



## Institutional Biosafety Committee and Biological Safety Manual

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## II. Summary Statement

The Montclair State University Biosafety Manual is intended to be a resource for information, guidelines, policies, and procedures that will enable and encourage those working in the laboratory environment to work safely and reduce or eliminate the potential for exposure to biological hazards. The information presented here also reflects the requirements and guidelines of federal and state regulations. It is intended that the Principal Investigator and supervisory personnel will supplement this information with instruction and guidance regarding specific practices and procedures unique to the work being done by those in their laboratories.

### A. Scope

This Manual is applicable to all laboratory, research, service and support activities that may involve exposure to biohazardous agents or materials and that come under the purview of the Biological Safety Committee. Other chemicals and safety precautions may be required but not covered by this manual.

Activities which are those specifically addressed are those involving:

- Work with recombinant DNA
- Various bacterial, fungal, and parasitic agents and toxins
- Live viruses
- Experimentally infected research animals
- Biohazards associated with animal handling
- Human blood and tissues
- Working with biological materials

### B. Regulatory Forces and Guidelines

Guidelines developed by the National Institute of Health,(NIH) and the Centers for Disease Control and Prevention, (CDC) form the basis for the biosafety practices included in this manual. These guidelines must be followed to ensure the continuation of grant funds from federal agencies.

**The NIH Guidelines** for Research Involving Recombinant DNA Molecules:

- Mandate the establishment of an Institutional Biosafety Committee for the review and oversight of biological research
- Outline roles and responsibilities for biosafety
- Establish the practices, procedures, and conditions under which recombinant DNA work must be conducted.

The guidelines from the **Centers for Disease Control and Prevention, Biosafety in Microbiological and Biomedical Laboratories, (BMBL)** address the appropriate measures and facilities for work with all microbial agents, including bacterial, viral, fungal, parasitic, and rickettsial agents.

The **Occupational Safety and Health Administration** (OSHA) sets requirements for work with human blood, body fluids and tissues. (Occupational Exposure to Bloodborne Pathogens standards)

**Federal code and regulations** regulate obtaining, possession, use, or transfer of any “ select biological agent or toxin.” Federal permits and inspection, as well as significant measures of lab security, personnel training, and accurate record keeping are strict requirements for the possession of these materials.

**NJ Department of Environmental Protection** regulates the Handling and disposal of biohazardous waste under the Regulated Medical Waste rules found in the NJ Administrative Code 7:26-3A.

### C. The Biological Safety Program at Montclair State University

The biological safety program at Montclair State University developed from the University’s commitment to address and comply with the NIH Guidelines regarding safe research with rDNA and associated viral materials. Oversight of Montclair State University’s biological safety program is provided by Institutional Biological Safety Committee. The key components of the program are:

- MSU Institutional Biosafety Committee
- The CSAM Safety Committee
- Research Compliance Officer
- Department Chairperson
- Principal Investigator
- Researcher
- Environmental Health and Safety Officer/ Biosafety Officer
- Occupational Health Department
- University Health Center
- Other committees

The roles and responsibilities of each are described as follows:

1. The Institutional Biosafety Committee:
  - Oversees the biological safety program
  - Oversees compliance with the University’s policies for research with potentially biohazardous materials based on the provisions of the *NIH Guidelines and the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5<sup>th</sup> Edition*.
  - Adopts policies supporting the safe use of biological materials and the elimination or reduction of exposure to potentially biohazardous materials or agents
  - Regularly reviews existing IBC policies and procedures
  - Addresses biosafety issues
  - Reports to the Biosafety Officer and Environmental Health and Safety Officer any significant violations of the *NIH Guidelines*, problems with containment, and any significant research-related accidents or illnesses.<sup>1</sup>

## 2. Biosafety Officer

- Provides oversight of the program in collaboration with other stakeholders
- Performs initial reviews of Biosafety protocol registrations
- Presents submitted protocol registrations to Committee (IBC)
  
- Consults with researchers on issues of biosafety and the safe use of biological materials in the laboratory
- Develops protocols and procedures to address issues of biosafety
  
- Responds to and investigates significant violations of the *NIH Guidelines*, problems with containment, and any significant research-related accidents or illnesses.<sup>1</sup>
- Reports to the Environmental Health and Safety Officer any significant violations of the *NIH Guidelines*, problems with containment, and any significant research-related accidents or illnesses.<sup>1</sup>

## 3. Research Compliance Officer

- Accepts research proposals involving the use of animals and coordinates their review by the Institutional Animal Care and Use Committee (IACUC)

