Ferris State University

INSTITUTIONAL BIOSAFETY COMMITTEE



BIOSAFETY MANUAL

AND

BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

Version: March 20, 2021

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I. Purpose and Scope

Ferris State University (FSU) is committed to ensuring the safe handling, storage, and disposal of infectious agents and potentially biohazardous materials used by faculty, staff, and students in research and academic activity at the University. The purpose of this manual is to provide the necessary procedures, guidance and information for the safe use of biohazardous or potentially biohazardous agents at FSU. Biohazardous materials addressed in this manual and of interest to the Institutional Biosafety Committee include the following:

- 1. Infectious agents or potentially biologically hazardous material (Risk Group 1 or unknown).
- 2. Recombinant DNA
- 3. Biological agents listed by National Institutes of Health in Risk Group 2, 3 & 4.
- 4. Human and non-human primate tissue and blood
- 5. Select agents and biological toxins identified by the Centers for Disease Control.

This manual contains procedures for acquiring authorization to use, purchase, and possess biohazardous agents; procedures for procurement of materials; safety precautions to follow when working with biohazards; emergency procedures for handling accidents involving biohazardous agents; and procedures for requesting the disposal of biohazards. All other appropriate regulations and guidelines (radiation, chemical, occupational safety, etc.) must also be followed.

This document serves as a guide for FSU compliance with the following regulations and guidance documents:

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)
- CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition
- OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030)
- Michigan Department of Environment, Great Lakes, and Energy Medical Waste Regulatory Act

A. Definitions

Biological Agent: Biological agents include bacteria, viruses, fungi, other microorganisms and their associated toxins. They have the ability to adversely affect human health in a variety of ways, ranging from relatively mild, allergic reactions to serious medical conditions, even death. These organisms are widespread in the natural environment; they are found in water, soil, plants, and animals. Because many microbes reproduce rapidly and require minimal resources for survival, they are a potential danger in a wide variety of settings.

Biohazard: A biological agent that constitutes a hazard to humans or the environment. Biosafety: Laboratory biosafety includes all containment principles, techniques and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or other accidental release (WHO).

Infectious Agent: Refers to the specific agent capable of producing an infection or disease, especially a virus or bacterium (i.e.: pathogen).

Recombinant DNA: Recombinant DNA molecules are defined as either:

- (i) Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or
 - (ii) Molecules that result from the replication of those described in (i) above (NIH).

II. Roles and Responsibilities

A. FSU Institutional Biosafety Committee

The FSU Institutional Biosafety Committee (IBC) is responsible for ensuring that biohazardous agents are used safely and in accordance with state and federal regulations as well as FSU policies. The IBC establishes policies for the program and evaluates procedures, proposals and records. The IBC is part of the University's Research Protections Program and reports to the University Provost.

i. Membership

The Intuitional Biosafety Committee shall consist of not less than 5 members, including representatives of users of biohazardous agents across FSU's campus. At least two members shall not be affiliated with the institution and who represent the environmental, health, or safety interests of the surrounding community. The members are appointed to alternating 3 year terms by the Institutional Official and shall meet not less than annually under direction of the Institutional Official. In order to conduct official business of the IBC, a majority of the committee must be present, including the Research and Integrity Compliance Officer (RICO).

The IBC Chair shall be appointed by the Institutional Official, with consultation of the membership and RICO. The Chair will hold the position for a 3-year term. The Chair of the IBC approves agendas, presides at all meetings, calls for motions and seconds, and closes the meeting. The Chair may also assign additional duties to other members of the IBC as deemed necessary for the conduct of the work of the IBC.

ii. Responsibilities

The responsibilities of the IBC are to maintain quality safety standards in regards to the use of biohazardous agents across the FSU Campus. This includes the authority to suspend or revoke permission to use biohazardous agents if found to be handled improperly.

The Committee shall do the following:

- Review and approve or disapprove applications for the use biohazardous agents.
- Review training of the authorized users to ensure qualified use.
- Review this Biosafety Manual not less than annually.
- Advise the safety officials on technical matters and approve proposed changes to the implementation of the biosafety program.
- Maintain written minutes of each meeting.
- Recommend improvements or procedures for safe use of biohazardous agents.
- Notifying the Principal Investigator of the results of the Institutional Biosafety Committee's review and approval.
- Set containment levels for biological agents.
- Periodically review recombinant DNA research conducted at the institution to ensure compliance with the *NIH Guidelines*.
- Adopt emergency plans covering accidental spills and personnel contamination resulting from research with infectious agents.

B. Academic Affairs Lab Safety (AALS)

The AALS manages laboratory safety at FSU to ensure safe use of biological materials. Specific duties of the AALS include:

- Oversee all activities involving potentially biohazardous materials
- Conduct training programs to ensure proper use from all authorized users
- Supervise and coordinate the waste disposal program, including recordkeeping
- Conduct periodic inspections.
- Report to the IBC any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents or illnesses.
- Provide advice on laboratory security
- Work with the IBC Chair to file an annual report with NIH/OBA which includes:
 - (i) A roster of all IBC members indicating the Chair, contact person, Biological Safety Officer, plant expert (if applicable), animal expert (if applicable), human gene therapy expertise or *ad hoc* consultant (if applicable).
 - (ii) Biographical sketches of all Institutional Biosafety Committee members (including community members).

