunodeficiency virus (HIV) types 1 and 2
Human T cell lymphotropic virus (HTLV) types 1 and 2
Lymphocytic Choriomeningitis - all neurotropic strains
Monkeypox virus - used only in in vitro studies
Rift Valley fever virus
St. Louis Encephalitis virus
Semliki Forest virus
Simian immunodeficiency virus (SIV)
Transmissible spongiform encephalopathies (TME) agents (Creutzfeldt-Jacob disease and kuru agents)
Venezuelan Equine Encephalitis virus
Vesicular stomatitis virus
West Nile virus
Western Equine Encephalomyelitis virus
Yellow Fever virus - wild strains - when used in in vitro experiments

7.4 RISK GROUP 4

This Risk Group includes dangerous exotic agents that pose high risk of life-threatening disease, aerosol-transmitted laboratory infections or where the risk of infection is unknown. **No work with Risk Group 4 agents is permitted at UAB.** Risk Group 4 agents include the following:

7.4.1 Viral Agents

Ebola virus
Equine morbillivirus
Hemorrhagic Fever viruses - including Congo, Junin, Machupa, and other isolates as yet unidentified
Herpes simiae virus (monkey B virus)
Lassa virus
Marburg virus
Monkeypox virus - when used for animal inoculation experiments
Tick-Borne Encephalitis virus - including Russian-Spring-Summer Encephalitis, Kyasanur Forest Disease, Omsk Hemorrhagic Fever, Central European Encephalitis, Hanzolova, Kumlinge, and Hypr
Venezuelan Equine Encephalitis virus - when used for animal inoculation
Yellow Fever virus - when used for animal inoculation

Please Note: A U.S. Department of Agriculture (USDA) permit is required for the importation or interstate transport of any animal pathogen permitted in the United States.

7.5 RESTRICTED AGENTS

7.5.1 Restricted microorganisms that **may not be studied in the United States include the following:**

Variola (smallpox) virus
Alastrim
Whitepox

All activities including storage of the above three viruses are restricted to the single national facility (World Health Organization [WHO] Collaborating Center for Smallpox Research, Centers for Disease Control in Atlanta, Georgia).

7.5.2 **Restricted Animal disease microorganisms which by United States Department of Agriculture policy cannot be imported into the United States:**

African Horse Sickness virus
African Swine Fever virus
Akabane virus
Besnoitia besnoitia
Borna Disease virus
Bovine Infectious Petechial Fever Agents
Camelpox virus
Ephemeral Fever virus
*Foot and Mouth Disease virus**
Fowl Plague virus
Goatpox virus
Hog Cholera virus - strains indigenous to the United States may be studied under appropriate conditions
Louping Ill virus
Lumpy Skin Disease virus
Nairobi Sheep Disease virus
Newcastle Disease virus (Asiatic strains)
Mycoplasma mycoides (*Contagious Bovine Pleuropneumonia*)
Rickettsia ruminantium (*Heart Water Fever*)
Rift Valley Fever virus
Rinderpest virus
Sheeppox virus
Swine Vesicular Disease virus
Teschen Disease virus
Trypanosoma vivax (Nagana), *T. evansi*
Theileria parva (East Coast Fever), *T. annulata*, *T. lawrencei*, *T. bovis*, *T. hirci*
Vesicular Exanthema virus
Wesselsbron Disease virus
Zyoonema farciminosum (psudofarcy)

* by United States law cannot be imported into the US.

9. ENGINEERING CONTROLS

9.1 Biological Safety Cabinets

Biological safety cabinets (BSC's) provide an integral part of primary containment when working with potentially hazardous biological materials. It is important that ALL users of biological safety cabinets are aware of the limitations of the equipment and work practices to assure a safe work environment for themselves and others in the area.

BSC's are divided into 4 different types depending on the design of the individual piece of equipment and how it is exhausted. Each type has unique features which allow the PI and others to use the BSC for his or her unique needs.

In 2002 the National Sanitation Foundation issued a change in its performance based standard #49. Standard #49 establishes performance criteria and provides minimum requirements for BSCs used for personnel, product, and environment protection in the US. Listed below is a chart to help the reader distinguish the difference between the 1992 standard and the revised standard of 2002 that is currently in use.

Risk Assessment	Protection Provided				Applications (Can be used with the following)					Duct Necessary	Air Tight Isolation Damper	Duct Connection
	Person	Prod.	Environ.	BSC Class	BSC Type (2002)	BSC Type (1992)	Min. Face Velocity	Nonvolatile Toxic Chemicals and Radionuclides	Volatile Toxic Chemicals and Radionuclides			
BSL 1-3	Yes	No	Yes	I	n/a	n/a	75	Yes	Yes	Yes	Yes	Hard
BSL 1-3	Yes	Yes	Yes	II	A1	A	75	Yes*	No	No	No	n/a
BSL 1-3	Yes	Yes	Yes	II	A2	B3	100	Yes	Yes*	Yes	Yes	Thimble
BSL 1-3	Yes	Yes	Yes	II	B1	B1	100	Yes	Yes*	Yes	Yes	Hard
BSL 1-3	Yes	Yes	Yes	II	B2	B2	100	Yes	Yes^	Yes	Yes	Hard
BSL 4	Yes	Yes	Yes	III	B1, B2	B1, B2	n/a	Yes	Yes^	Yes	Yes	Hard

- * minute amounts
- ^ small amounts

Definitions: BSL - an acronym for BioSafety Level as currently defined in the CDC/NIH publication [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#). The BSL represents the starting point for the risk based assessment of facilities, procedures and practices, and safety equipment under which a particular organism can be manipulated or stored. The Institutional Biosafety Committee may increase or decrease the BSL for individual projects/protocols depending on adequate justification and review.

Personnel protection – the individuals manipulating a particular organism at a particular time will achieve a particular protection factor afforded by the individual piece of equipment.

Product Protection – protection of the material with which the scientist is working.

Environmental Protection – any space outside the confines of the Biosafety cabinet. This could mean the lab space proper or the area with which the equipment is located in. It could also mean the outside of the building space in the case of a unit which is ducted to the outside.

BSC Class – There are three categories in which a biosafety cabinet can be placed (I, II, III). This is sub defined by the protection factors afforded by the equipment.

BSC Type – The subdivision of the different classes and is defined by air flow characteristics and methodology of exhaust flow connection if applicable.

Face Velocity – The speed of the air flowing around the operator sitting at the front of the equipment and flowing into the biosafety cabinet; usually expressed as feet per minute.

Duct necessity – dictated by the type of material being manipulated in the unit as well as HVAC dynamics of the laboratory. Careful attention must be placed on duct material and type of connection.

Air Tight Isolation Damper – a special damper used to facilitate gaseous decontamination of the equipment. Can also be used to make minor adjustments to face velocity and air flow balance.

Duct Connection – dictated by the class and type of biosafety cabinet. This can be a hard or gasketed, air tight connection or a thimble or canopy connection. Some units will not operate properly if the connection is not air tight.

The capability of a biological safety cabinet (BSC) to protect laboratory personnel and the environment from exposure to potentially hazardous material, as well as protecting the work being performed, is primarily dependent on proper functioning of the cabinet. No biological safety cabinet should be used to contain hazardous materials unless it has been demonstrated by appropriate test procedures to meet the minimum safety specifications given in APPENDIX P (recommended minimum performance specifications of BSC's)

The procedures to be used for the certification of biological safety cabinets at UAB shall be those recommended by the National Sanitation Foundation Standard #49 (NSF 49) and described in the NIH Laboratory Safety Monograph. To that end, only those units bearing the NSF 49 seal can be used to contain potentially hazardous aerosols of a biological origin, subject to the following exception applicable when cabinet units with the NSF 49 seal are not available:

9.1.1 BSCs and the NSF Seal

9.1.1.1 BSCs bearing the NSF 49 seal can be used to contain potentially hazardous aerosols of a biological origin.

9.1.1.2 Acceptable for use are biological safety cabinets that have no NSF seal, but whose manufacturers have represented to the Institutional Biosafety Committee (IBC) that using test procedures equivalent to those of NSF 49, they have demonstrated that the cabinets provide personnel, product, and environmental protection. A list of the units that have been approved is available through the Department of Occupational Health and Safety Biosafety Program

9.1.1.2.1 The typical unit within this exception is designed to maintain a twelve (12) inch sash opening, rather than the usual eight (8) or ten (10) inch sash opening.

9.1.1.2.2 If future unit(s) are approved by NSF 49 and therefore display the NSF 49 seal, then only those units can be purchased and used for potentially biologically hazardous material

9.1.1.2.3 These units will be certified according to the manufacturer's standard only.

9.1.2 Certification Requirements for Biological Safety Cabinets

When BSC are used for personnel protection, certification is required (1) before a newly installed cabinet is used, (2) after a cabinet is moved, relocated or partially dismantled for cleaning and/or repair, and (3) at least annually.

9.1.2.1 Annual recertification of BSCs is required if used in conjunction with material of human origin, human pathogens, primary animal or human cell/tissue culture, animal husbandry, or for processes that would create an infectious aerosol.

9.1.2.2 Biological Safety cabinets used for containment of organisms used at Biosafety Level 3 (BSL 3) must be recertified at least every six (6) months.

The Department of Occupational Health and Safety's Biosafety Program has established a mechanism of periodic inspection and certification for biological safety cabinets installed in buildings on the UAB campus.

The Department of Occupational Health and Safety maintains a current file on performance and certification data for each BSC. The responsibility for maintaining a current certification for each BSC lies with the principle investigator.

In order to minimize interference with laboratory work schedules, investigators responsible for BSCs may be contacted by individuals in the Biosafety Program Laboratory Ventilation Program to arrange a time suitable for certification. The PI is responsible for assuring that all work surfaces are effectively disinfected with a suitable disinfectant and that all procedures are suspended prior to the technicians' arrival in the lab. In certain instances it may be required to decontaminate the BSC with paraformaldehyde gas prior to the certification or repair process. The PI will be informed beforehand of the additional time required for this precautionary measure.