## 4. Department Chairperson(s)

- Supports compliance with the University's policies for research with potentially biohazardous materials

## 5. Principal Investigator

- Submit research involving biohazardous material for review and registration with the IBC
  
- Ensures proper lab orientation, training, and instruction for laboratory personnel in safe practices and protocols. This includes instruction in good microbiological techniques and practices needed to work safely with the biological agents and materials.
- Ensures that hazardous materials are not ordered prior to obtaining applicable IBC registration approvals.
- Ensures that laboratory personnel receive any necessary medical surveillance if applicable.
- Ensures compliance by laboratory personnel with the relevant regulations, guidelines, and policies
- Ensures biosafety cabinets are certified as needed and personal protective equipment is provided and used
- Reports problems with containment and any significant research - related accidents or illnesses

Each Principal Investigator (PI) is responsible for all research involving biological materials or agents including the assignment of the required Biosafety Level to the proposed research. This includes research involving:

- Recombinant DNA, including experiments that are specifically exempt under the *NIH Guidelines*
- Bacterial, fungal, parasitic, or other potentially infectious agents
- Live viruses
- Human blood and tissue

6. Researcher:

- Participates in appropriate training and instruction
- Becomes familiar with all biological agents being used in the lab and the potential risks associated with exposure
- Follows all laboratory practices and protocols and complies with all applicable guidelines and policies
- Completes any necessary medical surveillance
- Reports all accidents, spills, or contamination incidents to supervisor

7. Environmental Health and Safety (EHS) :

- Consults with researchers on issues of biosafety and the safe use of biological materials in the laboratory
- Develops protocols and procedures to address issues of biosafety
- Provides training in safe use and practices for those involved in work with potentially biohazardous materials and activities
- Advises researchers on proper waste disposal methods based on federal and state regulations and established University practice
- Provides oversight of the program and manages training programs for those with potential exposure
- Conducts periodic inspection of labs using biological materials

8. Occupational Health Department

- Available for medical surveillance and/or immunization for those employees exposed or potentially exposed to biological agents
- Provides medical review and medical surveillance, as appropriate, for live virus workers, and those personnel exposed to laboratory animals,

9. Other Committees and Safety Personnel (Animal Care and Use, Radiation Safety):

- Consult and coordinate with the Biosafety safety committee on the use of potentially biohazardous materials or activities

### III. IBC Covered Activities

Recombinant DNA, Agents, Toxins, and Other Microbiological and/or Potentially Biohazardous Materials

## A. Recombinant DNA

All research with recombinant DNA and other biological materials at Montclair State University is to be conducted in accordance with the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* and the CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5<sup>th</sup> edition*

All of the research involving recombinant DNA and other microbiological and/or potentially biohazardous material currently in progress at MSU falls within one or more of the following categories. For each category, the correct biosafety level (usually Biosafety Level 1 or 2, also designated BSL 1 or BSL 2) must be identified..

### B. A. Recombinant DNA (rDNA) IBC Status

#### 1. Exempt

This includes research in which DNA from an organism is cloned and propagated in *E. coli* or *Saccharomyces cerevisiae*, as long as the *E. coli* strain does not contain a conjugation proficient plasmid or a generalized transducing phage and as long as fermentations do not exceed 10-liter volumes at any one time. Also included in this category are experiments in which recombinant DNA molecules derived entirely from non-viral sources are propagated in cells in tissue culture.

Research work in the exempt category is normally carried out under BSL1 conditions.

#### 2. Non-Exempt Recombinant DNA Projects

Experiments in this category must be conducted at the appropriate biosafety level. Included in this category are transgenic experiments in which foreign DNA is introduced into organisms other than *E.coli* or *Saccharomyces cerevisiae*.

BSL1 biosafety procedures are appropriate for experiments with whole animals if the recombinant DNA vectors used either do not contain viral sequences or contain less than two-thirds of a eukaryotic viral genome.

BSL 2 biosafety procedures are required for work involving viral recombinant DNA vectors or viral vector systems, such as lentivirus systems. Included in this category are experiments using animal viruses as vectors, experiments in which parts of animal or plant viruses are cloned into any prokaryotic or lower eukaryotic host other than *E. coli* or *Saccharomyces cerevisiae*, experiments involving the use of infectious animal or plant viruses or defective animal or plant viruses in the presence of helper virus in tissue culture systems, and experiments using whole animals. Any of these experiments using any of the animal and plant viruses at MSU must be conducted under BSL 2 conditions.

