THE UNIVERSITY OF MEMPHIS®

Biological Safety Program

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The University of Memphis
Biological Safety Program

This Biological Safety Program represents official University policy on the possession, storage, and use of biological agents. Employees are expected to implement these prudent practices, precautions, and handling techniques for biological agents as a means of promoting a safe and healthful environment for the University community.

Responsibilities

The President of The University of Memphis has ultimate responsibility for biological safety within the University and, with other administrators, chairs, and directors, provides continuing support for the University's Biological Safety Program.

Biological Safety Officer

The Biological Safety Officer (BSO) is the chief administrative officer for the Biological Safety Program. The BSO's duties include:

- Working with the University Biosafety Committee and other employees to develop and implement appropriate biological safety guidelines
- Monitoring procurement, use, and disposal of biological agents
- Seeing that appropriate audits are maintained
- Helping faculty and staff develop precautions and adequate facilities
- Assisting in risk determination for biological agents present on campus
- Knowing the current legal requirements concerning regulated substances
- Seeking ways to improve the Biological Safety Program

Office of Environmental Health & Safety

Environmental Health and Safety (EH&S) executes the day-to-day administrative responsibilities of the Biological Safety Program including, but not limited to, audits, training, and consultation.

University Biosafety Committee

This body governs the development and implementation of the University Biological Safety Program, including review and approval of recombinant DNA (rDNA) protocols. The members of this committee are appointed by the President and are selected from the faculty, staff, and community on the basis of their knowledge and experience in this field. As a condition for NIH funding for recombinant DNA research, the UBC shall ensure that all research conducted at or sponsored by the University, irrespective of the source of funding, complies with NIH Guidelines.

Departments

Department chairs or directors are responsible for general oversight of the biological safety efforts within their respective areas, including:

- Implementing an information and training program for all individuals potentially exposed to biological hazards
- Ensuring implementation of and full compliance with procedures for decommissioning areas where biological agents have been used or stored
- Maintaining records, including but not limited to training records and hazard assessments

Faculty and Supervisors

These individuals have overall direct responsibility for biological safety in their work areas, including:

- Ensuring that workers know and follow policies outlined in this biological safety program; that personal protective equipment is available, adequate and used; and that appropriate training has been provided
- Developing and maintaining appropriate Standard Operating Procedures (SOPs) for the safe use of hazardous biological agents within their area(s)
- Providing regular biological safety and housekeeping inspections, including inspection of emergency equipment
- Ensuring that facilities and equipment within the work area are adequate
- Communicating with the Biological Safety Officer when new biological agents are introduced into their work areas
- Assessing the risks associated with biological agents used and determining requirements for protective apparel and equipment appropriate for the agents
- Initiating and following up on action to eliminate hazards and/or unsafe conditions within their work areas
- Initiating and complying with laboratory decommissioning procedures prior to vacating any laboratory space

Laboratory Personnel

These individuals shall be responsible for the following:

- Planning and conducting operations in accordance with this Biological Safety Program
- Developing good personal work practice and hygiene habits
- Complying with all rules, regulations, and instructions pursuant to occupational safety and health standards
- Wearing prescribed personal protective equipment
- Reporting unsafe conditions and practices to their supervisor

General precautions outlined in this document for handling biological agents shall be followed.

Information and Training

It is the responsibility of each department chair or director to implement an information and training program to assure that all individuals at risk are adequately informed of the work done in the Biohazard Work Area (BWA), the risks associated with the work, and the procedures to follow in case of accident. EH&S provides resources to assist with this task.

Each employee shall receive training at the time of initial assignment to the work area, prior to assignments involving new exposure situations, and at regular intervals as determined by the supervisor or the University Biosafety Committee. Departmental training should be a continuing activity rather than an annual event; however, formal training shall be offered at least annually by the Biological Safety Officer or designee.

Training shall include health hazards of the agents present in the BWA; measures employees can take to protect themselves and others from these hazards; signs and symptoms associated with exposure to the agents present in the laboratory; and location and availability of reference material on biological safety. Employees shall be informed in keeping with requirements of the OSHA Bloodborne Pathogens Standard and, where applicable, Tennessee Hazardous Chemical Right-to-Know Law and associated OSHA Right-to-Know Regulations (29 CFR 1910.1200), and the OSHA Laboratory Standard (29 CFR 1910.1450).

The form in the on-line appendix section entitled "Departmental Training Record" may be used to guide and document information and training activities; employee training records shall include documentation that they have been informed of the hazards associated with biological agents in the work area.

Every BWA worker shall know the location and proper use of protective apparel and emergency equipment and should have the opportunity to receive first aid training. Literature and consulting advice about biological safety should be readily available to lab workers, and they should be encouraged to use these resources. EH&S can provide assistance with these items.