After the unit has been certified a certification label will be placed on the unit describing what standard or criteria was used to certify the equipment and the date recertification should take place.

If the unit fails to meet performance standards during the certification process, the responsible person in the lab will be informed as to the nature of the problem and what actions should take place to rectify the problem. In some cases the unit may require replacement filters. The responsibility for the purchase of these filters lies with the PI. The Biosafety Program's Laboratory Ventilation Program maintains a list of filter vendors and prices. The PI is responsible for contacting the Laboratory Ventilation Program when the filters arrive so arrangements can be made to repair and certify the equipment.

For repairs other than filter replacement, the PI will be consulted by personnel in the Biosafety Program as to the nature of the repair and the procurement of the parts necessary for the repair.

9.1.3 Decontamination of Biological Safety Cabinets

Prior to changing HEPA filters, accessing the dirty side of the cabinet, or other events determined by risk assessment, decontamination of the BSC by paraformaldehyde gas or other approved methods may be required.

9.1.4 Working safely in a biological safety cabinet

In addition to the biosafety cabinet functioning properly the user must also work in the unit appropriately in order to maintain a safe work environment and protect the integrity of the work performed. There are several "rules-of-thumb" that apply to all biosafety cabinets to help accomplish this goal. The owner's manual for the unit must always be consulted prior to working in a BSC. Listed below are some suggestions.

1. Start-up
 - a. Turn off the UV light, if applicable.
 - b. Turn on fluorescent light.
 - c. Check air intake grills for obstructions.
 - d. Start blower and allow the unit to operate for 15 minutes.
2. Wipe down
 - a. Wipe interior with appropriate disinfectant.
 - b. Avoid the use of sodium hypochlorite on stainless steel unless it is followed up with ETOH.
3. Loading materials and equipment
 - a. Load only the materials needed for that particular procedure.
 - b. Do not obstruct the grills (front or rear).
 - c. After loading wait 2-3 minutes to purge contaminants from the work area.
4. Work techniques
 - a. Keep all materials at least 4 inches inside sash.
 - b. Separate clean from contaminated materials in the work area.
 - c. Work should progress from clean to contaminated.
 - d. Keep and use contaminated materials in the rear of the work area.
 - e. Avoid arm movements in and out of the unit.
5. Final purge and wipe down
 - a. Allow the unit to operate 2-3 minutes after work and before unloading materials.
 - b. Wipe interior surfaces with appropriate disinfectant.
6. Shut down
 - a. Turn off fluorescent light.
 - b. Turn on UV light if desired and equipped.

CAUTION: AVOID DIRECT EXPOSURE TO UV LIGHT

13. Emergency Response

All UAB employees injured in the course of employment at UAB or acquiring a disease or illness directly attributable to their employment at UAB will be offered a referral for evaluation as described in the UAB On-The-Job Injury/Illness Program (See POL312 [You and UAB Handbook](#) and/or the *Faculty Handbook and Policies*). Medical treatment for an on-the-job injury should be obtained immediately following the injury. (See On-The-Job Injury/Illness Program, *You and UAB Handbook* and/or the *Faculty Handbook and Policies*). Services are provided at the following locations as noted in specific subparts of this section:

- UAB Hospital Employee Health / 4-3675 / 619 19th Street South, SW 123
- OH&S Employee Health Clinic / 4-2487 / 933 19th Street South, Suite 412
- UAB University Hospital Emergency Dept / 6-4201 / Corner of 4th Ave South & 19th Street
- and/or *The Workplace* / 933-5300 / 2151 Highland Avenue, 933-5300 as noted below.

13.1 Needlesticks and Mucous Membrane Exposures

13.1.1 During Work Hours (Monday – Friday, 8am – 5pm)

If a needlestick or mucous membrane exposure to human blood, body fluids, or unfixed tissue occurs during work hours, immediately call the UAB Hospital Employee Health Rapid Response Team at 4-3675, page them through UAB Paging 4-3411, or follow your specific response plan (e.g. HIV, HBC, and HCV research labs). An RN is on duty to provide consultation and treatment as indicated. Complete a UAB On-the-job injury form and follow form submission instructions.

If a research related needlestick or other potential exposure to other potentially infectious materials, recombinant or synthetic nucleic acid molecules, or organisms containing recombinant or synthetic nucleic acid molecules occurs during work hours, immediately call OH&S Employee Health at 4-2487 or follow your specific response plan (e.g. Herpes B) . An Occupational Health Physician or MSN is on duty to provide consultation and treatment as indicated. Complete a UAB On-the-job injury form and follow form submission instructions.

13.1.2 After Work Hours, Weekends, and Holidays

If an exposure to human blood, body fluids, or unfixed tissue occurs after work hours, on weekend or holidays, immediately page the UAB Hospital Employee Health Rapid Response Team through UAB Paging 4-3411, or follow your specific response plan (e.g. HIV, HBV, HCV research labs). An RN is on duty to provide consultation and treatment as indicated. Complete a UAB On-the-job injury form and follow form submission instructions.

If a research related needlestick or other potential exposure to other potentially infectious materials, recombinant or synthetic nucleic acid molecules or organisms containing recombinant or synthetic nucleic acid molecules occurs during work hours, immediately page OH&S Director-on-call #8744 or by calling UAB Police 4-3411 and ask for pager #8744 or follow your specific response plan (e.g. Herpes B). An Occupational Health Physician or MSN is on duty to provide consultation and treatment as indicated. Complete a UAB On-the-job injury form and follow form submission instructions.

Notify UAB Institutional Biosafety Officer immediately 4-2487 of **all** research related needlesticks and mucous membrane exposures or potential exposures.

13.2 Other Personal Injury

13.2.1 Medical Emergencies On or Near the UAB Campus

If an injury is a medical emergency and has occurred on or near the UAB campus, the employee should be taken to the UAB University Hospital Emergency Department where initial assessment and emergency treatment will be provided. If possible, the employee should take a written On-the-Job-Incident report to the Emergency Department. If that is not possible due to the urgent nature of the injury, the Emergency Department may be verbally advised that the employee was injured in the course of UAB employment, and the Emergency Department should indicate that in the employee's medical record. A written incident report must be completed by the supervisor as soon as possible and submitted according to form instructions.

13.2.2 Non-Emergency Medical Treatment

If non-emergency medical treatment is required during the operating hours of *The Workplace*, the employee must report to *The Workplace* for initial evaluation and treatment. The employee must present an incident report in order to receive treatment.

If non-emergency medical treatment is required outside the operating hours of *The Workplace*, the employee must report to the UAB University Hospital emergency Department for evaluation. The employee must present an incident report in order to receive treatment.

13.2.3 Injuries Away from the UAB Campus

If a UAB employee is performing his or her job away from the UAB campus and suffers a job-related injury which results in a medical emergency, the employee should obtain necessary emergency attention from the closest medical facility, advise the treating facility that the injury occurred during the course of employment at UAB, and following reporting procedures as outlined in the UAB On-The Job Injury/Illness Program (See *You and UAB Handbook* and/or the *Faculty Handbook and Policies*).

13.3 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, it is important that the area be immediately isolated to prevent spread of the spillage, alert others in the area, and begin spill clean up according to your Laboratory Spill Response Plan. Take special care to avoid aerosolizing the material and avoid percutaneous exposure hazards that may be present in the spilled material, i.e., needles, broken glass, scalpel blades, etc.

Spill Response Plans contain five essential elements:

- **Personal protective equipment (PPE)**

Wear appropriate PPE when the potential infectious materials, recombinant or synthetic nucleic acid molecules, or organisms containing recombinant or synthetic nucleic acid molecules may be encountered. This could include gloves, lab coat, face shield, goggles, dust mask, HEPA mask, etc. Think exposure routes and protect yourself accordingly. If

the spilled material can be transmitted via the inhalation route then 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 there was a spill means that aerosolization has taken place.

- **Assessment of the extent and nature of the spill**
Is it a large spill or a small spill? A large spill is generally defined as a quantity sufficient to seek its own level. In other words it runs to a low point. The main concept that would cause one to treat the large spill differently is with containment in mind. One would want to make sure the spill did not spread and contaminate other areas.
- **Disinfection and methods of disinfection**
Cover the spill with absorbent towels and carefully pouring a suitable 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 effectiveness and precleaning may be required (as with blood spills). Remember two factors are associated with proper disinfection: concentration of the disinfectant and contact time. Follow the manufacturer's directions.
- **Disposal**
After the area has been thoroughly disinfected carefully place all the materials in the proper medical waste container. Contaminated glass should never be handled with hands (even gloved hands). Use tongs, dust pan and broom, hemostats, etc. and carefully place the broken glass in an approved sharps container. The rest of the spill clean up waste and disposable PPE can then be placed in red 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 OH&S as directed by lab manager or PI.
- **Report:**
All spills outside of primary containment that involve infectious materials, recombinant or synthetic nucleic acid molecules, or organisms containing recombinant or synthetic nucleic acid molecules requiring must be reported immediately to the Institutional Biosafety Officer at 4-2487. All major spills involving recombinant or synthetic nucleic acid molecules, or organisms containing recombinant or synthetic nucleic acid molecules must be reported to the Institutional Biosafety Officer at 4-2487 who will notify the IBC; the IBC Director will notify NIH OBA as required. Reporting should be in place not to place blame, but to look for common processes and allow for root cause analysis that may result in positive change for everyone.

The following procedures are provided as guidelines for developing your own spill response procedures to biohazardous (including recombinant or synthetic nucleic acid molecules, or organisms containing recombinant or synthetic nucleic acid molecules) spill cleanup. Procedures should be posted in prominent locations within the laboratory. In each of the following cases, depending on the size of the spill, notify everyone in the lab.