### C. Other Microbiological and/or Potentially Biohazardous Material

#### 1. Viruses, Bacterial or Fungal Pathogens, Biological Toxins and Other Potentially Biohazardous Material

Included in this category is research involving work with potentially biohazardous materials. Research that is included in this category involves studies with eukaryotic virus. According to CDC guidelines, BSL2 conditions are usually appropriate for this research.

## 2. Human Blood, Body Fluids, and Unfixed Human Tissue or Primary Cell Culture

For research using blood, certain other body fluids, unfixed human tissue or primary human cell culture, the requirements of the OSHA Bloodborne Pathogens Standard must be met, including (1) training, (2) offer of hepatitis B vaccine, (3) signing of informed consent form, and (4) compliance with other aspects of the Standard. According to the CDC guidelines, BSL2 conditions are usually appropriate for such work.

### D. Select Biological Agents and Toxins

The US Department of Health and Human Services (HHS) and the US Department of Agriculture (USDA) have developed a list of select Biological agents and toxins that have the potential to pose a severe biosecurity threat to public health, animals, and agricultural crops.

As directed by the US Patriot Act, HHS and USDA have adopted strict regulations for the obtaining, possession, use, or transfer of any of these selected agents. Failure to comply with the established regulations can result in significant civil and criminal penalties.

Therefore, any investigator considering the use of select agents or toxins must contact the University Environmental Health and Safety Officer to discuss the specifics of the requirements. HHS regulations in 42 CFR Part 73 Possession, Use, and Transfer of Select Agents and Toxins and the companion USDA regulations in 9 CFR Part 121 require federal registration and inspection; restricted lab access; development of written and strictly followed safety and security plans; personnel background checks by the FBI (including fingerprinting); specialized training; strict recordkeeping and reporting of agent use, transfer, loss, or destruction.

In determining whether to use select agents, researchers are encouraged to give careful consideration to the personal responsibilities, financial costs, and lengthy application and permit process involved with compliance. Any plans for use of select agents could easily take several months to get the appropriate permits and approvals and establish the security and protocols necessary to comply with the regulations. Sources of research funds to cover the cost of facility security improvements will need to be identified.

There is a small quantity exemption available for some of the select toxins. If the aggregate amount of toxin in the possession of a researcher can be kept below the specified exempt quantity, (see agent listing) most of the rules do not apply. It should be noted that even when taking advantage of the small quantity exemption, the investigator is required to establish an inventory system to ensure the limit is not exceeded. Regardless of the amount, the University Environmental Health and Safety Officer must be contacted prior to beginning work

**Alphabetical List Of Select Agents And Toxins ( as per the Final Select Agent Rules - website visited 12/3/2018 )**

Except for exclusions listed in the Appendix, the viruses, bacteria, fungi, toxins, genetic elements, recombinant nucleic acids, and recombinant organisms specified in this list are HHS, USDA or HHS/USDA overlap select agents and toxins.

- Abrin (HHS)
- African horse sickness virus (USDA, Animal)

- African swine fever virus (USDA, Animal)
- Akabane virus (USDA, Animal)
- Avian influenza virus (highly pathogenic) (USDA, Animal)
- Bacillus anthracis (Overlap)
- Bacillus anthracis Pasteur strain (Overlap)
- Bacillus cereus Biovar anthracis (HHS)
- Bluetongue virus (exotic) (USDA, Animal)
- Botulinum neurotoxin producing strains of Clostridium (Overlap) (HHS)
- Botulinum neurotoxins (Overlap) (HHS)
- Bovine spongiform encephalopathy agent (USDA, Animal)
- Brucella abortus (Overlap)
- Brucella melitensis (Overlap)
- Brucella suis (Overlap)
- Burkholderia mallei (formerly Pseudomonas mallei) (Overlap)
- Burkholderia pseudomallei (Overlap)
- Camel pox virus (USDA, Animal)
- Central European Tick-borne encephalitis virus (HHS)
- Cercopithecine herpesvirus 1 (Herpes B virus) (HHS)
- Chapare, virus (HHS)
- Classical swine fever virus (USDA, Animal)
- Clostridium perfringens epsilon toxin (Overlap)
- Coccidioides immitis (Overlap)
- Coccidioides posadasii (HHS)
- Coniothyrium glycines (USDA, Plant)
- Conotoxins (HHS)
- Cowdria ruminantium (Heartwater) (USDA, Animal)
- Coxiella burnetii (Overlap) (HHS)
- Crimean-Congo haemorrhagic fever virus (HHS)
- Diacetoxyscirpenol (HHS)
- Eastern Equine Encephalitis virus (Overlap) (HHS)
- Ebola viruses (HHS)
- Far Eastern Tick-borne encephalitis (HHS)
- Flexal virus (HHS)
- Foot-and-mouth disease virus (USDA, Animal)
- Francisella tularensis (Overlap) (HHS)
- Goat pox virus (USDA, Animal)
- Guanarito, virus (HHS)
- Hendra virus (Overlap)
- Japanese encephalitis virus (USDA, Animal)
- Junin virus (HHS)
- Kyasanur Forest disease (HHS)
- Lassa fever virus (HHS)
- Lujo virus (HHS)
- Liberobacter africanus (USDA, Plant)
- Liberobacter asiaticus (USDA, Plant)
- Lumpy skin disease virus (USDA, Animal)
- Machupo virus (HHS)
- Malignant catarrhal fever virus (Alcelaphine herpes virus type 1) (USDA, Animal)
- Marburg virus (HHS)