C. Principal Investigator/Laboratory Supervisor/Clinic Supervisor

A Principal Investigators/Lab and Clinic Supervisors are people whose training and experience have been reviewed and approved by the IBC and use or directly supervise the use of biohazardous agents. Their primary responsibility is to ensure that biological materials used in his or her particular lab or clinic are used safely and according to regulatory requirements.

These individuals must have adequate and appropriate training to provide reasonable assurance that they will use the material safely, including maintaining security of, and access to, hazardous material, and respond appropriately to events or accidents involving licensed material to prevent the spread of contamination. In addition they must procure and maintain adequate funding for appropriate safety supplies and lab termination.

- Ensure that operations involving biologically hazardous materials are performed only by personnel who have been properly instructed and authorized.
- Ensure that appropriate precautions are taken for workers under their supervision.
- Follow proper procedures for procurement of biological materials.

Upon approval, the authorized user shall have the following responsibilities:

- Provide correct and current posting and labeling of laboratory areas and biohazard containers.
- Ensure an accurate and current inventory records for all biohazard materials under his or her responsibility.
- Follow established procedures for biohazardous waste.
- Report immediately any potentially hazardous spills, exposures, loss of biological materials, or other incidents having possible biological safety implications.
- Provide adequate use-specific safety training for all workers under their supervision.
- Provide adequate security for biohazardous agents.
- Notify the IBC of changes in the use, location or quantities of biohazardous agents.
- Arrange for disposal or transfer of all biohazardous waste promptly upon termination of the authorized use or application.
- Attend meetings, assist with safety audits, and provide documentation as required by the AALS or IBC.
- Maintain each controlled area in a way that is both considerate of other users and eliminates risks to maintenance, janitorial, and security personnel if they are required to enter an unoccupied space.
- Maintain an inventory of all biohazardous agents.

III. Biosafety Approval Procedures

All research and coursework at FSU using biohazardous/potentially biohazardous materials are subject to review and approval by the Institutional Biosafety Committee. Principal Investigators, Department Heads, or any others wishing to use the biological agents covered in this manual must first notify the IBC well in advance of the proposed use.

Individuals wishing to work with biological agents must do the following:

- 1. Read, be familiar with, and follow the procedures outlined in this manual.
- 2. If the agent fits one of the categories in Section I of this manual, submit a "FSU Biosafety Application" to the IBC prior to procurements of the biological agents.
- 3. Submit with the "Application" a current curriculum vitae. The curriculum vitae should include practical experience in physically working with biological materials.

The IBC will approve proposals only if convincing evidence is provided that the user is competent in performing all applicable phases of the proposed experiments. If, after reviewing the proposal and supporting information, members have questions about the safety of the proposed use, they may require a personal interview with the applicant for specific details of the experiment and/or ask that the user first make trial runs of the experiment using nonhazardous materials. A proposal may be approved for a period of 1 to 5 years as determined by the IBC. Subsequent approvals may be granted for a longer period, but never to exceed 5 years. Certain academic coursework may be provided with approvals for an indefinite period. Approvals will be documented as part of the minutes of the meeting, unless certain conditions or modifications were made as part of the approval, in which case written notification will be provided.

Non-compliance with the provisions of this manual, the conditions of the protocol approval, requests from the IBC, or NIH requirements or any other condition that may result in substantial risk to human health, property damage, reputational harm, or legal liability as determined by the IBC may result in termination of the approval to conduct research with biological materials or removal of access to research space.

A. Biological agents or potentially biologically hazardous material

All work involving potentially infectious biological agents is subject to review by the IBC and is covered by this Manual. The application form can be found on the <u>FSU IBC homepage</u>. IBC protocol review and approval are required for all biological agents in Risk Group 2 and/or those that may require Biosafety Level 2 (BSL2). Projects requiring Biosafety Level 3 (BSL3) and Biosafety Level 4 (BSL4) are currently prohibited at FSU.

If the biological materials are identified as <u>not</u> requiring full IBC approval (RG 1/BSL 1) by this manual, use may begin immediately upon approval of the IBC Chair or designee. Applications not requiring full IBC review do not expire, but are subject to revocation in the event of substandard safety practices. Approved users must submit a new registration when there are changes to the use, location or types of biological materials or other circumstances that may increase the hazards. Users also must maintain a current inventory and any additional data necessary to verify the hazards associated with the agent.

Guidelines for determination of biosafety levels can be found in the Centers for Disease Control publication *Biosafety in Microbiological and Biomedical Laboratories*. The *NIH Guidelines* established a classification of human infectious agents into four "risk groups" on the basis of hazard. These descriptions generally correlate with, but do not equate to,

biosafety levels. A risk assessment will determine an agent's biosafety level. Risk Groups (from *NIH Guidelines*) and Biosafety Levels (from *CDC Biosafety*) are defined below:

Risk Group 1	Biosafety Level 1		
Agents not associated with	Biosafety Level 1 is suitable for work involving well-characterized agents not		
disease in healthy adult	known to consistently cause disease in immunocompetent adult humans, and		
humans.	present minimal potential hazard to laboratory personnel and the environment.		
	BSL-1 laboratories are not necessarily separated from the general traffic patterns		
	in the building. Work is typically conducted on open bench tops using standard		
	microbiological practices. Special containment equipment or facility design is not		
	required, but may be used as determined by appropriate risk assessment.		
	Laboratory personnel must have specific training in the procedures conducted in		
	the laboratory and must be supervised by a scientist with training in microbiology		
	or a related science.		
Risk Group 2	Biosafety Level 2		
Agents associated with human	Biosafety Level 2 builds upon BSL-1. BSL-2 is suitable for work involving		
disease that is rarely serious	agents that pose moderate hazards to personnel and the environment. It differs		
and for which preventive or	from BSL-1 in that:		
therapeutic interventions are	laboratory personnel have specific training in handling pathogenic		
often available.	agents and are supervised by scientists competent in handling infectious		
	agents and associated procedures;		
	2. access to the laboratory is restricted when work is being conducted; and		
	3. all procedures in which infectious aerosols or splashes may be created		
Di L C	are conducted in BSCs or other physical containment equipment.		
Risk Group 3	Biosafety Level 3		
Agents associated with serious or lethal human disease for	Facilities not available at FSU		
which preventive or			
therapeutic interventions may be available			
be available			
Risk Group 4	Biosafety Level 4		
Agents likely to cause serious	Facilities not available at FSU		
or lethal human disease for	1 wellings not withhalf wit 1 00		
which preventive or			
therapeutic interventions are			
not usually available			

B. Human and Nonhuman Primate Blood and Tissue

Human blood, tissue, cell culture, and certain other body fluids are considered potentially infectious for bloodborne pathogens such as hepatitis B, hepatitis C, and human immunodeficiency virus. Work with human material is also regulated OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030). In addition, non-human primates and their tissues pose risks of disease that may be transmissible to humans.

The following are requirements for the use of human and non-human primate blood and tissue products:

- 1. Complete the FSU Biosafety Application and receive approval from the IBC.
- 2. All research and academic staff as well as any other employees of FSU with potential to exposure to human blood must be trained in the hazards of bloodborne pathogens and 'Universal Precautions'.
- 3. Comply with all other applicable provisions of OSHA's Bloodborne Pathogen Standard.

C. Recombinant DNA

Biosafety Committee will use NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (NIH Guidelines) to determine what types of research will need only to be registered and those that will require IBC review and approval. Information below is taken from the NIH guidelines. For more information consult the full text at National Institutes of Health Office of Science Policy, Office of Biotechnology Activities.

i. Covered Recombinant DNA

Prior to conducting work as described below, Biosafety Committee review and approval is required

- 1. Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems
- 2. Experiments in Which DNA From Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems
- 3. Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
- 4. Experiments Involving Whole Animals
- 5. Experiments Involving Whole Plants
- 6. Experiments Involving More than 10 Liters of Culture
- 7. Experiments Involving Influenza Viruses
- 8. Experiments Involving the Formation of Recombinant DNA Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus
- 9. Experiments Involving Transgenic Rodents

ii. Exempt Recombinant DNA

The following recombinant DNA molecules are exempt from full approval of the biosafety committee, but require registration.

- 1. Those that are not in organisms or viruses.
- 2. Those that consist entirely of DNA segments from a single non-chromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.
- 3. Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.
- 4. Those that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
- 5. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will is available from National Institutes of Health.
- 6. Those that do not present a significant risk to health

D. Select Agents

A US Government multi-agency program has established the "National Select Agent Registry". The Registry includes biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) and the Centers for Disease Control and Prevention (CDC) have established regulations for using Select Agents.

All research involving the use of a Select Agent must be approved by the biosafety committee prior to initiating the research. In most cases, FSU does not have the facilities to accommodate Select Agent use.

IV. Training

Before beginning work with biohazardous agents, Authorized Users must receive biosafety training commensurate with their assigned duties (in addition to Lab Safety Training). Students enrolled in classes involving biohazards may do so only if biological safety instruction is provided as part of the coursework, clearly identified in the syllabus and is given by an Authorized User, the AALS, or an individual approved by the IBC.

A. Biosafety Training

All researchers using RG 2 agents and/or recombinant DNA must complete general biosafety training. Training will be conducted either through classroom sessions or online modules. The purpose of this training is to familiarize the Principal Investigator and lab personnel with good microbiological practices which include recognizing risk groups for biological materials, appropriate containment levels, and personal protective clothing and equipment. The IBC will be responsible for oversight of the biosafety training courses.

B. Bloodborne Pathogen Training

All employees/researchers who have occupational exposure to bloodborne pathogens must receive initial and annual training. Training includes epidemiology, symptoms, and transmission of bloodborne pathogen diseases. In addition, the training program covers, at a minimum, the following elements:

- an explanation of the OSHA bloodborne pathogen standard
- an explanation of the Exposure Control Plan
- an explanation of methods to recognize tasks and other activities that may involve exposure to blood and other potentially infectious material (OPIM), including what constitutes an exposure incident
- an explanation of the use and limitations of engineering controls, work practices, and PPE
- an explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE
- an explanation of the basis for PPE selection
- information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated.
- information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM
- an explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available
- information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident
- an explanation of the signs and labels required by the standard

V. Personal Protection

A. Personal Protective Equipment

Users of biohazardous agents must ensure fume hoods, biological safety cabinets, and other protective equipment are adjusted and functioning properly prior to initiating an activity requiring their use. Each authorized user shall develop written procedures for the use of personal protective equipment and shielding in their area. These should be included in the research protocols reviewed by the IBC. The minimum personal protective equipment for handling infectious agents includes lab coat, closed-toed footwear, safety glasses and disposable gloves. Protective equipment must not be worn outside the laboratory unless it has been monitored and found to be free of contamination. Gloves, while providing protection to the user, can spread contamination if worn outside the laboratory. Other personal protection recommendations are as follows:

- 1. Understand whether general lab ventilation, BSC's or fume hoods are necessary.
- 2. Protective laboratory coats, gowns, or uniforms are recommended to prevent contamination of personal clothing.
- 3. Wear protective eyewear when conducting procedures that have the potential to create splashes of microorganisms or other hazardous materials. Persons who wear contact lenses in laboratories should also wear eye protection.
- 4. Gloves must be worn to protect hands from exposure to hazardous materials. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed

B. Medical Restrictions

It is recognized that exposure to certain infectious agents may adversely affect a fetus during pregnancy if the mother is infected with the agent. Women that are pregnant or become pregnant are encouraged to inform their supervisors or Principal Investigators. It is also advised to notify your supervisor if your immune system is easily compromised (HIV, immunosuppressant drugs etc.).

VI. Working Safely with Biohazardous Agents

A. Standard Safety Procedures

In addition to procedures outlined in other sections of this manual, the following safety procedures must be followed when working with biohazardous agents:

- 1. Avoid hand to mouth or hand to eye contact in the laboratory. Never eat, drink, apply cosmetics or lip balm, handle contact lenses or take medication in the laboratory.
- 2. Wash hands after removing gloves and other personnel protective equipment, after handling potentially infectious agents or materials and prior to exiting the laboratory
- 3. Needles and syringes or other sharp instruments should be restricted in laboratories where infectious agents are handled. Never recap a used needle. Dispose of syringe-needle assemblies in properly labeled, puncture resistant, autoclavable sharps containers.
- 4. Airborne transmissible infectious agents should be handled in a certified Biosafety Cabinet (BSC) appropriate to the biosafety level (BSL) and risks for that specific agent.
- 5. Store and transport containers of biohazardous liquids in secondary containers that will hold the contents of the primary container in the event of breakage.
- 6. Never leave materials or contaminated labware open to the environment outside the BSC. Store all biohazardous materials securely in clearly labeled, sealed containers. Storage units, incubators, freezers or refrigerators should be labeled with the Universal Biohazard Sign when they house infectious material.
- 7. Clearly label all containers of hazardous material with an indication of the material, the quantity, the date of the assay and a standard biohazard warning label.
- 8. Only authorized persons may remove biohazards from storage and only designated cabinets, freezers, and refrigerators may be used for storing these materials.
- 9. The laboratory should be kept clean and organized so that contaminated items are clearly identified and confined to a local area. A sign clearly identifying the area(s) where biohazardous materials are stored and used must be posted.
- 10. Never allow contaminated, infectious waste materials to leave the laboratory or to be put in the trash or sanitary sewer without being decontaminated or sterilized. When autoclaving use adequate temperature (121°C), pressure (15psi), and time, based on the size of the load. Also use a sterile indicator strip to verify sterilization.
- 11. Any work performed with volatile material or operations that have a potential for personnel exposure or contamination must be performed in an appropriate hood or glove box. New procedures involving these types of materials must be approved by the Biosafety Committee prior to initiation.
- 12. All work surfaces must be covered with absorbent paper that is changed on a regular basis. Procedures with large volumes of material and/or material with high spill possibility must be done in an appropriate spill tray.
- 13. After each experiment, clean up the work area with an approved disinfectant and place disposable materials (Pasteur pipettes, kimwipes, etc.) in a plastic bag for disposal before removing gloves.
- 14. Principal Investigators/Lab Supervisors must maintain an inventory of infectious agents.

B. Warning Signs and Labels

A warning label that includes the universal biohazard symbol, followed by the term "biohazard," must be included on bags/containers of biohazardous waste, on bags/containers of contaminated laundry, on refrigerators and freezers that are used to store blood or biological hazards, and on bags/containers used to store, dispose of, transport, or ship blood or biological hazards (e.g., specimen containers).

The universal biohazard sign must be posted on all lab entrances, laboratory freezers or storage containers with human blood, RG2 or higher and covered recombinant DNA. Access doors should be labelled while experiments are in progress and on all doors leading to biohazard storage areas.

C. Biosafety Cabinets

The Biological Safety Cabinets (BSC's) are used to provide containment of infectious splashes or aerosols generated by many microbiological procedures. BSC's use High Efficiency Particulate Air (HEPA) filters to protect personnel and products inside the BSC from contamination from aerosols and particulates. They also protect the laboratory by isolating and containing the work in progress within the BSC.

All BSC's at FSU are Class II, defined as: A ventilated cabinet for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered exhausted air for environmental protection.

Properly maintained Biological Safety Cabinets are used whenever:

- 1. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious materials that may be under pressure, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.
- 2. High concentrations or large volumes of infectious agents

Guidance for safe use of biological safety cabinets:

- Never use chemicals with the potential to generate hazardous vapors. The HEPA filters are intended only to remove particulates and biological agents.
- Never work in or near the hood with the ultraviolet light turned on. UV light can damage eyes and exposed skin very quickly. Only use the light for the minimum period of time necessary for disinfection, never more than 15 minutes. Note: NIH, CDC, and ABSA all discourage the use of UV for disinfection (See position paper).
- Work surfaces should be decontaminated with an appropriate disinfectant on a routine basis, after work with infectious materials is finished, and especially after spills, splashes, or other contamination by infectious materials.
- If the unit is not left running continuously, turn the blower on and air purge for at least five minutes to remove airborne contamination before the next use.
- Each laboratory should develop procedures which identify the hazards that will or may be encountered, and which specifies practices and procedures designed to minimize or eliminate risks.
- Laboratory personnel must receive appropriate training on the potential hazards associated with the work involved, including the necessary precautions to prevent exposures, and the exposure evaluation procedures.
- BSC's must be certified annually or after repairs. Hoods and BSC's will be posted with the most recent date of certification. Notify Facilities Services or Lab Safety for operation or maintenance concerns.