13.3.1 Spills in a Biosafety Cabinet

Additional considerations for spills inside the biosafety cabinet may include:

- Leave biosafety cabinet blower motor turned on during cleanup.
- If necessary, flood work surface, as well as drain pans and catch basins below the work surface, with disinfectant.
- Wipe cabinet walls, work surfaces, and inside the front view screen with disinfectant.
- Lift front exhaust grill and tray, and wipe all surfaces. Ensure no paper towels or soiled debris has blown into the area below the grill.
- Expose non-autoclavable materials to 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 OH&S Biosafety at 4-2487 for an evaluation in the event more extensive decontamination of the cabinet is required.

13.3.2 Spills Inside a Centrifuge

Additional considerations for spills inside a centrifuge may include:

- Wait 30 minutes for aerosols to settle before attempting to clean up spill
- Remove rotors and buckets to nearest biological safety cabinet for cleanup.
- Thoroughly disinfect inside of centrifuge.

13.3.3 Other Spills, Environmental Releases

- Notify the Institutional Biosafety Officer (4-2487) immediately if the material spilled requires BSL-2 or greater containment, if there has been a release to the environment, or escape or improper disposition of a transgenic.
- 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 OH&S for information.

13.4 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.

13.4.1 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 (Ext. 4-5353 for campus buildings and Ext. 4-6181 for hospital buildings).

13.4.2 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.

13.4.3 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.

13.5 Reporting

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 NIH/OBA as applicable.

The following spills or accidents involving recombinant or synthetic molecules or organisms containing recombinant or synthetic nucleic acid molecules will be reported immediately to NIH OBA: overt exposure occurring in BSL2 laboratories, overt or potential exposure occurring in BSL3 laboratories (there are no BSL4 laboratories at UAB). Other significant problems, violations of the NIH Guidelines, or significant research-related accidents and illnesses must be reported to NIH OBA 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).

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

This plan was developed to be in compliance with applicable regulations and guidelines, including but not limited to the *NIH Guidelines*, Section IV-B-2-B-(6), Section IV-B-2-B-(7), Section IV-B-3-c-(2), and Section IV-B-3-c-(3). For Select Agent & Toxin emergency response, see Select Agent Plan.

Appendix A

Institutional Biosafety Committee (IBC) Roles and Responsibilities

The policies, rules, and procedures set forth in the UAB Safety Manuals have a single, straightforward purpose: to promote a safe environment for the protection of University of Alabama at Birmingham employees, students, and visitors as well as our community and the environment. For these rules and procedures to be effective, it is important to have a structured administrative format in place that defines the roles and responsibilities of each person or administrative office.

The UAB Vice President for Research in conjunction with the Associate Provost for Research are responsible for ensuring that research is conducted in full conformity with the provisions of the safety manuals and all federal, state, and local regulations.

The Institutional Biosafety Committee (IBC) is one of several committees that reports to the UAB Vice President for Research. Various University committees (i.e., IACUC, IBC, IRB) have overlapping responsibilities for safety issues in research and teaching. The IBC coordinates the biosafety-related activities of these committees and administrative units. The IBC works with and is advisory to the Institutional Biosafety Officer and OH&S, which have institutional responsibility and enforcement authority in matters of workplace safety.

A. Charge of the Institutional Biosafety Committee

The IBC and the Department of Occupational Health and Safety (OH&S) have been charged with the planning and implementation of the campus Safety Programs. Membership is appointed by the Vice President for Research and is comprised of the Chair and members representing the community and a variety of university interests as well as members who are knowledgeable in microbiology and infectious disease, chemistry, occupational health and safety, recombinant and synthetic nucleic acid technology, animal experimentation, public health, law, and UAB policy. The Committee is structured to ensure that collective experience and expertise exists to evaluate the occupational risks associated with the wide variety of research conducted at UAB. The Committee has the authority to impose disciplinary measures in cases where there is violation of UAB's established practices and procedures.

B. Membership

The IBC composition meets the criteria prescribed in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* and is responsible for ensuring that research conducted at UAB is in compliance with the Guidelines. Members are generally appointed for two-year terms but frequently serve more than one term. Two members represent the health and environmental interests of the surrounding community and have no affiliation with UAB other than membership on the IBC. Also included in the membership is at least one scientist with expertise in biological safety containment principles, one representing the laboratory technical staff, a representative from the

Animal Resources Program, and member(s) with expertise and training in human gene transfer, biological safety, physical containment, public health, law, and UAB policy. Each member is responsible for naming an alternate to act on their behalf in their absence. See Section F below for Membership Composition.

C. Responsibilities

The IBC reviews all institutional research activities involving the use of biohazardous agents and recombinant or synthetic nucleic acid material that require approval for "biosafety activities" as described in current governmental regulatory requirements. These regulatory requirements include, but are not limited to, the National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, the Centers for Disease Control and Prevention (CDC) Guidelines, the Department of Homeland Security, the United States Department of Agriculture (USDA), and the Occupational Safety and Health Administration (OSHA) regulations and compliance directives as adopted and adhered to by UAB. The IBC provides consultation on policies related to the use of recombinant or synthetic nucleic acid material in UAB hospitals, clinics or clinical laboratories and works collaboratively with the groups who have primary responsibility for them.

The 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 IBC advises and works with OH&S in administering the various aspects of the campus Biosafety Program. The Committee is also responsible for drafting campus policies and procedures under their purview and for ensuring that all aspects of Appendix M, *Points to Consider*, for human gene transfer have been appropriately addressed by the Principal Investigator.

Principal Investigators who wish to perform research using recombinant or synthetic nucleic acid material or work with material classified as Risk Group 2 or above must register their project with OH&S using the appropriate forms (see OH&S website www.uab.edu/ohs for project registration forms). A detailed description of the proposed work (equivalent to the methodology section of the grant) must be submitted with the registration, and a copy of grant may be requested.

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 documentation from the sponsor. Any Serious Adverse Event reports must be submitted to NIH OBA as well as the IBC (See http://oba.od.nih.gov/oba/rac/Guidelines/APPENDIX_M.htm#_Toc7255836 for more information). Further, any modifications or any documentation submitted to or from the Sponsor regarding the project must also be provided for review.

OH&S forwards proposals involving work performed by UAB faculty, to the IBC for review at its monthly meeting (see section 5 of this document). Electronic comments may be submitted. The IBC reviews and approves UAB campus research projects, research involving UAB faculty members who work off-campus, UAB sponsored private business initiatives conducted within UAB owned facilities, work performed on campus by outside

entities, and Veterans Administration-funded projects conducted within UAB owned facilities.

Completed registration documents and a summary that includes the methodologies proposed in the protocol must be received by OH&S by the last working day of the month, in order to be included in the next month's IBC review.

1. Non-Exempt Recombinant Research

The IBC reviews applications that involve non-exempt recombinant or synthetic nucleic acid material work. This review includes an independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research, an assessment of the laboratory facilities, compliance with policies, regulations and guidelines, and of the training, expertise, and enrollment and compliance with the OHS Employee Health Program for all personnel involved with the project. PIs may be asked to present new research applications or novel approaches in person to the committee. IBC approval is required as specified in the NIH Guidelines for all non-exempt recombinant research.

2. Risk Group 2 or Higher Research

The IBC is responsible for assuring the safe use of biological material and will review applications that involve work at Biosafety Level 2 or above. This review includes an independent assessment of the containment levels for the proposed research, an assessment of the laboratory facilities, compliance with policies, regulations and guidelines, and of the training, expertise, and enrollment and compliance with the OHS Employee Health Program for all personnel involved with the project. PIs may be asked to present new research applications or novel approaches in person to the IBC. The IBC will determine the level of medical surveillance for programs in conjunction with the recommendations from OH&S Employee Health. IBC approval is required prior to work with the proposed agent.

3. Human Gene Transfer Research

The IBC reviews applications that involve Human Gene Transfer work. This review includes an independent assessment of the containment levels for the proposed work, an assessment of the laboratory and clinical facilities, compliance with policies, regulations, and guidelines, training and expertise of personnel, and Appendix M, *Points to Consider*, for human gene transfer. PIs may be asked to present new research applications or novel approaches in person to the IBC. IBC approval is required for all Human Gene Transfer protocols prior to patient enrollment in the study.

D. Additional Responsibilities

The IBC will set required containment for research projects and may, at its discretion, increase or reduce the Biosafety Level depending on the circumstances presented by a specific project.

Accidents and near-accidents shall be carefully analyzed by the Committee in conjunction with OH&S with results and recommendations for the prevention of similar occurrences distributed to all who might benefit. The intent shall not be in attributing blame but contributing to a safer environment.

The IBC shall adopt emergency plans to cover accidental hazardous material spills and personnel contamination. The IBC will coordinate with institutional officials and will cooperate with state and local public health departments and provide reports to the UAB Vice President for Research.

The IBC shall periodically review the UAB Biosafety manual and ascertain compliance with the policies and procedures outlined in the manual. The IBC shall review the effectiveness of the UAB Biosafety program and make recommendations for improvements.

The IBC shall assure that Deans, Chairs, and other administrators are aware of and require compliance with the safety policies and procedures outlined in the UAB safety manuals.