- Menangle virus (USDA, Animal)
- Monkeypox virus (HHS)
- Mycoplasma capricolum/ M. F38/M. mycoides capri (contagious caprine pleuropneumonia) (USDA, Animal)
- Mycoplasma mycoides mycoides (contagious bovine pleuropneumonia) (USDA, Animal)
- Newcastle disease virus (velogenic) (USDA, Animal)
- Nipah virus (Overlap)
- Omsk Hemorrhagic Fever (HHS)
- Peronosclerospora philippinensis (USDA, Plant)
- Peste des petits ruminants virus (USDA, Animal)
- Ralstonia solanacearum, race 3, biovar 2 (USDA, Plant)
- Rathayibacter toxicus (USDA, Plant)
- Reconstructed 1918 Influenza virus (HHS)
- Ricin (HHS)
- Rickettsia prowazekii (HHS)
- Rickettsia rickettsii (HHS)
- Rift Valley fever virus (Overlap)
- Rinderpest virus (USDA, Animal)
- Russian Spring and Summer encephalitis (HHS)
- Sabia virus (HHS)
- SARS- associated coronavirus (SARS-CoV) (HHS)
- Saxitoxin (HHS)
- Sclerophthora rayssiae var. zae (USDA, Plant)
- Sheep pox virus (USDA, Animal)
- Shiga-like ribosome inactivating proteins (HHS)
- Shigatoxin (Overlap)
- Siberian Tick-borne encephalitis subtype (HHS)
- Staphylococcal enterotoxins (Overlap)
- Swine vesicular disease virus (USDA, Animal)
- Synchytrium endobioticum (USDA, Plant)
- T-2 toxin (Overlap) (HHS)
- Tetrodotoxin (HHS)
- Variola major virus (Smallpox virus) (HHS)
- Variola minor virus (Alastrim) (HHS)
- Venezuelan Equine Encephalitis virus (Overlap)
- Vesicular stomatitis virus (exotic) (USDA, Animal)
- Xanthomonas oryzae pv. oryzicola (USDA, Plant)
- Xylella fastidiosa (citrus variegated chlorosis strain) (USDA, Plant)
- Yersinia pestis (HHS)

## E. Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms

- Nucleic acids that can produce infectious forms of any of the select agent viruses.
- Recombinant nucleic acids that encode for the functional form(s) of any of the select agent toxins if the nucleic acids:
  - can be expressed *in vivo* or *in vitro*, or

- are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.
- Select agents that have been genetically modified.

**Exclusions:**

- Any select agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
- Non-viable select agent organisms or nonfunctional toxins.
- The following toxins (in the purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified:
  - 100 mg of Abrin
  - 0.5 mg of Botulinum neurotoxins
  - 100 mg of *Clostridium perfringens* epsilon toxin
  - 100 mg of Conotoxins
  - 1,000 mg of Diacetoxyscirpenol
  - 100 mg of Ricin
  - 100 mg of Saxitoxin
  - 100 mg of Shigatoxin
  - 100 mg of Shiga-like ribosome inactivating proteins
  - 5 mg of Staphylococcal enterotoxins
  - 100 mg of Tetrodotoxin
  - 1,000 mg of T-2 toxin
- The following attenuated strains are exempt if used in basic or applied research, as positive controls, for diagnostic assay development, or the development of vaccines and therapeutics:

*Coccidioides posadasii*  $\Delta$ chs5 strain

Conotoxins specifically *excluded* are: the class of sodium channel antagonist  $\mu$ -conotoxins, including GIIIA; the class of calcium channel antagonist  $\omega$ -conotoxins, including GVIA, GVII, MVIIA, MVIIC, and their analogs or synthetic derivatives; the class of NMDA-antagonist conantokins, including con-G, con-R, con-T and their analogs or synthetic derivatives; and the putative neurotensin agonist, contulakin-G and its synthetic derivatives.