The Biohazard Work Area

All work with biological agents shall be confined to a specified area known as a Biohazard Work Area (BWA). This may be an entire room, or a portion thereof, set aside for work with these materials. If only a portion of the work area is designated as the BWA, it shall be delineated with floor markings, either fluorescent orange or orange/red in color. If the entire area is designated as the BWA, all doors into the BWA shall be properly marked. Minimum design specifications, access limitations, equipment needs, and examples of organisms that may be included in the BWA are found in the on-line appendix to this manual.

Security and Admittance

Due to the potentially infectious nature of materials used in various laboratories, only individuals who complete required initial training and subsequent refresher training should be allowed admittance into the BWA. No untrained housekeeping or maintenance personnel should access or maintain the BWA. Due to the technical knowledge specific to such environments, housekeeping should be the responsibility of trained personnel only.

Security of the BWA may be provided by such devices as card reader locks. If conventional key access door locks are to be employed for BSL-1 and, in some cases, BSL-2, doors should be securely locked when the area is not in use. Most BSL-2 and all BSL-3 and BSL-4 environments require a greater degree of security. Access to biological agents subject to anti-terrorism laws and associated regulations shall be limited to those individuals meeting regulatory requirements.

Signage

Areas in which biological agents are used, stored, or disposed shall be clearly marked with a sign or label with the biohazard symbol and names of personnel to contact in case of emergency. Work practice restrictions (e.g., no eating, drinking, or smoking) should also be posted. Sample labels may be viewed in the on-line appendix or copies obtained from Environmental Health and Safety (EH&S).

Safety Equipment

Appropriate safety equipment shall be in place, be unobstructed, and in good working order. Emergency showers and eyewash stations shall be properly maintained and undergo periodic checks, including activation, by EH&S. If the BSL dictates that equipment such as chemical decontamination showers be present, then such equipment shall also undergo periodic inspection. Chemical fume hoods and biological safety cabinets shall be inspected at least annually.

Storage

Areas in which biological agents are stored should be within the confines of the BWA, be dedicated solely for the purpose of biological materials containment, and shall be properly

labeled. All biological agents shall be properly stored within containment befitting the inherent risk of the agent. In case of mixed hazards, such as flammable biohazards, care should be taken to store these materials in suitable containment for all inherent risks. In cases of radioactive biohazards, the Radiation Safety Officer and the Biological Safety Officer should be contacted for consultation prior to initiation of procedure. An accurate inventory must be maintained for purposes of hazard assessment and to reduce unnecessary handling.

Containers used for storage shall be closeable or sealable, leak-resistant, disposable or sterilizable, and clearly labeled as a biohazard with a listing of the contents.

Periodic Laboratory Audits

Biohazard Work Areas are subject to periodic safety assessments conducted by EH&S. It is strongly suggested that a general self-audit be periodically executed by the principal investigator, lab manager, or designee. A copy of an inspection/audit form may be found in the on-line appendix to this manual.

Decommissioning of Biohazard Work Areas

Prior to the closing of a laboratory or other area where biological agents have been used or stored, departments shall certify that the area has been fully decommissioned. Laboratory decommissioning is required prior to a PI leaving the University, relocating to another laboratory space, retiring from research pursuits, and, as appropriate, renovating a laboratory. It is the responsibility of the PI to initiate the decommissioning process; however, the department chair or director is responsible for ensuring its full implementation. In the event of a PIs death, disability, or other unforeseen event, the department chair or director shall implement the decommissioning process. Departments failing to ensure that all deficiencies are corrected by the PI are accountable for resulting costs. The Decommissioning Certification Form is found in the on-line appendix.

Risk Assessment (Biosafety Levels)

Before beginning work with a biological agent, the Principle Investigator (PI) must assess the level of risk posed by the manner in which the agent will be used in the experimental protocol. The initial risk assessment should be based on the biosafety level (BSL) of the agent as described in *Biosafety in Microbiological and Biomedical Laboratories*. Each of the four biosafety levels (BSL) requires a specific combination of laboratory practices and procedures, safety equipment, and laboratory facilities. Where biological agents are associated with a host animal, Animal Biosafety Levels (ABSL) are applicable. See on-line appendices for ABSL classifications and practices.

- **BSL-1** contains well-characterized agents not known to consistently cause disease in healthy adult humans. BSL-1 practices, safety equipment, and facility design are appropriate for undergraduate training and teaching laboratories. These practices represent a basic level of containment, the cornerstone of which is standard microbiological technique.
- **BSL-2** contains a broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity. BSL-2 practices, equipment, and techniques are applicable to clinical, diagnostic, and teaching laboratories. The primary hazard with these agents is associated with accidental splashes, needlesticks or cuts, or ingestion of infectious materials. These agents may be used on the open bench only if potential for producing splashes or aerosols is low.
- **BSL-3** contains indigenous or exotic biological agents with a potential for respiratory transmission and which may cause serious or life-threatening infection. Use of containment equipment and advanced facility design are necessary.