E. Meeting Schedule – 2015

The IBC proposed meeting dates for 2015 are as follows:

- January 26
- February 23
- March 23 (4th Monday)
- April 27
- May 18 (3rd Monday due to Memorial Day)
- June 29
- July 27
- August 31
- September 28
- October 26
- November 30
- December 21 (3rd Monday due to holiday schedule)

F. Membership Composition

Suzanne M. Michalek, Ph.D., IBC Chair

Department of Microbiology
258 BBRB – 2170

Donna S. Williamson, M.S. in Microbiology, Director Research Safety Committees and Employee Health (IBC Contact Person)

Occupational Health & Safety
Ch19 445, -2041

Carolyn Dobbs, M.P.H., M.D., Ph.D., Non-UAB Affiliated Member

Jefferson County Department of Public Health
1400 6th Avenue South

Birmingham, Alabama 35205

Julie Cobb, R.N., Non-UAB Affiliated Member Alternate
Jefferson County Department of Public Health
1400 6th Avenue South
Birmingham, Alabama 35205

James J. Odom, Jr., M.S. L.L.B., Non-Affiliated Member
Practicing Attorney
P.O. Box 11244
Birmingham, Alabama 35202-1244

Michael B. Odom, B.A., J.D., Non-Affiliated Member Alternate
Haskell Slaughter Young & Rediker, LLC
1400 Park Place Tower
2001 Park Place North
Birmingham, Alabama 35203

H. Joseph Ronsisvalle., Non-Affiliated Member
Special Agent
WMD Coordinator
Federal Bureau of Investigation
US Department of Justice
1000 18th Street North
Birmingham, Alabama 35203

Pam Bounelis, Ph.D., Assistant Dean for Biomedical Research
School of Medicine Dean Office
FOT 1203 – 3412

Kyle Boyett, Assistant Director of Biosafety
Assistant Director of Biosafety
CH19 445 – 2041

**Elaine E. Broussard, M.P.H., Executive Director OH&S, Research Health and Safety
(Biosafety Officer)**
Occupational Health & Safety
CH19 445 – 2041

David G. Cannon, BA, CPIA
Director
Institutional Animal Care and Use Committee
CH19 403, 2041

Samuel C. Cartner, D.V.M., M.P.H., Ph.D., Animal Expert
Assistant VP Animal Research Services
Animal Resources Program
RSB 220L, -2800

Erik D. Dohm, D.V.M., Animal Expert Alternate Member
Senior Clinical Veterinarian

Animal Resources Program
RSB 220, -2800

Julie Gibbs-Erwin, B.S., B.S., MT (ASCP)

Office of the Vice President for Research and Economic Development
RSB 220, -2800

Joel N. Glasgow, Ph.D.

Assistant Professor
Department of Medicine
BMR2 572, -2180

Meredith Preuss, Ph.D., Alternate Member

Assistant Professor
Endocrinology, Diabetes, & Metabolism
SHEL 1207, -2182

Harry G. Johnson, B.S.

Occupational Health & Safety
CH19 – 2041

Stephen A. Moser, Ph.D.

Professor, Laboratory Medicine
WP P230, -7331

Max L. Richard, B.S., M.P.H.

Assistant Vice President
Occupational Health & Safety
445 CH19 1- 2041

Justin Roth, Ph.D.

Instructor
Department of Pediatrics
CHB 140A2

Theresa V. Strong, Ph.D.

Professor
Department of Medicine
WTI 510H, -3300

Amanda Watts, MS, CPIA, Alternate Member

Assistant Director
Institutional Animal Care and Use Committee
CH19 403, -2041

Ad Hoc Members:

(UAB Faculty and Staff)

Mitchell S. Pate, Ph.D., RBP, SM (NRCM), CBSP, Corporate Biosafety Officer, Southern Research Institute
Birmingham, AL 35224

Judith McBride, CIH, Director Institutional Chemical Safety and Environmental Management Committee
CH19 445 - 2041

J. Daniel Lynn, M.S., School of Medicine, Chairman's Office
409A BDB – 0012

Michael A. Markiewicz, PHA
Pharmacist
JT 1728 – 6860

Margaret M. Lawson, CIM, Institutional Review Board (IRB) Assistant Director
AB 470 – 0111

Alan M. Stamm, MD, Infection Control Committee (ICC) Chair
MEB 612 – 3296

Ex-Officio Members:
(UAB Occupational Health & Safety Staff)

Robert Heath
Director of Radiation Safety
CH19 445 - 2041

Randy Pewitt
Executive Director OH&S, Emergency Management, Campus, and Health Care Safety
CH19 445 – 2041

UAB Biosafety Manual Appendix B

UAB EMPLOYEE OCCUPATIONAL HEALTH PROGRAM

The UAB Employee Occupational Health Program (Program) is designed to focus on anticipating, recognizing, evaluating, and controlling potential health and safety hazards and environmental factors that may affect the health, comfort, or productivity of the entire research campus community. The program accomplishes these goals through risk assessment, risk management, risk education, and preventive medicine (health maintenance). Medical surveillance is a critical component of effective occupational health programs and involves the evaluation of health risks associated with an individual's exposure to animals and hazardous agents. The initial evaluation establishes a baseline of an individual's health and potential exposure risks and health status. Subsequent biennial periodic reviews and updates are then performed to assess an individual's changing risks. In many cases, an initial evaluation and risk assessment is all that is necessary until an update is required. For some individuals, however, a clinical examination and vaccination(s) may be required as well.

A. 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 animals at UAB, must provide proof that their proposed work/potential exposure at UAB along with their medical history has been reviewed by their personal physician. A clearance document indicating the above, along with any work restrictions, must be signed by the physician on his/her office letterhead and provided to UAB Employee Occupational Health along with a copy of the Health Screening Questionnaire prior to being granted access to the animals or the animal facility. Examples of those not included in this UAB Employee Occupational Health program include:

- Non-paid students
- Volunteers
- Individuals from private companies conducting work at UAB
- Visiting Scientists
- UAB Hospital Employees (should be covered by the Hospital Employee Health Program)

B. Enrollment

Enrollment is initiated when an individual completes the Initial Health Screening Questionnaire (http://www.healthsafe.uab.edu/pages/home/occupational_health/default.html) and submits this form to the Occupational Health Program for review. An individual has successfully met the requirement when s/he is enrolled in the UAB Occupational Health Program and has 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 s/he has received the evaluation and any required interventions such as immunizations.

Individuals are required to update their information whenever they experience a change in health status and whenever their job responsibilities and/or potential exposures change, but at least every other year. This is accomplished by completing and submitting the Health Screening Update Form (http://www.healthsafe.uab.edu/pages/home/occupational_health/default.html). An individual has

successfully met the requirement for annual or semi-annual update when s/he has completed and submitted the update form in the UAB Occupational Health Program and has received either:

- A risk assessment notification that indicates no further medical evaluation is necessary or
- A risk assessment notification that indicates further medical evaluation is necessary and s/he has received the evaluation and any required interventions such as immunizations.

C. Health Services

A variety of health services are provided by the UAB Occupational Health Program. Access to and recommendation for these services is based on the health history of the individual and the exposure to any job-related potential hazards.

C.I. Vaccination Programs:

Depending upon work activities and potential exposures, vaccinations may either be required or recommended for individuals. All required vaccinations must be accepted in order to perform the associated job duties. Employees have the right to refuse any recommended vaccines, but must complete a declination form (INSERT LINK HERE) and return it to the UAB Employee Occupational Health Program for their Occupational Health file.

C.I.a. Hepatitis A Virus (Hep A) Vaccine

The hepatitis A vaccine is recommended for individuals whose work activities place them in contact with sewage or feces (e.g., plumbers) and those who work with nonhuman primates. A two dose series of injections is recommended for pre-exposure prophylaxis to develop adequate antibodies to hepatitis A infection.

C.I.b. Hepatitis B Virus (Hep B) Vaccine

The hepatitis B vaccine is highly recommended for individuals whose work activities potentially expose them to infectious materials such as human and non-human primate blood, blood products, body fluids, cells, (established) cell lines, or tissues. This includes lab staff, animal care staff, plumbers, and some facilities and environmental services personnel. A three dose series of injections (0, 1-2, and 4-6 months) is recommended for pre-exposure prophylaxis to develop adequate antibodies to hepatitis B infection.

C.I.c. Hepatitis A/B Vaccine

If it is recommended that an individual receive both Hep A and Hep B vaccines, a combination vaccine is available and may be recommended. The combination vaccine is a three dose series of injections (0, 1-2, and 4-6 months).

C.I.d. Tetanus Vaccine

Tetanus (lockjaw, painful spasms of all muscles) is a serious disease caused by a bacterium that enters the body through a cut or wound. All individuals should have knowledge of the date of their most recent tetanus immunizations. It is recommended that all individuals receive a booster dose once every 10 years to maintain protective antibodies against tetanus. Tetanus toxoid injection is often combined with Diphtheria vaccine (Td).

C.I.e. Measles Vaccine

The measles vaccine (rubeola) is required for individuals born after 1958 (who cannot document evidence of immunization) who work with non-human primates.

C.I.f. Streptococcus pneumonia Vaccine

The pneumonia vaccine may be recommended for individuals working with certain strains of *Streptococcus pneumoniae*.

C.I.g. Neisseria meningitidis Vaccine

It is recommended that employees who work with *Neisseria meningitidis* receive booster vaccinations every five years.

C.I.h. Influenza Vaccine

Since influenza virus can be transmitted to and from non-human primates and ferrets, it is recommended that individuals working with these animals receive annual influenza vaccinations.

C.I.i. Other Vaccines

Other agent-specific vaccines may be required or recommended depending upon proposed work.

C.II. Medical Surveillance

Depending upon work activities and potential exposures, medical surveillance may either be required or recommended for individuals. All required medical surveillance must be accepted in order to perform the associated job duties. Employees have the right to refuse any recommended medical surveillance, but must complete a declination form and return it to the UAB Employee Occupational Health Program for their Occupational Health file.

C.II.a. Tuberculosis (TB) Screening

Certain individuals must provide evidence of a negative TB status annually. This includes those working with or who have exposure to non-human primates as well as individuals conducting research with the organism. Based upon the individual medical history, one of the following methods of surveillance will be recommended or required:

- Screen by administration of the Tuberculin Skin Test (TST) under the skin,
- QuantiFERON-TB blood test
- Chest X-Ray, or
- Completion and submission of an Annual Tuberculosis Screening Questionnaire.

An annual TB screen with TST administered under the skin is the primary method of screening. Once the skin test is performed, employees must return to have TB tests read by designated trained personnel between 48 and 72 hours. *Tests not read within this period must be repeated.*

Employees previously immunized with the BCG vaccine must obtain a baseline PPD skin test.