*Yersinia pestis* strains which are Pgm - due to a deletion of a 102-kb region of the chromosome termed the *pgm* locus (i.e.,  $\Delta$ *pgm*). Examples are *Y. pestis* strain E.V. or various substrains such as EV 76. *Yersinia pestis* strains (e.g., Tjiwidej S and CDC A1122) devoid of the 75 kb low-calcium response (Lcr) virulence plasmid.

*Bacillus anthracis* strains devoid of both plasmids pX01 and pX02 & *Bacillus anthracis* strains devoid of the plasmid pX02 (e.g., *Bacillus anthracis* Sterne, pX01 +pX02 -).

*Brucella abortus* Strain 19 & *Brucella abortus* strain RB51 (vaccine strain).  
*Coxiella burnetii* Phase II, Nine Mile Strain, plaque purified clone 4.

*Francisella tularensis* subspecies *novicida* (also referred to as *Francisella novicida*) strain, Utah 112 (ATCC 15482) & *Francisella tularensis* subspecies *holartica* LVS (live vaccine strain; includes NDBR 101 lots, TSI-GSD lots, and ATCC 29684) & *Francisella tularensis* ATCC 6223 (also known as strain B38).

Rift Valley fever virus, MP-12 vaccine strain.

Venezuelan Equine Encephalitis (VEE) virus vaccine candidate strain V3526 & Venezuelan equine encephalitis virus, TC-83 strain.

Highly pathogenic avian influenza (HPAI) virus, recombinant vaccine reference strains of the H5N1 and H5N3 subtypes.

Japanese encephalitis virus, SA14-14-2 strain..

## F. Live Viruses

Individuals who will be working with certain live viruses in the laboratory must successfully complete the training and medical review and informed consent process prior to such work.

Completing this live virus worker process:

- Provides the individual with information on the risks and the necessary safety measures associated with the work
- Acknowledges the individual's acceptance of risks and responsibilities for the work
- Initiates the necessary medical review with the Occupational Health Department

The live virus worker informs the PI and Occupational Health Department when the worker:

- Becomes pregnant
- Is exposed to live virus by accident or injury
- Has a change in immune status

## G. Human Blood and Tissue

In any laboratory where work involves the use of and/or exposure to human blood, certain other body fluids, or unfixed human tissue, there is the danger of exposure to bloodborne pathogens, and the disease-causing microorganisms that may be found in such material. Work with any of these materials in a laboratory setting usually requires that workers be enrolled in the Blood Borne Pathogens Program. The BBP Program ensures compliance with the Federal Occupational Health and Safety Administration (OSHA) Bloodborne Pathogens Standard (29 CFR 1910.1030) which has been adopted by New Jersey Public Employee Occupational Safety and Health (PEOSH).

The Bloodborne Pathogens Program requires each department or laboratory to develop an Exposure Control Plan that documents how the risk of exposure will be reduced or eliminated. Specifically, the Plan:

- Defines who has potential exposure and what tasks or duties cause exposure
- Indicates the engineering and work practice controls in place
- Describes the personal protective equipment provided and used
- Describes the good housekeeping practices initiated
- Provides for the offer of hepatitis B (HBV) vaccination to those exposed
- Provides for medical follow-up after exposure
- Provides for proper hazard signage and labeling
- Provides for initial and annual training and necessary record-keeping

As part of this plan, the potentially exposed individuals must:

- Complete the training, Protection Against Bloodborne Pathogen, which includes offer of Hepatitis B vaccination and registration in the Bloodborne Pathogens Program
- Use appropriate personal protective equipment and follow established safe work practices
- Report all exposures to the MSU Occupational Health Department for post-exposure treatment or referrals

## H. Biohazards Associated with Animal Handling

When research involves exposure to and handling of animals, there are considerations that must be given to the potential allergens, zoonoses, and physical hazards, e.g. bites and scratches, that may be encountered by researchers and staff.

Successful completion of the appropriate animal training and medical review form must be completed before the individual will be provided access to the animal facility.

The medical review includes:

- Update of tetanus immunizations
- Discussion of allergen exposure and potential zoonoses
- What to do if bitten, or after other injury with animals or contaminated caging/equipment
- Vaccination for zoonoses, when indicated and available
- Completion of an Animal Worker Personnel Information Form and a Health History Form.