D. Decontamination

Physical and chemical means of decontamination fall into three main categories: heat, liquid decontaminants, and vapors and gases.

i. Heat

The application of heat, either moist or dry, is recommended as the most effective method of sterilization. Steam at 121°C under pressure in the autoclave is the most convenient method of rapidly achieving sterility under ordinary circumstances.

- Autoclaves present significant safety hazards and must be operated properly to ensure proper sterilization. Each autoclave unit must have standard operating practices posted nearby with procedures for safe use and instructions for proper disinfection.
- Laboratory personnel should be cautioned that steam under pressure could be a source of scalding jets if the equipment is misused. Loads of manageable size should be used.
- Fluids treated by steam under pressure may be superheated if removed from the sterilizer too soon after treatment. This may cause a sudden and violent boiling of contents from the containers that can splash scalding liquids onto personnel handling the containers.

ii. Liquid Decontaminants

In general, the liquid decontaminants are used in surface decontamination and decontamination of liquid wastes for final disposal in sanitary sewer systems.

- Proper consideration should be given to such factors as temperature, contact time, pH, the presence and state of dispersion, penetrability and reactivity of organic material at the site of application. Small variations in the above factors may make large differences in the effectiveness of decontamination. For this reason even when used under highly favorable conditions, complete reliance should not be placed on liquid decontaminants when the end result must be sterility.
- There are many liquid decontaminants available under a wide variety of trade names. In general, these can be categorized as halogens, acids and alkalines, heavy metal salts, quaternary ammonium compounds, phenols, aldehydes, ketones, alcohols, and amines. Unfortunately, the more active the decontaminant the more likely it will posses undesirable characteristics such as corrosivity. None is equally useful or effective under all conditions for all infectious agents.
- Particular care should be observed when handling concentrated stock solutions of disinfectants. Personnel assigned to the task of making up use-concentrations from stock solutions must be informed of the potential hazards and trained in the safe procedures to follow and appropriate personal protective equipment to use as well as the toxicity associated with eye, skin and respiratory exposure.

iii. Vapors and Gases

A variety of vapors and gases possess decontamination properties. The most useful of these are formaldehyde and ethylene oxide. When these can be employed in a closed system and under controlled conditions of temperature and humidity, excellent decontamination can result. Vapor and gas decontaminants are primarily useful in decontaminating biological safety cabinets and associated air-handling systems and air filters; bulky or stationary equipment that resists penetration by liquid surface decontaminants; instruments and optics that may be damaged by other decontamination methods; and rooms, buildings and associated air-handling systems.

VII. General Waste Procedures

Procedures for hazardous waste disposal must be included in the research protocols for review and approval by the IBC. Specific rules, regulations, and guidelines must be followed for the disposal of hazardous waste. General procedures are provided below:

- 1. Minimize quantities of waste and segregate non-hazardous from hazardous waste.
- 2. Waste must be stored in secure restricted access areas and containers must be clearly labeled with the appropriate warning sign (universal biohazard symbol).
- 3. All hazardous waste disposals must be entered on the inventory form.
- 4. All off-site disposal of hazardous material will be coordinated through the Biosafety Officer.
- 5. Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding

Michigan's Medical Waste Regulatory Act defines the following regulated wastes:

- 1. Cultures and stocks of infectious agents and associated biologicals (defined as: if a susceptible host is exposed to the pathogen in an adequate concentration and through a portal of entry, the result could be transmission of disease to a human), including laboratory waste, biological production wastes, discarded live and attenuated vaccines, culture dishes, and related devices.
- 2. Liquid human and animal waste, including blood and blood products and body fluids, but not including urine or materials stained with blood or body fluids.
- 3. Pathological waste
- 4. Sharps needles, syringes, scalpels, and intravenous tubing with needles attached.
- 5. Contaminated wastes from animals that have been exposed to agents infectious to humans, these being primarily research animals.

Storage, decontamination, and disposal requirements:

- 1. Cultures and stocks of material contaminated with an infectious agent shall be stored in closed, puncture-resistant containers, decontaminated by autoclaving or incineration, and disposed of in a sanitary landfill.
 - a. Solid biohazardous waste, excluding sharps that have been decontaminated by autoclaving, may be disposed of in regular trash if they are securely packaged in leak-proof containers and the biohazard warning labels have been removed or the container is clearly labeled as decontaminated biohazardous waste.
 Decontaminated waste in biohazard bags with an "Autoclaved" bag indicator must be placed inside a non-transparent box or bag prior to disposal.
 - b. Liquid biohazardous waste that has been autoclaved can be disposed in sanitary sewer, unless other hazardous chemical or radiological constituents are present.
- 2. Blood, blood products and other potentially infectious materials as defined in the exposure control plan shall be disposed of by one of the following methods:
 - a. Flushing down a sanitary sewer.
 - b. Placing in a biohazard bag for disposal by a licensed medical waste contractor.
 - c. Decontaminating by autoclaving or incineration.
 - d. Items contaminated with dried blood not capable of removal by dripping or flaking are not considered medical waste and can be disposed as regular trash and transferred to a sanitary landfill.
- 3. Pathological waste shall be disposed of by 1 or more of the following methods:
 - a. Incineration or cremation.
 - b. Grinding and flushing into a sanitary sewer.