Individuals who have not previously been screened will initially require a 2-step PPD test. This 2-Step method of testing will help prevent future misinterpretation of a subsequent skin test as a newly acquired TB infection. This “boost phenomenon” can result, because the ability of some people (those who have had a previous TB infection or BCG vaccine) to react to PPD may gradually wane. Individuals requiring a 2-Step screen will be asked to return in 1 to 3 weeks for a second PPD test.

Negative results

If a skin test is read as negative, TB infection is not indicated.

Positive results

A positive skin test and no symptoms of TB can be interpreted to mean a person has been exposed to the agent that causes TB sometime during his/her life (latent TB infection). It does not indicate that a person has active TB or is contagious. If a skin test is read as positive, the individual will be sent to the Jefferson County Health Department for a chest x-ray to evaluate whether or not TB infection is active.

If the chest x-ray is read as negative (clear), subsequent annual chest x-rays are not routinely needed unless symptoms develop that could be attributed to TB. The employee must complete and submit an Annual Tuberculosis Screening Questionnaire (INSERT LINK) to UAB Employee Occupational Health to screen for active TB symptoms.

Once a positive PPD is determined, annual screening via PPD will no longer be an effective means for determining TB status. Alternative screening via chest X-ray and/or QuantiFERON-TB blood test and the Annual Tuberculosis Screening Questionnaire will thenceforth be used to determine TB status.

C.II b. Allergy Screening and Evaluation

The Occupational Health Medical Staff may contact the employee if the individual's medical history and current work description indicate the potential need for allergy evaluation and screening. In certain circumstances, it may be recommended that the individual be referred to an allergist for evaluation.

C.II c. Measles (Rubeola) Titer

In certain instances, an employee may be asked to submit for a measles antibody titer.

C.II d. Hepatitis B Titer

In certain instances, an employee may be asked to submit for a hepatitis B antibody titer.

C.III. Additional Components

C.III.a 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. ***This program is currently under development.***

C.III.b. HAZMAT Physicals

Employees whose job responsibilities include the role of HAZMAT 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 "drug free",
- Ensure that the individual is capable of wearing proper personal protective equipment, and
- Determine exposure levels of certain substances.

D. Cost

The UAB Employee Occupational 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.

E. Compliance

The Public Health Service (PHS) requires that an animal care and use program include an occupational health program for personnel with substantial animal contact. The UAB Employee Occupational 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 Occupational 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 Occupational Health Program and must satisfy all mandatory requirements in order to gain access to animals and facilities housing animals. For example, individuals working with non-human

primates must provide documented annual evidence of a negative TB status. All such employees will receive annual notification that they are due for screening. If the employee fails to provide documented evidence, access to the animals and the facilities housing animals will be denied until the status of the individual is known. Refer to Table 1 for a listing of requirements and recommendations based on potential exposures.

For all UAB employees, vaccinations and screenings will be offered based upon job duties and medical history outlined in the Health Screening Questionnaire and Update 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 Occupational Health). Costs associated with routine vaccination and/or screening will be covered by the UAB Employee Occupational Health Program. PIs may need to budget within their department or grant funds for special vaccinations not routinely available. If the employee is referred to an allergist for evaluation, the evaluation will be covered by the Program. Any cost associated with medications or treatments recommended by the allergist, however, will be the responsibility of the employee.

All individuals not employed by UAB (students, volunteers, visiting scientists, outside companies) listed on protocols involving the use of animals for research purposes must provide documented evidence of participation in an equivalent plan. The individual must provide the UAB Employee Occupational Health Program proof that their proposed work/potential exposure at UAB along with their medical history has been reviewed by their private physician. A clearance document indicating the above, along with any work restrictions, must be signed by the physician on his/her office letterhead and provided to UAB Employee Occupational Health along with a copy of the Health Screening Questionnaire prior to being granted access to the animals or the animal facility. All non-UAB personnel must comply with all mandatory requirements for access to animals and facilities housing animals. Refer to Table 1 for a listing of requirements and recommendations based on potential exposures.

Table 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
Ferrets	Current Tetanus Annual Influenza	
Cats	Current Tetanus	All women of childbearing age must receive counseling on the inherent hazards associated with toxoplasmosis.
All other animals	Current Tetanus	
Noise above 85 dBA	Current Tetanus	Hearing Conservation Program
HAZMAT First Responders	Current Tetanus	HAZMAT Physical Respiratory Protection Program Drug Screen Applicable Screening Assays
Plumbers	Current Tetanus Hepatitis A Hepatitis B	
Material of Human or Non-Human Primate Origin	Current Tetanus Hepatitis B	
<i>Mycobacterium tuberculosis</i> Research	Current Tetanus	Annual TB Screen
<i>Neisseria meningitidis</i>	Current Tetanus Meningitidis booster every 5 years	
Risk Group 3 Biologic Agents		Entrance to room evaluated on a case-by-case basis

EXPOSURE CONTROL PLAN – Appendix C Template for UAB Laboratories

Purpose
Scope
Definitions
Exposure Determination
Responsibilities
Requirements
Occupational Medicine Program
Resources/References
Review Schedule

PURPOSE

The use of some techniques or specimens in UAB laboratories may result in employee exposure to human disease agents. The purpose of this Exposure Control Plan is to describe ways to eliminate or minimize the danger of exposure to human blood or other potentially infectious materials, in compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), the CDC Tb Guidelines (FR 59:208, pp54242-54303), and the Respiratory Protection Standard (29 CFR 1910.134) and in conjunction with UAB Safety Manuals.

SCOPE

Each laboratory working with material of human origin must include this document or a similar document plus a copy of their laboratory monitoring reports (audit reports) and/or lab registration form (UABLR) in the lab's safety manual and have it available for all employees who may have occupational exposure to human bloodborne pathogens or *Mycobacterium tuberculosis*.

This plan may be customized within departments (adding to or deleting from this document) but must be in compliance with the UAB guidelines.

The PI or designee must review and update this plan annually or whenever any significant changes in procedure or personnel occur. Each Dean, Department Chair, and 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.
- **Universal Precautions** – a method of infection control in which all human blood, tissue and certain other potentially infectious material (OPIM) are treated as if known to be infectious for HIV, HBV, HCV, or other bloodborne pathogens. OPIM includes semen or vaginal secretions; cerebrospinal, synovial, pleural, peritoneal, pericardial, or amniotic fluids, or tissue.
- **Occupational Exposure Event** – a specific eye, mouth, non-intact skin, inoculation, or injection contact with blood or other potentially infectious material or inhalation contact with material potentially infected with *Mycobacterium tuberculosis* as a result of the performance of job duties.

- **Regulated 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 nonneedle 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.
- **Needless Systems** – a device that does not use needles for a: the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established, b) the administration of medication or fluids, or c) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps

EXPOSURE DETERMINATION

The Principal Investigator, laboratory supervisor and/or designated laboratory safety officer will identify positions and procedures in the laboratory which present the possibility of occupational exposure to human or primate blood or other potentially infectious material. 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 primate 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 material used in this laboratory that may be associated with potential exposure to *Mycobacterium tuberculosis* or other pathogens warranting use of a respirator include the items checked below:

- Manipulation of cultures of *Mycobacterium tuberculosis*
- Entrance into infected primate quarters
- Work involving the potential for aerosol production of a pathogen where a biosafety cabinet or other closed system cannot be used
- Entrance into an AFB (acid fast bacillus) Isolation room
- Other(s), specify:

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

Classification	✓ = Yes
Professor	<input type="checkbox"/>
Postdoctoral Researcher	<input type="checkbox"/>
Medical Technologist/Technician	<input type="checkbox"/>
Staff Research Associate	<input type="checkbox"/>
Laboratory Assistant	<input type="checkbox"/>
Graduate Student	<input type="checkbox"/>
Undergraduate Student	<input type="checkbox"/>
Other(s), specify:	<input type="checkbox"/>

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.

Grounds and Maintenance personnel or Environmental Services personnel may face the risk of exposure to bloodborne pathogens during the performance of their duties. Blood or blood-contaminated needles or containers may be encountered.

Occupational risks for exposure to HIV, HBV, and HCV are well documented and specifically are associated with injection, inoculation (including contamination of broken skin) or mucous membrane exposure to blood and other potentially infectious body fluid. As a precaution, when differentiation between fluid types is difficult, University employees must treat all human body substances as if contaminated.

RESPONSIBILITIES

I, _____, as the Principal Investigator/Laboratory Director, recognize my responsibility to implement and monitor this bloodborne pathogen 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 within ten days of starting work with human or primate specimens, and annually thereafter with records maintained by the PI or the department for at least 3 years.

REQUIREMENTS

Each laboratory where human or primate blood or OPIM is used must prepare an Exposure Control Plan.

Universal precautions and Biosafety Level 2 practices and procedures (see Biosafety Manual) will be followed to minimize exposure to bloodborne pathogens.

Documentation for equipment requiring regular examination or maintenance will be kept by laboratory staff as noted in the Laboratory Registration and Lab Monitoring documents for this lab.

The worksite is 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 disinfectant(s) as declared in the Laboratory Registration and Lab Monitoring documents for this lab.

Protective gloves are worn if exposure to blood or OPIM is probable. They must be replaced frequently and immediately if they become contaminated or damaged in any way. Hand creams and lotions may affect the protective properties of gloves and their use in conjunction with protective gloves is avoided.

Employees must be made aware of signs and symptoms of latex sensitivity and provided with prevention strategies (see NIOSH document).

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. In specific situations where it can be justified that 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.

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.

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.

Personal protective equipment (PPE) and clothing is used in this laboratory to minimize or eliminate exposure to human bloodborne pathogens. The PI or department is responsible for supplying personal protective equipment and clothing and making arrangements for replacement or cleaning as needed. Respiratory protection must be made available and employees trained and fit tested if their work involves potential exposure to *Mycobacterium tuberculosis*, including but not limited to, contact with non-human primates or entrance to rooms where they are housed.