Personnel also receive training and safe handling techniques for those animals with which they will have contact.

All research involving the care and handling of animals is reviewed and approved by the Institutional Animal Care and Use Committee. (IACUC) Hazards associated with animal exposure are addressed through this committee.

## **IV. IBC Committee, Submission Process, Closure and non-compliance**

### **A. Composition and Membership**

The Institutional Official will appoint the chairperson of the IBC committee. In accordance with NIH Guidelines, committee members are drawn from each represented school's research departments, functional units, and other non-affiliated institutions. Each department that conducts research reviewed by the IBC should have at least one representative on the committee. Membership may include personnel with infectious disease expertise, both clinical and experimental, experience in recombinant and synthetic nucleic acid technology, knowledge of biological safety and containment, proficiency in plant and animal containment, and a representative of the laboratory technical staff. At least two members who are not affiliated with the institution will sit on each subcommittee to represent the interest of the surrounding community with respect to health and protection of the environment.

Recruitment of new members is conducted by the IBC chairperson and/ or the Research Compliance Officer. The need for new members are identified through feedback from the chairperson, administrator or other pathways. When candidates for membership are identified, the IBC administrator reaches out to the individual to explain the function of the committee and to request their participation.

Members are formally appointed by the Institutional Official. Appointments are generally made for a two or three-year term.

Removal of a member from the IBC requires documented and sustained "just cause" that demonstrates the member to be unfit or unable to serve on the IBC. Just cause may include lack of regular attendance at meetings, a finding of misconduct, or an unresolved conflict of interest. The decision to remove a member is made by the Institutional Official/Provost.

### **B. Submission of Protocol**

The Principal Investigator (PI) for a project will prepare and submit an IBC form to the IBC (via e-mail). When a proposal is submitted, it is assigned a unique number that is used in correspondence with the committee and the PI. Renewal of protocols occurs every 5 years for biosafety level (BSL) 1 protocols, every 3 years for BSL2 protocols and annually for BSL3 protocols. The committee reserves the right to change the cycle for renewals if warranted by the risk and type of research performed.

### **C. Routing of Protocol**

The IBC Chair and/or Biosafety Officer will conduct a pre-review of the protocol and relevant documents and upload all documents to a user-based web system and e-mail the committee members. The IBC Chair in consultation with the Biosafety Officer will determine whether the

study can be reviewed by the Biosafety Officer and Chair or whether it must go for full committee review.

#### 1. Designated Review

The Biosafety Officer will review the proposal to determine whether the proposed research follows IBC guidelines. The reviewer will then either approve the protocol, request further information or modification from the PI, or request full committee review with 14 business days.

#### 2. Full Committee review

If the Chair determines a full committee review is necessary, the full committee will meet to discuss the proposal. For a full committee review, a quorum (majority of the total number of voting members) must be present. The committee will review the proposal and then vote to either approve the protocol, request further information or modification from the PI, or withhold approval.

If the designated reviewer or full committee feels that modification is needed, the protocol is returned to the investigator by the IBC Chair with appropriate instructions. The PI will have 30 days to respond to the modifications. When the modifications have been made, the protocol is again distributed to the IBC designated reviewer or full committee review procedure.

### D. Approvals

Original approved protocols and letters are kept on file by the IBC and a copy of the approval letter is sent to the investigator.

#### 1. Periodic Protocol Review

Protocols are renewed every five years for BSL1, every 3-5 years for BSL2 and annually for BSL3, even if there are no changes. New protocols do not need to be submitted for continuation of an approved project. Personnel changes and amendments can be submitted at any time during the life of a protocol. Hazards may not be ordered or received by the University or employees until protocols have received registration approval from the IBC.

### E. Conflict of Interest (COI)

Should the IBC chair have a COI in assigning or reviewing a protocol the Research Compliance Officer will be required to step in assigning or reviewing the protocol.

During full committee meetings, the IBC chair or committee member is required to disclose a COI prior to final discussion and voting on a protocol.

### F. Procedure for Review of Protocol Closure

The Principal Investigator (PI) for a project will prepare and submit an closure form to the IBC (via e-mail). The IBC chair will review the final project information and either approve the protocol, request further information or modification from the PI, or withhold closure.