- **BSL-4** contains dangerous and exotic biological agents that are pose a high risk of life-threatening disease. These are agents that may be transmitted via aerosol route and for which there is no available vaccine or therapy. Work at BSL-4 requires highly specialized facilities with sophisticated isolation equipment.

Risk Reduction

Exposure to and infection by biological agents occurs through inhalation, ingestion, absorption, or injection. Therefore, measures must be taken to eliminate these routes of exposure through application of work practices, engineering controls, and personal protective equipment. The Principal Investigator is responsible for assessing risks posed by the use of biological agents and for incorporating appropriate risk reduction methodologies into experimental protocols. The BSO is available to assist in this endeavor.

Work Practices

Containment and technique are the primary factors in working safely with biological agents. Strict observance of standard microbiological practices and techniques is the cornerstone of containment. If standard techniques do not afford the required protection with a given biological agent, it shall be the responsibility of the principal investigator or supervisor to select additional safety precautions to minimize or eliminate risk potentials to the workers.

Personal Responsibility

Individuals are ultimately responsible for their own actions. Personal safety awareness is irreplaceable in settings where the potential for personal harm is present. This awareness includes a thorough knowledge of procedures, surroundings, and inherent risks. Prior to initiating a procedure, its potential impact on personnel in the surrounding area should be thoroughly considered.

Eating, Drinking, and Use of Personal Items

Eating, drinking, and using or applying personal items, such as contact lenses and cosmetics (including lipsticks and lip balms), while in a BWA is prohibited. No foodstuffs for human consumption shall be stored in any refrigeration unit within any biohazard area. Refrigeration units shall have a label affixed stating, “Not for storage of food for human consumption.”

Engineering Controls

Biological Safety Cabinets

Procedures that are likely to produce aerosols, and thereby raise the risk of infection to laboratory employees, must be performed in a Biological Safety Cabinet (BSC) designed to prevent the escape of aerosols and prevent airborne contamination of the experiment from outside sources. These units should never be confused with laminar flow “clean bench” units. Such laminar flow units should never be employed when utilizing biohazards, toxins or sensitizing agents. A chart showing each classification of BSC may be viewed in the on-line appendix to this manual. Biological Safety Cabinets must undergo re-certification on an annual basis, and after certain repairs, by a certified technician; a copy of the certification must be forwarded to Environmental Health and Safety. A certified technician must perform most repairs, change filters, and perform certain decontamination processes.

Since all clean benches and many biological safety cabinets exhaust air back into the work area, they cannot be used safely with hazardous gases and vapors. Even when a biosafety cabinet is equipped with 100% external exhaust, the HEPA filter can impede the venting of volatile materials. While incidental volumes of low toxicity volatiles may be used in such a

cabinet, it is vital that flammable or highly toxic volatiles be used in a properly functioning chemical fume hood.

Personal Protective Equipment

Personal protective equipment (PPE) suitable for the inherent risks of the biological agent studied shall be made available to all employees without cost to them. Prior to assignment of PPE, a workplace hazard assessment shall be completed and a copy held on file for inspection. Appropriate PPE may include eye and face protection, protective clothing, gloves, footwear, and respiratory equipment as the nature of work dictates.

When protective clothing is required for work with biological agents, it shall be removed and left in the laboratory before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). Disposable gloves are not to be used for touching "clean" surfaces (keyboards, telephones, etc.) and are not to be worn outside the lab.

It is the responsibility of each employee to wash, clean, and store PPE in accordance with regulations and University procedures. It is the responsibility of supervisory personnel to ensure that PPE is correctly used. A chart is included in the on-line appendix to this manual listing recommended PPE for specific biosafety levels. EH&S can assist in recommending PPE.

Personnel using any form of PPE must be trained in accordance with OSHA standards found in Title 29 of the Code of Federal Regulations at 29 CFR 132 through 136; those required to use a respirator must receive a medical clearance and proper qualitative or quantitative fit testing as specified in 29 CFR 1910.134.

Facility Design and Construction

Exposure risks for BSL-1 and BSL-2 agents are largely through direct contact with the agent or through contaminated work surfaces. Special design considerations for these labs may include separation of the laboratory work area from public access areas, availability of decontamination equipment such as autoclaves, and hand washing facilities. When there is substantial risk from infectious aerosols (such as with BSL-3 or 4), it may be necessary to incorporate specialized ventilation equipment, controlled access zones, or even separate buildings into the risk reduction methodology.