- c. Burial in a cemetery
- d. Grinding until rendered unrecognizable, stored in closed, puncture-resistant, properly labeled containers, and, if not in liquid form, disposed of in a sanitary landfill.
- 4. Sharps (as defined by the Michigan Medical Waste Act) shall be disposed of by the following methods:
 - a. Placement in rigid, puncture-resistant containers that are appropriately labeled and transported to a sanitary landfill in a manner that retains the integrity of the container. Sharps must never be placed into autoclave bags or waste bins used for normal trash.
 - i. Handling: Sharps containers must be available wherever sharps are used. Dispose of used needles immediately without capping after use, and keep syringes and needles intact and place together in a sharps bin. Do not overfill sharps bins above three quarters full. Before moving a sharps bin to the collection point the bin is securely closed.
 - ii. Packaging: Sharps shall be contained for disposal in individual leakproof, rigid, puncture-resistant containers that are secured to preclude loss of the contents and must be labeled with the word "sharps". Sharps contaminated with infectious agents must also be labelled with the biohazard symbol. Filled containers should be transported to the nearest hazardous waste storage area. Sharps that are contained this way may be disposed of as regulated medical waste by a certified hauler. Sharps shall not be compacted or handled during transport in a manner that will result in breakage of a sharps container.
 - b. Laboratory waste not defined as medical waste but has been in contact with infectious agents, including any object with corners, edges, or projections that when inappropriately handled or disposed are capable of cutting or piercing skin, regular trash bags or waste containers, shall be packaged and managed as medical waste sharps.
 - c. Non-contaminated broken glass or other glass or plasticware capable of piercing regular trash bags should be placed in large cardboard or other puncture-resistant containers for transport to and disposal in the trash dumpsters.
- 5. Animal waste contaminated with or organisms infectious to humans shall be disposed of by incineration or by burial in a sanitary landfill in properly labeled, double containers that are leak-proof and puncture-resistant and are tightly sealed to prevent escape of fluids or material. Contaminated animal organs disposed of separately shall be rendered unrecognizable.

VIII. Emergency Procedures

Standard emergency response procedures are as follows:

- In a medical emergency call 911. Provide assistance to individuals and remove them from exposure to further injury if necessary. Responders should render first aid to the extent they are capable.
- Warn others in the area if there is a potential safety hazard
- In case of a fire, pull the fire alarm, evacuate the area, and dial 911. For small fires only try to extinguish if it can be done safely.
- In case of serious accident and/or injury involving biohazards call the Biosafety Officer, and dial 911. Tell the dispatcher your name, the building and location, and the seriousness of injury, if any.
- Stay on the line until all necessary information is furnished to the dispatcher. The dispatcher will notify the appropriate emergency response agencies. If the AALS cannot be reached, SHERM or a member of the IBC must be notified. Other emergency personnel may also be notified. If no serious injury is involved, call the AALS or SHERM.
- For an exposure or injury, wash the affected area with soap and water and treat with first aid or stay with victim until further help arrives.
- In case of a small spill, notify others in the area of the spill, apply gloves, clean spill, disinfect and dispose of waste properly.
- In case of a large spill, notify others in the area and notify the supervisor or Principal Investigator for help. Check shoes and clothing for contamination and place all towels or other disposable materials in the proper waste containers.
- Each lab shall have equipment necessary to clean up a spill.

IX. APPENDIX

Ferris State University Exposure Control Plan

POLICY STATEMENT

Ferris State University (FSU)_is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this goal, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 *CFR* 1910.1030, "Occupational Exposure to Bloodborne Pathogens."

CONTENTS

The ECP is a key document to assist our organization in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes:

- Definitions
- Program Administration
- Determination of employee exposure.
- Implementation of various methods of exposure control, including: Universal precautions Engineering and work practice controls Personal protective equipment Housekeeping.
- Hepatitis B vaccination.
- Post-exposure evaluation and follow-up.
- · Communication of hazards to employees and training.
- · Recordkeeping.
- Procedures for evaluating circumstances surrounding exposure incidents

Implementation methods for these elements of the standard are discussed in the subsequent pages of this ECP.

DEFINITIONS

Blood means human blood, human blood components, and products made from human blood.

<u>Bloodborne Pathogens</u> means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

<u>Contaminated</u> means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface. *Contaminated Sharps* means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

<u>Decontamination</u> means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

<u>Exposure Incident</u> means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

Other Potentially Infectious Materials means

- 1. The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;
- 2. Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
- 3. HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

<u>Personal Protective Equipment</u> is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

<u>Regulated Waste</u> means 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 materials.

<u>Sterilize</u> means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

<u>Universal Precautions</u> is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

<u>Work Practice Controls</u> means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

PROGRAM ADMINISTRATION

The Institutional Biosafety Committee (IBC) is responsible for implementation of the ECP. The IBC will maintain, review, and update the ECP annually, and whenever necessary to include new or modified tasks and procedures. Contact information located at www.ferris.edu/ibc

Employees who are determined to have occupational exposure to blood or other potentially infectious materials (OPIM) must comply with the procedures and work practices outlined in this ECP.