### G. Non-compliance with IBC policies, procedures, protocol or decisions

Protocol non-compliance occurs when procedures or policies approved by the IBC are not being followed. Examples include performing animal research without IBC approval, unauthorized

persons participating in a research project, or not completing assigned initial or refresher training as assigned by the IBC. When faced with protocol noncompliance, the IBC's first step, if possible, should be to find a way to bring the protocol into compliance.

If allegations of protocol non-compliance are verified, the IBC can apply sanctions. If, in the opinion of the IBC, sanctions are not appropriate, they need not be applied. A clearly minor and unintentional misinterpretation of an IBC policy that has created no hazards, is an example of where a verified allegation of protocol non-compliance might lead to an explanation, not a sanction.

### 1. Consequences of Non-Compliance

Subsequent actions of the IBC may include:

- Implementing measures to prevent recurrence;
- Notifying the Dean or Institutional Official of its actions;
- Institutional Sanctions;
- Notifying funding or regulatory agencies, as required; and/or
- Notifying the complainant, any persons against whom allegations were directed, and pertinent program officials (appropriate supervisory and management staff, the public affairs office, institutional attorneys, etc.).
- Suspend project

### 2. Non-Compliance with Training

Non-compliance with training occurs when individuals do not complete training assignments by their given due dates. When training is assigned, the individual is given 30 days to complete it. If they have not completed the training after these 30 days, a second notice will be sent to them allotting a 15 day extension to complete the training. If they have not completed the training after this 15 day extension, a third and final notice will be sent to them allotting a 10 day extension to complete the training. If the individual fails to complete the training after the final 10 day extension, and does not provide documented verification of alternative training, the following actions will be taken:

- If the individual is the PI, their project will be suspended (see G.2. for details).
- If the individual is a research assistant, the project will not be suspended, but rather there will be removal of the individual from the protocol until training is completed.

### 3. Project Suspension

The IBC is empowered to suspend a project if it finds violations of University policy, or applicable regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IBC, and a vote for suspension by a majority of the quorum present. Further, the IBC must consult with the Institutional Official regarding the reasons for the suspension. The Institutional Official is required to take appropriate corrective action, and report the action and the circumstances surrounding the suspension to appropriate regulatory agencies. Because an IBC action to suspend a project is a serious matter, the action must be reported promptly.

## V. Working Safely with Biological Materials

- A. Exposure Control
- B. Biosafety Levels
- C. Animal Biosafety Levels

### A. Exposure Control

The term "containment" is used in describing safe methods for managing infectious agents in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other people, and the outside environment to potentially hazardous agents.

The three elements of containment include laboratory practice and technique, safety equipment, and facility design.

#### 1. Laboratory Practice and Technique

The most important element of containment is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or infected materials must be aware of potential hazards, and must be trained and proficient in the practices and techniques required for handling such material safely. The Principle Investigator(PI) is responsible for providing or arranging for appropriate training of research assistants.

Each PI should identify specific hazards that will or may be encountered, and consider practices and procedures needed to minimize or eliminate risks. Personnel should be advised of special hazards and are expected to follow the required practices and procedures.

#### 2. Safety Equipment (Primary Barriers)

Safety equipment includes biological safety cabinets, enclosed containers, and other engineering controls designed to eliminate or minimize exposures to hazardous biological materials. The biological safety cabinet (BSC) is the principal device used to provide containment of infectious splashes or aerosols generated by many microbiological procedures. More information on BSCs may be found in Section II B.

Safety equipment may also include items for personal protection such as personal protective clothing, respirators, face shields, safety glasses or goggles. In some situations, personal protective clothing may form the primary barrier between personnel and the infectious materials.

#### 3. Facility Design (Secondary Barriers)

The design of a facility is important in providing a barrier to protect those working inside and outside the laboratory and to protect people or animals in the community from infectious agents which may be accidentally released from the laboratory. Facilities must be commensurate with the laboratory's function and the recommended biosafety level for the agent being manipulated.

The secondary barrier(s) needed will depend on the risk of transmission of specific agents. For example, all Montclair State University research falls within Biosafety Levels 1 and 2 (see Biosafety Levels below) and exposure risks involve direct contact with the agents, or inadvertent

contact through contaminated work environments. Secondary barriers in these laboratories include separation of the laboratory work area from public access, availability of a decontamination facility (e.g., autoclave) and hand washing facilities.