Housekeeping and Maintenance

Good general housekeeping is essential in the BWA. Cleanliness and the removal of refuse, both general and biohazardous, reduce the potential for contamination and exposure, thereby reducing hazards. Cleaning and decontamination are fundamental biological safety practices. No unauthorized, untrained personnel are to be allowed access to the BWA for maintenance or cleaning. Handling of biohazardous waste must follow proper containment and disposal criteria. If vacuuming is required as part of housekeeping, vacuum lines or units equipped with appropriate HEPA filters shall be used.

Decontamination

Decontamination is a routine method of risk reduction whereby biological agents are destroyed or inactivated to protect workers from potential infection and the work area from contamination. Decontamination can be achieved by disinfection or sterilization. Disinfection significantly reduces or destroys infectious organisms; however, some organisms (e.g., bacterial spores) will survive. Sterilization results in complete killing of all organisms.

Active work areas shall be disinfected at least daily and after each procedure with the potential to contaminate the area. Any potentially contaminated equipment requiring repair, transfer out of the BWA, or calibration must undergo thorough cleaning and decontamination prior to that event; decontamination must be documented on an Equipment Release Form affixed to the equipment.

Autoclaves

Autoclaves may be utilized to sterilize equipment used in biological procedures. Autoclaves may also be utilized to sterilize biological waste suitable for disposal in the building solid waste stream (trash). Effective sterilization requires a combination of temperature, pressure, and time; for most applications, 30 minutes at 121^{o}C and 15 psi is considered sufficient. Under certain circumstances (e.g., unusually heavy loads or very dense materials) an adjustment in these parameters may be indicated. Steam penetration into the center of the load should be confirmed with each run; a biological indicator should be used periodically to confirm sterilization. The on-line appendices include instructions for effective autoclave sterilization.

Since operation varies from model to model, always read and thoroughly understand the owner's manual before using a different type autoclave. Because autoclaves use saturated steam under high pressure, preventing scald and burn injuries must be a continuing objective. Special diligence must be exercised when unloading the autoclave. Injuries can be prevented by observing the following rules:

- Use a metal tub or tray in the autoclave to contain liquids and catch any spills.
- Loosen caps on liquid-filled containers before placing them in the autoclave.
- Never place chemicals (e.g., phenol, chloroform, bleach) or radioisotopes into an autoclave.
- Crack the door and wait 10 minutes before removing items from the autoclave.
- Wear heat-resistant gloves and a rubber apron when opening the autoclave door and when removing items.

Chemical Disinfectants

Items that cannot be autoclaved can generally be decontaminated using a chemical disinfectant. Selection of an appropriate chemical disinfectant depends on the contaminant present and the type of material to be decontaminated. Liquid disinfectants are most useful for decontamination of solid surfaces and equipment. The level of disinfection achieved depends on factors such as time, pH, concentration, temperature, and the amount and type of organic material present. Remember that most chemical disinfectants are not sterilizers and should not be relied on to destroy all organisms on a surface or piece of equipment. Refer to the on-line appendices for information on selection and use of chemical disinfectants.

Laundry

Uniforms, lab coats, or other clothing worn within an area that utilizes, studies or, comes in contact with biohazardous agents are to be properly disposed or cleaned and disinfected to remove contamination. Contaminated clothing may be properly laundered in-house or be given to a suitable outside contractor; contaminated clothing, including lab coats and other protective clothing, shall not be taken home by personnel.

Contaminated laundry handled on-site shall be washed in separate loads utilizing hot water cycles and include bleach as well as standard detergent. Laundry collected for cleaning should be handled and packaged as any other biohazard; it should be bagged in red, tagged as a potential biohazard, and handled under strict Universal Precautions.

Emergency Preparedness

Emergency Spill/Release Situations

Contingency provisions shall be made for spills/releases with clear designation made between small and large spills/releases. Each type of incident should have a separate procedure. Each department shall post these procedures in work areas that would be potentially affected by such an occurrence. A copy of procedures on handling of general spills/releases may be obtained in the on-line appendix to this manual or directly from EH&S. MSDSs are available for certain biological agents; MSDSs are available through the EH&S web page or the on-line appendix to this document.

A list of personnel to be contacted in an emergency should be developed for each area where people handle biological agents. This list should be affixed to the door of the BWA, and a copy forwarded to the Department of Public Safety and EH&S. Door placards are available from EH&S.

Biohazard Spill Kits

A biohazard spill kit shall be available in each area where the potential for spills/releases of a biohazardous nature is seen. Kits may be purchased through safety supply vendors or be put together by individual departments. These kits should include such items as:

- Suitable disposable gloves (double thickness suggested)
- Disinfectant spray (commercially produced or 10% bleach solution)
- Sharps container for needles and other sharps
- Containers for contaminated broken glass
- Tongs for handling broken glass (should be autoclavable)
- Paper toweling or disposable sponge material

Recombinant DNA

Recombinant DNA (rDNA) molecules are molecules that are either constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from the replication of such. *All* research conducted at or sponsored by The University of Memphis, irrespective of the source of funding, shall adhere to the recombinant DNA guidelines set forth by the most recent National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant DNA Molecules*.