Principal Investigators and/or Laboratory/Clinic Supervisors will provide and maintain all necessary personal protective equipment (PPE), engineering controls (e.g., sharps containers), labels, and red bags as required by the standard and will ensure that PPE are available in appropriate sizes.

The AALS will be responsible for ensuring that all medical actions required by the standard are performed and that appropriate employee health and OSHA records are maintained.

The AALS will be responsible for training, documentation of training, and making the written ECP available to employees, OSHA, and NIOSH representatives.

EMPLOYEE EXPOSURE DETERMINATION

Each department will develop a list of all job classifications with a reasonably anticipated risk of occupational exposure to blood or other potentially infectious materials. In addition, for job classifications in which some employees may have occupational exposure, a list of tasks and procedures in which occupational exposure may occur for these individuals must be developed.

For exposure in research and academic activity, the Institutional Biosafety Committee will approve the activity and identify job classifications required to be trained.

METHODS OF IMPLEMENTATION AND CONTROL

- 1. Universal Precautions: All employees will utilize universal precautions.
- 2. **Exposure Control Plan:** Employees covered by the bloodborne pathogens standard receive an explanation of this ECP during their initial training session. It will also be reviewed in their annual refresher training.

The Institutional Biosafety Committee is responsible for reviewing/updating the ECP at least annually if necessary to reflect any new or modified tasks and procedures that affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

- 3. Engineering Controls and Work Practices: Engineering controls and work practice controls will be used to prevent or minimize exposure to bloodborne pathogens. The specific engineering controls and work practice controls are identified in the Biosafety Manual, and are listed below:
 - Sharps disposal containers are inspected and maintained or replaced by either the Laboratory/Clinic Supervisor or Principal Investigator every 90 days or whenever necessary to prevent overfilling.
 - b. FSU facility identifies the need for changes in engineering controls and work practices through IBC meetings.
 - c. We evaluate new procedures and new products regularly by engagement with vendors and membership in professional organizations (i.e.: ABSA).
 - d. Both front-line workers and management officials are involved in this process by representation on the IBC.
 - e. The IBC is responsible for ensuring that these recommendations are implemented.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

PPE is provided to our employees at no cost to them. Training in the use of the appropriate PPE for specific tasks or procedures is provided by the employee's supervisor classroom instructor The types of PPE available to employees are as follows: Gloves, eye protection, lab coats.

PPE is located in different locations in each lab and may be obtained through the Principal Investigator, Lab/Clinic Supervisor or the AALS.

All employees using PPE must observe the following precautions:

- Wash hands immediately or as soon as feasible after removing gloves or other PPE.

- Remove PPE after it becomes contaminated and before leaving the work area.
- Used PPE may be disposed of in autoclavable bags.
- Wear appropriate gloves when it is reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated items or surfaces; replace gloves if torn, punctured or contaminated, or if their ability to function as a barrier is compromised.
- Utility gloves may be decontaminated for reuse if their integrity is not compromised; discard utility gloves if they show signs of cracking, peeling, tearing, puncturing, or deterioration.
- Never wash or decontaminate disposable gloves for reuse.
- Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth.
- Remove immediately or as soon as feasible any garment contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface.

The procedure for handling used PPE is provided in the waste section of the Biosafety Manual.

HOUSEKEEPING

Regulated Waste: The Biosafety Manual contains a Waste Management Plan for waste contaminated with infectious agents. Regulated waste must be placed in containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled or color-coded (see the following section "Labels"), and closed prior to removal to prevent spillage or protrusion of contents during handling.

<u>Contaminated Sharps</u> are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled or color-coded. Sharps disposal containers must be easily accessible and as close as possible to the source of generation. Broken glassware that may be contaminated is only picked up using mechanical means, such as a brush and dustpan

<u>Bins and pails</u> (e.g., wash or emesis basins) are cleaned and decontaminated as soon as feasible after visible contamination.

<u>Laundry</u>: Labs or clinics may choose to decide to use a laundry service. If so, the following laundering requirements must be met:

- handle contaminated laundry as little as possible, with minimal agitation.
- place wet contaminated laundry in leak-proof, labeled or color-coded containers before transport. Use properly labelled bags from the laundry for this purpose.
- wear the following PPE when handling and/or sorting contaminated

LABELS

Labeling requirements are provided in the Biosafety Manual. Lab/Clinic Supervisors and/or Principal Investigators are responsible for ensuring that warning labels are affixed or red bags are used as required if regulated waste or contaminated equipment is brought into the facility. Employees are to notify the AALS if they discover regulated waste containers, refrigerators containing blood or OPIM, contaminated equipment, etc., without proper labels.

HEPATITIS B VACCINATION

Clinic Supervisors will provide training to employees on hepatitis B vaccinations, addressing safety, benefits, efficacy, methods of administration, and availability.

The hepatitis B vaccination series is available at no cost after initial employee training and within 10 days of initial assignment to all employees identified in the exposure determination section of this plan.

Vaccination is encouraged unless:

- 1) documentation exists that the employee has previously received the series;
- 2) antibody testing reveals that the employee is immune; or
- 3) medical evaluation shows that vaccination is contraindicated.