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

Regulated medical waste will be handled in accordance with the UAB Medical Waste Management Plan.

OCCUPATIONAL MEDICINE PROGRAM

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

- **BLOODBORNE PATHOGENS**

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. Copies of the Declination form are available on the OH&S website. Medical records are confidential and are to be maintained by the UAB Occupational Medicine Program or healthcare provider for at least 30 years post employment.

Post-Exposure Evaluation and Follow-up: 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 and notify your PI or supervisor **and...**

If an exposure to human blood, body fluids, or unfixed tissue occurs during normal work hours: Immediately call the Employee Health Rapid Response Team at 4-3675, page them through UAB Paging at 4-3411 or follow your specific response plan (ex., HIV, HBV, and HCV research labs).

If an exposure to human blood, body fluids, or unfixed tissue occurs after work hours or on holidays: Immediately page the Employee Health Rapid Response Team through UAB Paging at 4-3411 or follow your specific response plan (ex., HIV, HBV, and HCV research labs).

Prompt medical attention may reduce the risk of serious health consequences after an exposure event. If contact to Employee Health cannot be made, proceed directly to the UAB Hospital Emergency Room and tell them you have had an occupational exposure involving bloodborne pathogens.

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

If an exposure to concentrated virus, altered strains, exotic strains, or recombinants of bloodborne pathogens occurs: During their regular business hours (M-F 8am to 4:30pm) proceed directly to *The Workplace* (933-5300). Otherwise, proceed to UAB Hospital Emergency Room and tell them you have had an occupational exposure involving research strains of bloodborne pathogens. Specify that the Occupational Medicine Physician on-call be contacted to assist in the evaluation.

In all cases a [UAB Incident/Accident](#) form must be completed.

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 Occupational Health & Safety (4-2487). OH&S will investigate the circumstances surrounding the exposure, and work with the PI/Manager to modify work practices and/or develop additional prevention strategies.

- **TB EXPOSURE CONTROL**

Respirator Fit Testing: Fit testing is conducted under the supervision of Mr. Bill Davis, Industrial Hygienist, UAB Department of Occupational Health & Safety (4-2487). For activities where respiratory protection is indicated, NIOSH-certified respirators may be used.

Each employee planning to use a respirator will complete a health screening questionnaire, fit testing, and training before they are cleared for use. During the fit testing session, employees learn the brand and size of respirator to wear, how to place it on the face and check for proper fit, how to care for and store it, and when to replace it.

The choice of respirator is based on activity specific risk assessment. In general, NIOSH-certified N-95 respirators are used for activities which may include spill clean up of material containing Tb; entrance into infected primate quarters; work involving the potential for aerosol production and where a biosafety cabinet or other closed system can not be used; entrance into an AFB Isolation room.

Employees may only use the respirator brand and size for which they have been fitted based on the tasks to be performed.

Tb Screening: The PI/Manager will ensure that all persons in the laboratory/unit area who are determined to have occupational exposure to non-human primates and/or *Mycobacterium tuberculosis* are screened for tuberculosis before being assigned to work where potential exposure may occur and regularly thereafter as prescribed by the UAB Occupational Medicine Program. Tb screening is conducted by *The Workplace* (933-5300) in the form of the Mantoux skin test or chest x-ray. The PI or department must maintain documentation of participation or declination. Copies of the Declination form are available on the OH&S website. The PI and/or the department are responsible for arranging and financing these medical services.

Post-Exposure Evaluation and Follow up:

If an exposure to *Mycobacterium tuberculosis*, altered strains, exotic or drug resistant strains (ie., MDR-Tb), or recombinants of Mtb occur: During their regular business hours (M-F 8am to 4:30pm) proceed directly to *The Workplace* (933-5300). Otherwise, proceed to UAB Hospital Emergency Room and tell them you have had an occupational exposure involving research strains of Mtb. Specify that the Occupational Medicine Physician on-call be contacted to assist in the evaluation. Complete a [UAB Incident/Accident](#) form.

RESOURCES/REFERENCES

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

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

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

UAB Biosafety Manual, 5th Edition, October 2000.

UAB Medical Waste Management Plan, Appendix J, UAB Biosafety Manual 5th Edition, October 2000.

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.

US Department of Health and Human Services, Centers for Disease Control and Prevention Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities, 1994. FR 59.208, pp54242-54303

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

US Department of Labor/Occupational Safety and Health Administration. 1993. Respiratory Protection 29 CFR 1910.134.

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.

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

REVIEW SCHEDULE

This plan was implemented on _____
Date PI, Manager or Supervisor Signature

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

**Appendix G
Project Registration**

OH&S USE ONLY Project # _____

Instructions: Submit completed and signed form for each project to:
 UAB Occupational Health and Safety, CH19 Suite 445. (FAX: 934-7487).
 A notice that OH&S has received this form will be sent to the address you provide below.

A

Name (Principal Investigator/Title) _____ e-mail address _____ Title of Project _____ _____ Campus/Business Phone # _____ Address _____ Location of Project _____ (Buildings and Rooms) UAB Affiliation _____ (Department, Center or Institute)

B

Check all that apply: Status of this submission: <input type="checkbox"/> New <input type="checkbox"/> Continuation of OH&S # _____ <input type="checkbox"/> Renewal <input type="checkbox"/> Resubmission of OH&S # _____ <input type="checkbox"/> Core <input type="checkbox"/> Program Project	Check all that apply: Funding source: <input type="checkbox"/> Private Business in UAB facility; specify: _____ <input type="checkbox"/> External Grant, specify: _____ <input type="checkbox"/> UAB Internally funded, specify: _____
----- Original title if different from title in section A : _____	

C

Instructions: Respond to all questions in Section C by checking "No" or "Yes" as it applies to this project. For all "Yes" responses, complete the corresponding question on Page 2.		
Does this project involve: 1. Radioisotopes 2. Carcinogenic/mutagenic/teratogenic chemicals 3. Highly toxic chemicals/drugs 4. Toxins or toxic products 5. Microbial agents or products (bacterial, viral, fungal, parasitic) 6. Human blood, body fluids, tissues, or human subjects 7. Recombinant DNA./RNA molecules 8. Animals (what species: _____) 9. Cell/Tissue Culture	Check Response No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/>	PLEASE NOTE Each Appendix G must be accompanied by a brief project description that includes: <ul style="list-style-type: none"> • Overall project objective • Specific aims • If your Laboratory Safety Plan is not on file with OH&S, explicitly state personnel safety precautions and the reason for their selection • A copy of the grant may be requested at a later date. See OH&S web site for details www.healthsafe.uab.edu

UAB Safety procedures applicable to the materials listed above are described in the *UAB Chemical Safety and Waste Management Manual*, *UAB Biosafety Manual*, *NIH Guidelines for Research Involving Recombinant DNA Molecules*, *UAB Radiation Safety Procedures Manual*, and the *UAB General Health and Safety Management Program Manual*.

The signature of the investigator below indicates that he/she is familiar with UAB safety policies relevant to any hazardous procedures or materials used in his/her laboratory and has incorporated safety training, practices, and procedures into the routine of his/her laboratory.

Date _____ Signature _____

OH&S Use Only Pending Review RAD CHEM BIO
--

Appendix G – Project Registration

Personnel involved in the project _____

Yes No Personnel have received documented safety training.

If the response to any question in Section C of this form is "Yes", please **complete all parts** of the corresponding question in Section D. See Instructions for Completing Appendix G at our web site www.healthsafe.uab.edu

1. Radioisotopes used _____

Chemical Form _____ Used in: tissue culture animal tissue administered to animals

Yes No Is this protocol on file in the UAB Radiation Safety? If yes, date approved _____

Licensee Name _____ License Number _____ Contact _____ Phone # _____

2. Carcinogenic/mutagenic/teratogenic chemicals used _____

3. Highly toxic chemicals/drugs used _____

4. Toxins or toxic products used _____

5. Microbial agents/products used _____

6. Human blood body fluids unfixed tissues fixed tissue will be used.

Yes No Is this a Human Gene Therapy protocol?

7. The host/vector system used in this project is _____.

I have reviewed the NIH Guidelines and this project is non-exempt exempt according to Section _____ of the Guidelines. For non-exempt projects attach page 3 of Appendix H Registration Document of Recombinant DNA Research.

8. Yes No Will any of the agents listed in section C of this form be administered to animals? If yes describe the following:

Agents administered _____

Route of administration _____

Place of administration (Building and room #) _____

Animal Housing location _____

Precautions to be used to protect personnel and animals _____

Animal disposal method/location _____

Bedding disposal method/location _____

9. Check all that are used in this project: Animal cell culture Continuous Primary Human cell culture Continuous Primary

Complete these statements if this project involves microbial agents, recombinant DNA, human blood, body fluids, or tissues, human or animal cell culture or introduction of any of the above material(s) into animals or humans.

The laboratory biosafety containment level used for this project will be (check one):

BSL1 BSL2 BSL3

The animal biosafety containment level used for this project will be (check one):

ABSL1 ABSL2 ABSL3

Appendix H
Registration of Recombinant DNA Research

OH&S USE ONLY
Project # _____

Instructions: Complete this form and attach to the Appendix G for projects involving recombinant DNA that are non-exempt from the [NIH Guidelines](#).
Send to UAB Occupational Health and Safety, CH19 Suite 445. (FAX: 934-7487).
A notice that OH&S has received this form will be sent to the address you provide below.

Instructions : If this form is submitted at the same time as the Appendix G, discard this page and send page 2 (Section H) of this form, the Appendix G and a copy of the grant to OH&S, CH19 Suite 445.

E

Name (Principal Investigator/Title) _____

e-mail address _____

Title of Project _____

Campus/Business Phone # _____ Address _____

Location of Project _____ (Buildings and Rooms)

UAB Affiliation _____ (Department, Center or Institute)

F

Attach a brief project description that includes:

- Overall project objective
- Specific aims
- If your Laboratory Safety Plan is not on file with OH&S, explicitly state personnel safety practices and procedures to be used and the reason for their selection.