All recombinant DNA protocols shall be submitted to the BSO. Those protocols requiring committee approvals will be forwarded to the University Biosafety Committee (UBC) for action; once approval is secured, the BSO will notify the principal investigator. Approved protocols are subject to annual review.

Risk Assessment

Risk assessment is ultimately a subjective process. The investigator must make an *Initial Risk Assessment* based on the Risk Group (RG) of the agent. Agents are classified into Risk Groups according to their relative pathogenicity for healthy adult humans based on the following criteria (see Appendix B of the NIH Guidelines, *Classification of Human Etiologic Agents on the Basis of Hazard*):

- Risk Group 1 (RG1) agents are not associated with disease in healthy adult humans
- Risk Group 2 (RG2) agents are associated with human disease that is rarely serious and for which preventive or therapeutic interventions are *often* available.

- Risk Group 3 (RG3) agents are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available.
- Risk Group 4 (RG4) agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available.

Containment

The first principle of containment is strict adherence to good microbiological practices. *Physical* containment is achieved through the use of laboratory practices, containment equipment (such as biosafety cabinets and other engineering controls), and special laboratory design. Some experiments involving recombinant DNA may additionally lend themselves to *biological* containment. Biological containment manipulates or enhances natural barriers that either:

- Limit the infectivity of a plasmid or virus for specific hosts, or
- Limit its dissemination and survival in the environment (replication deficiency)

All recombinant DNA research proposals require the PI to make an initial determination of the required level of physical and biological containment. In deciding on the appropriate containment for an experiment, the initial risk assessment should be followed by a thorough consideration of the agent itself and how it is to be manipulated. Factors to be considered in determining the level of containment include agent factors and gene product factors.

Agent Factors		**Gene Product Factors**
virulence	pathogenicity	toxicity
infectious dose	route of spread	physiological activity
quantity	communicability	allergenicity
operations	environmental stability	
availability of vaccine or treatment		

Any strain that is known to be more hazardous than the parent (wild-type) strain should be considered for handling at a higher containment level. Likewise, certain attenuated strains or strains that have been demonstrated to have irreversibly lost known virulence factors may qualify for a reduction of the containment level. Careful consideration should also be given to the types of manipulation planned. For example, organisms that may be cultured under BSL-2 may require a higher level of containment when used for animal inoculation or transmission studies.

Committee Approval

The NIH has developed six categories of experiments involving recombinant DNA. All rDNA protocols require notification of the University Biosafety Committee (UBC). Category III-E and III-F experiments can be initiated as soon as the *Registration Form for Recombinant DNA Research* has been submitted to the Biological Safety Officer; others must receive UBC approval *prior* to initiation of the experiment. The following chart shows the necessary approvals for each category:

Category	Examples/Comments	IRB Approval	UBC Approval	RAC Review	NIH/OBA Approval
III-A	"major actions" human gene transfer		✓	✓	✓
III-B	cloning of toxin molecules		✓		✓
III-C	human subjects	✓	✓	✓	
III-D	RG1, 2, or 3 agents whole animals or plants		✓		
III-E	transgenic rodents		notification only		
III-F	exempted experiments		notification only		
All recombinant DNA protocols must be on file with the BSO.					

IRB = Institutional Review Board; UBC = University Biosafety Committee; RAC = Recombinant DNA Advisory Committee (part of U.S. Dept Health & Human Services); OBA = Office of Biotechnology Activities

Institutional Policies

The University of Memphis has implemented additional policies and procedures for the purpose of protecting its employees and complying with state and federal regulations. Those policies and procedures, which must be adhered to in biohazard work areas, are discussed below.

Bloodborne Pathogens

In each department where personnel may be exposed to human blood, blood products, and other potentially infectious materials, a bloodborne pathogen exposure control plan shall be implemented and maintained per University Occupational Safety and Health Program (UM1293) and OSHA regulations (29 CFR 1910.1030(c)). When preparing an exposure control plan for your department, please consult the on-line appendices to this document or call EH&S.

Universal Precautions

The work practice of "Universal Precautions" requires that all potentially infectious materials be treated as if known to be infectious. Therefore, all materials and equipment coming in contact with human blood, blood products, bodily fluids, unfixed tissue, and other potentially infectious materials shall be considered potentially infectious and appropriate precautions implemented. Refer to your departmental bloodborne pathogens exposure control plan for additional information.

Respiratory Protection

In each department where respiratory protection is required, a respiratory protection program tailored to fit the department must be in place. This program is to be implemented per University Occupational Safety and Health Program (UM1293) and OSHA regulations (29 CFR 1910.134). Please direct questions to EH&S.