However, if an employee declines the vaccination, the employee must sign a declination form. Employees who decline may request and obtain the vaccination at a later date at no cost. Documentation of refusal of the vaccination is kept with the Human Resources Department.

If a medical evaluation determines the vaccine is contraindicated, a copy of the health care professional's written opinion will be obtained and provided to the employee within 15 days of the completion of the evaluation.

POST-EXPOSURE EVALUATION AND FOLLOW-UP

Procedures

Should an exposure incident occur, contact the AALS. An immediately available confidential medical evaluation and follow-up will be conducted by Spectrum Health. Following initial first aid (clean the wound, flush eyes or other mucous membrane, etc.), the following activities will be performed:

- Document the routes of exposure and how the exposure occurred.
- Identify and document the source individual (unless the employer can establish that identification is infeasible or prohibited by state or local law).
- Obtain consent and make arrangements to have the source individual tested as soon as possible to determine HIV, HCV, and HBV infectivity; document that the source individual's test results were conveyed to the employee's health care provider.
- If the source individual is already known to be HIV, HCV and/or HBV positive, new testing need not be performed.
- Assure that the exposed employee is provided with the source individual's test results and with information about applicable disclosure laws and regulations concerning the identity and infectious status of the source individual (e.g., laws protecting confidentiality).
- After obtaining consent, collect exposed employee's blood as soon as feasible after exposure incident, and test blood for HBV and HIV serological status
- If the employee does not give consent for HIV serological testing during collection of blood for baseline testing, preserve the baseline blood sample for at least 90 days; if the exposed employee elects to have the baseline sample tested during this waiting period, perform testing as soon as feasible.

Administration

FSU Human Resources ensures that health care professional(s) responsible for employee's hepatitis B vaccination and post-exposure evaluation and follow-up are familiar with OSHA's

bloodborne pathogens standard. They will also ensure that the health care professional evaluating an employee after an exposure incident receives the following:

- a description of the employee's job duties relevant to the exposure incident
- route(s) of exposure
- circumstances of exposure
- if possible, results of the source individual's blood test
- relevant employee medical records, including vaccination status (Name of responsible person or department) provides the employee with a copy of the evaluating health care professional's written opinion within 15 days after completion of the evaluation.

Investigation

In accordance with current policy, the AALS will review the circumstances of all exposure incidents to determine:

- engineering controls in use at the time
- work practices followed
- a description of the device being used (including type and brand)
- protective equipment or clothing that was used at the time of the exposure incident (gloves, eye shields, etc.)
- location of the incident (O.R., E.R., patient room, etc.)
- procedure being performed when the incident occurred
- employee's training

If revisions to this ECP are necessary the IBC will ensure that appropriate changes are made. (Changes may include an evaluation of safer devices, adding employees to the exposure determination list, etc.)

EMPLOYEE TRAINING

All employees who have occupational exposure to bloodborne pathogens receive initial and annual training conducted by the AALS or their clinical or laboratory supervisor.

All employees who have occupational exposure to bloodborne pathogens receive training on the epidemiology, symptoms, and transmission of bloodborne pathogen diseases. In addition, the training program covers, at a minimum, the following elements:

- a copy and explanation of the OSHA bloodborne pathogen standard
- an explanation of our ECP and how to obtain a copy
- an explanation of methods to recognize tasks and other activities that may involve exposure to blood and OPIM, including what constitutes an exposure incident
- an explanation of the use and limitations of engineering controls, work practices, and PPE
- an explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE
- an explanation of the basis for PPE selection
- information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine will be

- offered free of charge
- information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM
- an explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available
- information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident
- an explanation of the signs and labels and/or color coding required by the standard and used at this facility
- an opportunity for interactive questions and answers with the person conducting the training session. Training materials for this facility are available on Blackboard.

RECORDKEEPING

Training Records

Training records are completed for each employee upon completion of training. These documents will be kept for at least three years.

The training records include:

- the dates of the training sessions
- the contents or a summary of the training sessions
- the names and qualifications of persons conducting the training
- the names and job titles of all persons attending the training sessions

Employee training records are provided upon request to the employee or the employee's authorized representative within 15 working days. Such requests should be addressed to (Name of responsible person or department).

Medical Records

Medical records are maintained for each employee with occupational exposure in accordance with 29 *CFR* 1910.1020, "Access to Employee Exposure and Medical Records."

Human Resources Department is responsible for maintenance of the required medical records. These confidential records are kept for at least the duration of employment plus 30 years.

Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days. Such requests should be sent to HR.

OSHA Recordkeeping

An exposure incident is evaluated to determine if the case meets OSHA's Recordkeeping Requirements (29 CFR 1904). This determination and the recording activities are done by the Biosafety Officer.

Sharps Injury Log

In addition to the 1904 Recordkeeping Requirements, all percutaneous injuries from contaminated sharps are also recorded in a Sharps Injury Log. All incidences must include at least: date of the injury, type and brand of the device involved (syringe, suture needle), department or work area where the incident occurred and an explanation of how the incident occurred. This log is reviewed as part of the annual program evaluation and maintained for at least five years following the end of the calendar year covered. If a copy is requested by anyone, it must have any personal identifiers removed from the report.

HEPATITIS B VACCINE DECLINATION (MANDATORY)

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

hepatitis B vaccine, I can receive the vaccination series at no	charge to me.
Signed:	
(Employee Name)	Date:

FSU Biosafety Application

Visit www.ferris.edu/ibc for the most recent biosafety application form.