1. The laboratory biosafety containment level used in this project is:

BSL1 BSL2 BSL3

The animal biosafety containment level used in this project is:

ABSL1 ABSL2 ABSL3

2. Personnel involved in the project _____

Yes **No** Personnel have received documented safety training.

G

UAB Safety procedures applicable to the materials listed above are described in the *UAB Chemical Safety and Waste Management Manual*, *UAB Biosafety Manual*, *NIH Guidelines for Research Involving Recombinant DNA Molecules*, *UAB Radiation Safety Procedures Manual*, and the *UAB General Health and Safety Management Program Manual* located on the OH&S website <http://www.healthsafe.uab.edu/>.

The signature of the investigator below indicates that he/she is familiar with UAB safety policies relevant to any hazardous procedures or materials used in his/her laboratory and has incorporated safety procedures into the routine of his/her laboratory.

Date _____ **Signature** _____

Appendix I

UAB Select Agent Permit System Procedure

Contact UAB Occupational Health & Safety at (205) 934-2487 for information on the CDC Laboratory Registration and Select Agent Transfer Program.

Link to [Select Agent Registration](#)

Appendix J

University of Alabama at Birmingham Medical Waste Management Plan

- I. Definitions per the Alabama Department of Environmental Management Land Division 13-Solid Waste Program, Chapter 335-13-1, 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 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 patient treatment areas, 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.

- C. Microbiological Waste: Discarded cultures and stocks of human 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.

- 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. They will be transported to treatment and disposal facilities by UAB or its 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.

II. Collection of Untreated Waste

- A. Medical and surgical waste will be separated from non-medical waste and placed into designated and approved medical waste containers at the point of generation, i.e., patient rooms, surgical suites, patient treatment areas, laboratories, etc. The specific criteria to make the separation of medical vs. non-medical waste will be in accordance with the definition as stated in Section I of this document.
- B. Medical waste (except sharps) will be placed in red, plastic bags (usually 35 gallon capacity). ASTM-D tested red transport container liners containing medical waste will be properly and completely secured into labeled, designated transport containers with covers or other approved containers to avoid leakage or spillage. Sharps (see definitions) will be placed into leak proof, rigid, puncture resistant containers (approved sharps containers) and sealed to prevent loss of contents (ADEM 335-13-7-.02). The outermost container for medical waste shall meet state and federal regulations and be conspicuously labeled with the words "Medical Waste" or "Bio-Hazardous" or "Infectious" and/or contain the International Biological Hazard Symbol.
- C. In research areas medical waste shall be securely located away from traffic flow.

III. Identification of Medical Waste

Medical waste contained in sealed, red, plastic bags and sharps containers will be placed in transport containers with covers which are rigid, puncture resistant, and leak resistant and prepared for pickup by UAB or its contractor. In UAB Hospital areas, medical waste will be moved to 2 collection points in and adjacent to the UAB hospital(s) for temporary storage before being picked up by UAB or its contractor. The outside container will be identified by bar codes which will contain the name and address of the generator (UAB) and the date the medical waste was moved to the pickup location or if temporary storage is utilized (see definition below), prior to pick up by UAB or its contractor.

All secondary containers, carts, or transport vehicles used in the collection or movement of medical waste within the labs, departments or units shall be identified and decontaminated as appropriate by the user.

IV. Temporary Storage of Untreated Medical Waste

"Storage" as used in this sense would mean storage of the packed outside containers prior to pickup by UAB or its contractor.

Temporary storage for UAB Hospital will be accomplished at the solid waste compactor buildings. These buildings will be single-purpose (waste handling) for the purpose of this plan. The Medical Waste Temporary Holding Facilities will be identified by contrasting color signage specifying "Medical Waste". The "facilities" will be capable of full closure and will be secured and locked when not attended. Floors and wall surfaces which may come in contact with medical waste will be cleaned with a germicidal soap solution on a weekly schedule. The management of this facility will be under the direction of the Director of University Hospital Environmental Services (205) 934-4782.

The Medical Waste Temporary Storage Facility premises will be included in the UAB (Hospital) pest control contract coverage for insects and vertebrate pests.

Any UAB employee whose duties require exposure/contact with medical waste in any form will be furnished with and required to wear gloves and such other protective clothing as required by their department supervisor(s).

Hospital units and departments should avoid holding medical waste in any temporary holding area on UAB Hospital premises longer than six (6) days before pickup by UAB or its contractor where treatment will be rendered by appropriate methodology. When temporary holding areas are used, they are to be clearly identified and secured.

UAB shall maintain records for three (3) years. UAB OH&S will maintain transport/treatment records for campus locations. Hospital Environmental Services will maintain records for UAB Hospital. This information will include the name and location of the generator, i.e., UAB Hospitals, Birmingham, Alabama.

V. Transportation of Untreated Waste to Treatment Facility

Any medical waste collection, transport or disposal company contracted by UAB must meet all local, state, and federal requirements and provide copies of permits to OH&S.

Certain categories of medical waste (eg, Select agent, CJD) may be transported from the several collection sites on the properties of UAB to the following UAB storage and treatment facility:

University of Alabama at Birmingham
221 14th Street South
Birmingham, Al 35194
(205) 934-3797
Contact: Eric Grace, Manager of Hazardous and Regulated Materials

Transportation of medical waste will comply with the following conditions:

- A. There shall be no mixing of radioactive waste, chemical waste, or any other type of hazardous waste with untreated medical waste prior to transportation to the treatment/disposal facility.
- B. Untreated medical waste shall not be mixed with other solid waste in the same transport vehicle unless all of the waste is treated as medical waste. Leaking, improperly sealed or unlabeled containers shall not be accepted by the medical waste transporter. Medical waste shall not be compacted in a transported vehicle. Medical waste shall be transported only in an enclosed vehicle and no untreated medical waste shall be released to the environment.

UAB employees who transport medical waste from those designated collection sites at UAB to the disposal facilities shall be thoroughly familiar with all rules and

regulations pertaining to the movement of untreated and treated medical waste. Instructors for transportation training will be one of following:

Incinerator Plant Supervisor
Hazardous and Regulated Materials Facility Manager
Biosafety Officer

Training records for these employees will be available for inspection at the HRMF located at 221 14th Street South Birmingham, AL 35294.

Additionally, the following conditions shall be met and followed by UAB and its contractor:

All vehicles shall be identified with the transporter, business name, telephone number, a "Medical Waste" designation (or appropriate name or symbol), and the ADEM permit number.

VI. Transportation Treated Waste

Treated medical waste will be transported to an approved landfill in approved containers. Appropriate certification of treatment will be provided on an "as needed basis" from the treatment facility permittee to the permittee of the disposal facility.

VII. Treatment Measures

All medical waste, according to the definitions (ADEM 335-13-1.03 and 49 CFR 173.134 Hazardous Materials Regulations and UAB policy), generated by UAB hospitals, clinics and medical research laboratories will be treated according to the treatment schedule as indicated by ADEM 335-13-7 and 49 CFR 173.134 Hazardous Materials Regulations and UAB policy.

Complete treatment of medical waste will be accomplished by incineration, and/or steam sterilization.

A. Incineration Methods

Incinerators decontaminate and destroy medical waste using high temperature combustion. Specific conditions and regulations as these may apply to the incineration process conducted by UAB's medical waste contractor or at the UAB Hazardous and Regulated Materials Facility are as follows:

1. Storage requirements for untreated medical waste shall comply with those storage regulations stated in this Program.
2. Combustible medical waste shall be rendered non-recognizable during the incineration process and prior to disposal in the sanitary landfill.

B. Steam Methods

Decontamination of waste by autoclaving uses the combination of moisture, pressure and heat to kill microorganisms.

Portions of medical waste generated at UAB will be treated at the point of generation by autoclaving. This waste will then be transported to the final treatment facility by UAB or its contractors before disposal.

1. Hazardous chemicals and radioactive wastes will not be included in any autoclaving process.
2. Autoclaves at UAB shall be equipped with a continuous temperature and pressure monitoring device or an equivalent ADEM approved test. Efficiency of each autoclave used for medical waste treatment at UAB shall be checked using Bacillus stearothermophilus at least once after each forty hours of operation.
3. An operational, written log for each UAB autoclave used for medical waste shall include at least the following information:
 - a. Date, time and operator for each cycle
 - b. Temperature and pressure maintained during cycle
 - c. Method used for confirmation of temperature and pressure
 - d. Dates and results of calibration and maintenance

VIII. Disposal of Treated Waste

All treated medical waste intended for disposal in a sanitary landfill shall be disposed of in an approved facility. Specific conditions and requirements regarding proper disposal of treated medical waste include the following points:

- A. Written certification to the effect that medical waste has been properly treated shall be provided to the transporter permittee or his designee and to the waste disposal facility.
- B. Certification shall be provided at least on an annual basis.
- C. Proper records shall be maintained concerning storage, transportation and final disposal of medical waste generated by UAB hospitals, clinics and medical research laboratories. These records will be maintained for at least three years and will be available for review upon request by ADEM or DOT representatives.

IX. 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 Occupational Health & Safety to all employees who manage or have contact with medical waste.
- B. All employees who manage or have contact with medical waste are required to attend one in depth medical waste training session at the time of their initial assignment and a refresher every three years. Periodic updates may be conducted thereafter in conjunction with other safety programs or as separate courses. Hospital employees will receive updates during their annual safety update sessions.

- C. Consultation and response to questions regarding medical waste issues will be provided on request by contacting the UAB OH&S Biosafety Program.

X. 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 Department of Occupational Health & Safety in conjunction with the Institutional Biosafety Committee and other affected parties reviews and revises the plan yearly and as regulations and guidelines mandate.
- B. Any modifications to this plan are to be reviewed by the UAB Department of Occupational Health & Safety. Container approval must be coordinated through the UAB Department of Occupational Health & Safety's Biosafety Program.