Use of Human Subjects

Research protocols involving human subjects must be submitted to the Institutional Review Board (IRB) for approval before work begins. Any questions regarding policy, research, or protocol review may be directed to the IRB Chair.

Use of Animals

Research protocols involving animals must be submitted to the Institutional Animal Care and Use Committee (IACUC) for approval before work begins. Any questions regarding policy, research, or protocol review may be directed to the IACUC Chair.

Research involving animals must comply with federal mandates of the Animal Welfare Act of 1990 as well as pertinent state laws/regulations covering the treatment of animals.

Animal Handling

All laboratory personnel and animal care workers should be informed of the inherent risk related to the specific species with which they are working. It is the responsibility of the department chair and the principal investigator to disseminate information of any potential dangers related to work within the laboratory or animal care facility (see “Responsibilities” section of this manual).

The following work practices are to be strictly followed in areas where animals are involved:

- Animal care personnel shall wear a uniform or lab coat, and where appropriate, other PPE, such as facemask, gloves, and hair cover in animal holding rooms. These shall not be worn in public areas and shall never be taken home. Disposable gloves shall be worn when handling any animal or related equipment. Sinks, which shall be stocked with an adequate supply of soap and paper towels, must be available in animal handling rooms. Gloves shall be discarded and hands washed thoroughly upon leaving an animal room.
- When bare hands, arms, neck, face, or head become contaminated with animal blood, urine, feces, or hair, such contamination shall be removed as soon as possible by washing thoroughly with soap and water. When such contamination enters the mouth or eyes, the material should be quickly removed by irrigation with copious amounts of water.
- Personnel shall not eat, drink, smoke, or apply personal products in rooms or areas where laboratory animals are housed or where animal research is conducted.

Zoonotic Disease

The term zoonosis is applied to diseases naturally transmitted from animals to humans, excluding diseases produced by non-infective agents such as toxins and poisons. Because of the potentially serious effects of zoonoses, it is important to recognize the potential problems existing within each work environment. Care should be taken with respect to inherent zoonoses that research animals may present. Factors that influence the possibility of disease transmission from animals to humans include length of time the animal is infective, incubation period in animals, stability of the agent, population density of animals in the colony, husbandry practices, and virulence of the agent.

A list of many zoonotic diseases is included in the on-line appendix to this manual. If other diseases are encountered as a direct result of animal contact, the Biosafety Officer (BSO) should be contacted as soon as possible. For guidance on safe practices for work with specific species, contact the Director of Animal Care.

Vaccinations

A vaccination program shall be implemented and maintained per University Policy UM1452 and OSHA regulations (29 CFR 1910.1030(f)); this program should include vaccination

for hepatitis B and pre-exposure rabies as appropriate. In instances where vaccination is declined by an employee, a refusal form shall be completed and placed in that employee's medical file. A copy of the refusal form may be obtained from the EH&S website, in the on-line appendix to this manual, or directly from EH&S.

Select Agents and Toxins

Federal anti-terrorism laws and associated regulations enacted after September 11, 2001, restrict possession, use, and transfer of certain toxins and biological agents that are capable of harming humans, animals, plants, other living organisms, or the environment. These laws/regulations include penalties of one to five years imprisonment and/or $250,000 to $500,000 in fines for individuals and organizations found to be in violation. The lists of CDC Select Agents/Toxins and USDA Plant Pathogens are available for review in the on-line appendices to this document.

Major requirements of these laws/regulations include: (1) limiting access only to personnel with a legitimate need to handle or use such agents and toxins; (2) submitting for federal background checks the names, and other identifying information, of personnel with a legitimate need to handle or use agents and toxins; (3) denying or limiting access to nationals of countries determined to support terrorism, persons convicted of serious crimes, and other restricted persons as determined by the U.S. Attorney General; (4) registering facilities with appropriate federal agencies; (5) reporting inventories to appropriate federal agencies; (6) notifying appropriate federal agencies of the release or loss of select agents and toxins; (7) implementing appropriate security measures; and (8) other requirements. Please call EH&S for guidance.

Prions

Prions are proteinaceous, infectious materials that lack nucleic acids. They are composed of an abnormal isoform of a normal cellular protein and are the causative agent for a number of neurodegenerative diseases including scrapie, bovine spongiform encephalopathy (BSE), and Creutzfeldt-Jakob disease. Prion diseases are invariably fatal, with no known treatment or cure.

Prions are characterized by extreme resistance to conventional inactivation procedures including irradiation, boiling, dry heat, and most chemical disinfectants. Infectivity is strongly stabilized by drying or fixation with alcohol, formalin or glutaraldehyde. The on-line appendix to this manual outlines a number of prion decontamination options, including those using sodium hydroxide, sodium hypochlorite, and prolonged high-temperature steam autoclaving.

Under most experimental conditions, human prions and those propagated in apes and monkeys are considered biosafety level 3 pathogens. All other animal prions are considered biosafety level 2. While no laboratory acquired prion infections have been documented, exposure to prion agents through sharps injuries, accidental ingestion, and splashes to the eye remain a serious hazard

Biological Agents Registration and Inventory

An inventory system will be developed and maintained by EH&S. This system will be updated at least annually and upon any significant change in inherent risk levels of biological agents. In order to maintain integrity of the inventory and monitor the influx of biological agents on campus, biological agents should be registered with EH&S upon receipt. A copy of the Biological Agents Registration Form may be found in the on-line appendix to this manual.

Shipping and Receiving Biological Agents and Toxins

Personnel shipping and/or receiving biological agents must comply with regulations promulgated by the U.S. Department of Agriculture (USDA) to regulate importation and interstate shipment of animal and plant pathogens. These regulations prohibit importation, possession, and use of certain biological agents that could pose a health risk to domestic livestock. Any potentially harmful agent that is imported is subject to U.S. Public Health Service Quarantine.

U.S. Department of Transportation (DOT) regulations cover all aspects of shipping biological agents and regulated medical wastes, including packaging, labeling, and other shipping requirements. All University personnel who ship and/or receive hazardous materials, including biological agents, must be trained and certified prior to engaging in such activities.

Biological Waste

Only those individuals who have successfully completed the proper training (refer to Training & Employee Information) should handle biohazardous waste. Universal Precautions and proper PPE are vital to safe handling of such waste.

Departments working with biological agents or potentially infectious material must properly dispose of such waste in accordance with all pertinent regulations, including but not limited to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) and U.S. DOT Hazardous Materials Regulations (49 CFR 173.134, 173.196 and 173.197, inclusive).

Quantity of Waste Generation

Under the current biohazardous waste disposal program offered by EH&S, departments are considered small volume generators if they generate 2 or fewer sharps containers per month and generate 1 bag (two cubic feet or less) of biohazardous waste per month.

As small volume generators, these departments are eligible to take advantage of the disposal program provided that the containers:

- Do not contain free-flowing liquids
- Do not contain other hazardous or radioactive wastes
- Are sealed
- Are properly labeled

Departments that fall into this category may contact EH&S for waste disposal assistance.
Those generating larger quantities of waste must arrange for disposal through the University medical waste contractor.

Mixed Wastes

Creation of mixed wastes (radiation/biowaste and hazardous/biowaste) shall be avoided whenever possible. If experimental design or procedure leaves no other option, EH&S must be consulted prior to initiation of procedure.

Sharps Containers

Each department that works with hypodermic needles or encounters contaminated broken glass shall have appropriate sharps containers for safe disposal of these materials. Appropriate sharps containers are closeable, puncture resistant, leakproof on sides and bottom, and labeled with the biohazard symbol or color-coded red.

On-line Appendices to this Manual

- Animal Biosafety Levels & Practices
- Autoclave Sterilization Guidelines
- Biohazard Spill/Release Procedure
- Biological Agent Registration Form
- Biological Safety Cabinets – Types and Selection
- Biosafety Audit Form
- BSL Environments – Design and Equipment Recommendations
- CDC Select Agents and Toxins
- Decommissioning Certification Form
- Decontamination Methods for Prions
- Departmental Training Record
- Disinfectants – Types and Selection
- Model Exposure Control Plan
- MSDS for Biological Agents
- NIH Guidelines for Research with Recombinant DNA
- Recombinant DNA Registration Form
- Signs & Symbols
- USDA High Consequence Livestock Pathogens/Toxins and Plant Pathogens
- Vaccination Declination Form
- Zoonotic Concerns

GLOSSARY

Antisepsis	The application of an antimicrobial chemical to living tissue to prevent growth or destroy potentially infectious organisms.
BWA	(Biohazard Work Area) The designated laboratory environment in which work with biological agents may be accomplished.
BBP	(Bloodborne Pathogens) Microorganisms that are present in human or primate blood, blood products, tissues or fluids and can cause disease in humans. These pathogens include (but are not limited to) Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV).
BSC	(Biological Safety Cabinet) An enclosed, properly exhausted device which is designed where the work space is under positive pressure, drawing air inward by mechanical means. These cabinets are specifically designed for work with virulent organisms. There are three classes of BSC's, from Class I to III, each affording an increased level of protection.
BSL	(Biosafety Level) A hazard rating system for laboratories in which work with biohazardous materials is performed. It is dependent upon the hazard potential of the agent or material under study and the procedures used within the laboratory, with Level 1 having the least risk and Level 4 having the highest risk. Each level has an inherent set of safeguards, including specific techniques, PPE, and laboratory facilities based on potential hazards unique to each level.
Bioagent	See Biological Agent
Biohazardous Material	(Biohazards) Biological materials which can cause disease in healthy humans and/or may have significant environmental or agricultural impact, including: a) infectious organisms (bacteria, fungi, parasites, prions, viruses, etc.); b) human or primate tissues, fluids, cells or cell cultures; c) recombinant DNA; and d) animals known to be vectors of zoonotic diseases.
Biological Agent	Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthetized component of any such microorganism or infectious agent capable of causing: death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.
CDC	Centers for Disease Control and Prevention