References:

Alabama Department of Environmental Management Land Division-Solid Waste Program, Division 13, Code 335-13, November 1993.

US Department of Transportation Hazardous Materials Regulation 49 CFR 173.134

Fleming, Diane O. et. al. Laboratory Safety - Principles and Practices, 2nd Edition. Washington, DC: ASM Press, 1995

U.S. Department of Health and Human Services, Centers for Disease Control/National Institutes of Health, Biosafety in Microbiological and Biomedical Laboratories, Atlanta, GA: 1993.

U.S. Environmental Protection Agency, "Managing and Tracking Medical Wastes - A Guide to the Federal Program for Transporters", EPA/530-SW-89-022. Washington, DC: September 1989.

U.S. Environmental Protection Agency, "Managing and Tracking Medical Wastes - A Guide to the Federal Program for Generators", EPA/530-SW-89-021. Washington, DC: September 1989.

Congress of the United States Office of Technology Assessment, "Issues in Medical Waste Management", OTA-BP-O-49. Washington, DC: October 1988.

REVIEW SCHEDULE

Implementation Date: _____

Reviewed (Circle Responses)		Updated		Date	Biosafety Officer
Yes	No	Yes	No		
Yes	No	Yes	No		
Yes	No	Yes	No		
Yes	No	Yes	No		
Yes	No	Yes	No		
Yes	No	Yes	No		
Yes	No	Yes	No		

UAB Biosafety Manual - Appendix L

Immunization Policy and Biosafety Considerations for Users of Vaccinia, Vaccinia Vectors & Other Orthopox Viruses

A. Background

Pox viruses and their recombinants are useful microbiological research tools. Research personnel working with ones that can affect human health are at risk for infection with these agents. Infection may result not only in the production of wild type organism, but also in the expression of foreign genes, the product of which may enhance the infection process, interfere with immune response or otherwise adversely affect the host.

Pox viruses are stable in a wide range of environmental temperatures and humidity and may be transmitted by fomites. Virus may enter the body through mucous membranes, broken skin, or by ingestion, parenteral inoculation or droplet or fine-particle aerosol inhalation. Sources of laboratory-acquired infection include exposure to aerosols, environmental samples, naturally or experimentally infected animals, infectious cultures, or clinical samples, including vesiculopustular rash lesion fluid or crusted scabs, various tissue specimens, excretions and respiratory secretions.

B. Exposure risks

- Naturally or experimentally infected laboratory animals are a potential source of infection to exposed unvaccinated persons.
- Genetically engineered recombinant vaccinia viruses pose risk through direct contact or contact with clinical materials from infected persons or animals.
- Virus may be present in lesion fluids or crusts, respiratory secretions, or tissues of infected persons or animals.
- Ingestion, parenteral inoculation, and droplet or aerosol exposure of mucous membranes or exposure of broken skin to infectious fluids or tissues are the primary hazards to laboratory and animal care personnel
- Risks may be increased for persons with personal or family history of atopic disease (eczema and/or asthma), altered immunocompetence, HIV infection, pregnancy, documented allergy to polymyxin B sulfate, streptomycin sulfate, chlortetracycline hydrochloride and neomycin sulfate.

C. Vaccinations

There is considerable debate over the use of the vaccinia vaccination for the prevention of laboratory acquired orthopox infection. The following information is based on national guidelines issues by the CDC's Advisory Committee on Immunization Practices (ACIP):

Vaccination is not recommended for those working with the following highly attenuated strains:

Highly Attenuated Strain:	Derived from:
MVA	Vaccinia virus (Ankara)
NYVAC	Vaccinia virus (Copenhagen)
TROVAC	Fowlpox virus
ALVAC	Canarypox virus

- Although there is no formal surveillance system in place, there have been no reports of laboratory-acquired infection resulting from exposure to any of the above named strains.
- Even if vaccination is not indicated, appropriate biosafety guidelines and infection control procedures must always be observed when working with viral material.

Vaccinia vaccination is recommended for laboratory workers who directly handle cultures or animals infected with:

- Nonhighly attenuated vaccinia virus strains
- Recombinant vaccinia viruses derived from nonhighly attenuated vaccinia strains
- Other orthopox viruses that can infect humans (e.g. monkeypox and cowpox).

Nonhighly Attenuated Strain:	Other Orthopox viruses
WR (Western Reserve, mouse neuroadapted derivative)	Cowpox
NYCBOH (vaccinia vaccine strain)	Monkeypox
Copenhagen	
Temple of Heaven	
Lister	

All research personnel who directly handle:

- Nonhighly attenuated or wild type vaccinia cultures
- Animals contaminated or infected with nonhighly attenuated or wild type vaccinia virus
- Dryvax® vaccine
- Recombinant vaccinia viruses derived from nonhighly attenuated or wild type vaccinia strain
- Other similar orthopoxviruses that infect humans

must be counseled and offered vaccinia vaccine by the UAB OH&S Employee Health Program staff prior to initiating work with vaccinia virus. A declination form will be used to document individual non-participation in the vaccinia vaccination program.

Vaccination may be required under certain conditions based on individual laboratory risk assessment.

The vaccine, Dryvax®, is a live virus preparation of vaccinia virus manufactured by Wyeth and distributed by the CDC. It is administered with a bifurcated needle using a multi-puncture technique.

Individuals with certain conditions are more likely to experience severe side effects or complications from the vaccine and should not be vaccinated. Contraindications include eczema, atopic dermatitis, immunosuppression and pregnancy, or having household contacts with any of these conditions.

Revaccination every 10 years is recommended for people working with nonhighly attenuated vaccinia strains; more frequent revaccination may be required for more virulent orthopox viruses.

Laboratory personnel not directly handling cultures of vaccinia or animals infected with vaccinia, but working in the same lab where nonhighly attenuated strains are being used should be offered medical screening for potential contraindications to vaccinia exposure.

Vaccination Procedure:

To obtain vaccinia vaccination, or information about vaccinia vaccination, call UAB OH&S Employee Health Nurse at 4-2487.

Initial counseling and evaluation will be conducted by the UAB OH&S Employee Health Physician and/or Nurse Practitioner as medical conditions or household contact medical conditions may restrict individual vaccination.

Vaccinations will be provided by referral from the UAB OH&S Employee Health Physician and appointment only through Jefferson County Department of Public Health.

Emergency Response Procedure:

S

If you have been exposed to vaccinia virus, or you have had a laboratory accident while working with vaccinia virus:

- Wash the exposure site well
 - If the exposure was by needle stick or other route which breaks the skin, wash with soap and water for 5-15 minutes and cover with a bandage
 - If exposure was by splash to eyes or mucous membranes, irrigate thoroughly for 15 minutes at an emergency eye wash station.
- If you have already developed lesions that you suspect may be the result of a recent vaccinia exposure:
 - Cover the lesions with a bandage
- Report the event to the laboratory supervisor and UAB Biosafety IMMEDIATELY (4-2487 during regular working hours; page Director-On-Call 8477 after hours).
- Follow UAB's On-The-Job Injury (OJI) plan and seek immediate medical attention at "The Workplace" during regular work hours or the UAB Emergency Department after hours and weekends.
 - The occurrence of vaccinia infection and its course will vary depending on the route of exposure, the strain of vaccinia, the dose of exposure, your medical history and your "smallpox" (vaccinia virus) vaccination immunization status. Immediate medical "first-aid" interventions may help prevent or lessen the severity of infection.
- Provide healthcare personnel with the following information:
 - Whether or not you have ever received a smallpox vaccination
 - Date of your last vaccination
 - The strain of vaccinia you were working with (ex. Western Reserve, MVA, Ankara, etc)
 - If the strain was recombinant, the identity of the inserted foreign gene
 - The dose/titer of vaccinia exposure (estimate the concentration of virus suspension, and possible volume of inoculum.)
 - Clearly state if you or any of your close contacts:
 - Have a history of eczema/atopic dermatitis or other active skin conditions, such as acne or psoriasis
 - Have an immunodeficiency or immunosuppressive condition (taking steroids, etc.)
 - Have heart disease
 - Are currently pregnant (or could be pregnant) or nursing

- In the weeks following exposure, take note of the following symptoms which may indicate a need for further medical attention:
 - Lesions or swelling at the site of exposure
 - Rash
 - Fever
 - Report the event to the laboratory supervisor and UAB Biosafety IMMEDIATELY (4-2487 during regular working hours; page Director-On-Call 8477 after hours).

References:

1. Centers for Disease Control and Prevention and National Institutes of Health. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Atlanta, Ga, US Department of Health and Human Services, 2007.
2. Centers for Disease Control and Prevention. *Vaccinic (Smallpox) Vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2001*. MMWR, 2001. **50**(RR-10).
3. Centers for Disease Control and Prevention. *Laboratory-acquired vaccinia exposures and infections—United States, 2005-2007*. MMWR, 2008. **57**(15): p. 401-4.
4. MacNeil, A., M.G. Reynolds, and I.K. Damon, *Risks associated with vaccinia virus in the laboratory*. Virology, 2009. 385(1):p. 1-4.
5. Centers for Disease Control and Prevention. *Laboratory-acquired vaccinia exposures and infections—Virginia, 2008*. MMWR, 2009. **58**(29): p. 797-800.
6. Centers for Disease Control and Prevention. *Information Sheet for Laboratory Workers – Accidental Vaccinia Virus Exposure (Aug 2009 CDC Packet)*

Tracking Record Vaccinia Policy, Immunizations & Biosafety Considerations

Action				Reasons for Development/Change of Standard				Change in Practice		
Developed	Reformatted	Reviewed Program	Revised	Required Review	New Knowledge	Regulation Change	Other, specify	No	Yes	
10/22/2007										<i>Initial SOP</i>
Supersedes: None										
11/5/2009			X					X		
Supersedes: All										
Supersedes:										
Supersedes:										