Containment	The management of infectious agents within a laboratory environment where they are stored, incubated or handled. Containment controls/eliminates exposure to employees, students, and the environment.
Decontamination	A routine method of exposure control/elimination within a laboratory in which microorganisms are destroyed or inactivated to protect laboratory workers from potential infection and work area from contamination. This method includes such methods as sterilization, disinfection and antisepsis.
Disinfection	A method of decontamination which employs the use of antimicrobial agents on inanimate objects to destroy/inactivate microorganisms that could exhibit infectious hazards to lab personnel and/or compromise the integrity of the equipment.
DNA	Deoxyribonucleic Acid
DOT	Department of Transportation
Etiological Agent	See Biological Agents
Exposure Control Plan	A written document notating policies, procedures, equipment and controls which show a step-by-step plan that is designed to eliminate or minimize employee/student exposure to infectious agents or biohazardous materials.
Gene Therapy	The delivery of exogenous DNA to mammalian cells to cause the expression of this material thereby altering the cells phenotypically.
HBV	Hepatitis B Virus
HEPA	High Efficiency Particulate Air Filter has an efficiency of 99.97% for particles of 0.3 microns. Biological Safety Cabinets filter air through one or more sets of HEPA filters.
HIV	Human Immunodeficiency Virus
Infectious Substance	See Biological Agent
IACUC	Institutional Animal Care and Use Committee
Laminar Flow Hood	Cabinets that are designed to protect the product only. These types of cabinets are designed to blow air out of the cabinet back into the face of the worker. This type of cabinet should not be used within a BSL environment.
Medical Waste	Waste generated within the confines of a clinical or biomedical facility. These wastes may include (but not be limited to) sharps containers, soiled linen, cell cultures, and autoclaved waste. Such waste should be handled utilizing universal precautions.

NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
Pathogen	Microorganisms that are capable of producing disease.
Principal Investigator	Faculty member responsible for the laboratory environment in which research is being performed.
Prions	Proteinaceous infectious materials lacking nucleic acids composed of an abnormal isoform of a normal cellular protein; causative agents for several neurodegenerative diseases.
Recombinant DNA	Molecules that are constructed extracelluarly by joining natural or synthetic DNA segments to DNA molecules that can replicate within a living cell; or molecules that result from said replication.
RNA	Ribonucleic Acid
Select Agents/Toxins	Any of the biological materials listed by the Secretary of DHHS and Secretary of Agriculture in 42 CFR 72 and in 42 CFR 121 respectively.
Sterilization	A method of decontamination in which the process of cleaning combined with steam or gas autoclaving is used to destroy or inactivate microorganisms.
Toxin	The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes: any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative substance.
UN	United Nations
Universal Precautions	The practice of infection control in which all human blood, blood products, tissue, and certain body fluids are treated as though they were infectious.
USDA	United States Department of Agriculture
Zoonotic Diseases	Diseases that are readily communicable from animals to humans under normal conditions.

References

Biohazards Reference Manual, American Industrial Hygiene Association, Akron, Ohio, 1995.

Biosafety in the Laboratory: Prudent Practices for Handling and Disposal of Infectious Material, National Research Council, Washington, D.C., 1989.

Biosafety in Microbiological and Biomedical Laboratories, 4rd edition, U.S. Department of Health and Human Services, Centers for Disease Control and National Institutes of Health, Washington, D.C., 1999.

Guide for the Care and Use of Laboratory Animals, U.S. Department of Health and Human Services, Public Health Service, Washington, D.C., 1986, NIH # 85-23.

Guidelines for Research with Recombinant DNA Molecules, 63 FR 26018, NIH, 1998.

"Infectious Waste Management," U.S. Environmental Protection Agency, Washington, D.C., 40 CFR Part 261, 1988.

Michigan State University Biological Safety Program

"Primary Containment of Biohazards: Selection, Installation & Use of Biological Safety Cabinets," Center for Disease Control/ National Institute of Health, 1995.

"Public Health Service Policy on Humane Care and Use of Animals," U.S. Department of Health and Human Services, Public Health Service, Washington, D.C., 1986.

Turnberg, Wayne L., *Biohazardous Waste: Risk Assessment, Policy & Management*, John Wiley & Sons, New York, New York, 1996.

University of Arizona Biological Safety Program

University of Mississippi Biological Safety Program

WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies, Report of a World Health Organization Consultation, Geneva, Switzerland, 23-26 March 1999.