## B. Biosafety Levels

CDC-NIH has established **four levels of biosafety**, based on the degree of hazard associated with an organism, to describe the combination of laboratory practices and techniques, safety equipment, and facilities needed to protect against exposure. These four biosafety levels (BSL) require successively more restrictive practices and facilities as work moves from the least restrictive BSL1 to work with the highest hazard level of BSL4. Exposure to biohazardous agents is intended to be prevented or limited by establishing and following the appropriate biosafety level practices and conditions. Research in Montclair State University facilities is currently limited to BSL1 and BSL2. (See section IIA for an outline of good practices at BSL1 and BSL2)

- **BSL1** applies to the basic level of containment and essentially represents good microbiological practice with no special primary or secondary barriers required. This applies to work with defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy adult humans. This includes such organisms as the bacteria *Bacillus subtilis*, *Vibrio harveyi*, or host/vector strains of *E coli* and yeast *Saccharomyces cerevisiae*.
- **BSL2** applies to work with a broad spectrum of moderate-risk agents that are generally present in the environment at large and are associated with human disease of varying severity.

All of the viral agents, such as adenovirus, cytomegalovirus, and other herpes viruses fall within the BSL2 level of work. Other microorganisms assigned to this containment level include salmonella spp., toxoplasma spp., hepatitis B, and HIV. With the use of good microbiological techniques, much of this work can be done on open bench tops as long as there is limited potential for splashes and aerosol creation. **In addition to BSL1 conditions**, this level of work also requires that:

- Laboratory personnel have specific training in handling any pathogenic agents used
- Access to the laboratory is limited when BSL2 work is being done
- Gloves, lab coat, safety glasses, and other suitable personal protective equipment are worn
- Extreme precautions are taken with contaminated sharps
- Biosafety cabinets are used when there is potential for splash or aerosol creation
- **BSL3 and BSL4** apply to work with exotic agents of increasingly greater potential for causing serious human illness or death. No work at the BSL3 or 4 is currently being done and facilities that would meet the requirements of these biosafety levels are not available at Montclair State University.

A good summary of requirements at each laboratory biosafety level can be found at <http://bmb1.od.nih.gov/sect3tab1.htm>

## C. Animal Biosafety Levels

A similar set of four biosafety levels are provided for work with vertebrate animals infected with agents which may infect humans. These **Animal Biosafety Levels, ABSL 1 thru 3**, provide for practices, equipment, and facilities that are comparable to the laboratory biosafety levels described above. However, there are unique hazards associated with infected animals that must be understood by those personnel with animal contact and addressed in the animal facility. Animal activity can create aerosols and bites and scratches can occur.

See <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4s3t.htm> for a good summary of the Animal Biosafety Levels.

## VI. Laboratory Procedures and Equipment

- A. Guidelines for Good Laboratory Practices at BSL1 and BSL2
  - B. Biological Safety Cabinets (BSC's)
    - Types of BSC's
    - Working in a BSC
    - Certification of the BSC
  - C. Decontamination
    - Definitions
    - When to decontaminate
    - Autoclave use
    - Chemical Disinfectant use
  - D. Exposure to Infectious Agents
    - Intact Skin
    - Broken, Cut or Damaged Skin or Puncture Wound
    - Eye
    - Ingestion or Inhalation
  - E. Biological Material Spills
    - Spills and Preparing for them
    - Spills inside a Biological Safety Cabinet
    - Small Spill of Material Outside a Biological Safety Cabinet
    - Large Spill of BL2 Material (>500 ml) Outside of a Biological Safety Cabinet
  - F. Biological Waste Handling
    - Biohazardous Waste (Regulated Medical Waste)
    - Animal Bedding Waste
    - Animal Carcasses
    - Animal Waste
- A. Guidelines for Good Laboratory Practices at BSL1 and BSL2\*

(Excerpted from the *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories* and the *NIH Guidelines for Research Involving Recombinant DNA Molecules*)

**\*Indented and bulleted items indicate additional requirements for work at BSL2.**

1. Immediately notify the laboratory supervisor or Principal Investigator (PI) in case of an accident, injury, illness, or overt exposure associated with laboratory activities. As appropriate, proceed to MSU emergency services, MSU Occupational Health Department (employees) or

MSU Student Health Center for any necessary medical surveillance and/or treatment. **Note:** The University is required to report to regulatory officials any significant research-related accidents/injuries and violations of NIH Guidelines so it is important that the lab notify the Institutional Health and Safety Committee immediately under such circumstances.

2. For those intending to work with live viruses or research animals: complete Live Virus Worker and/or the Animal Worker training and the required medical review. For live virus work, serum draw and titring may be required or desired depending on the virus involved.

3. For those intending to work with blood or human tissue: complete the Protection Against Bloodborne Pathogens training and entry into the Blood borne Pathogens Program.

4. Be aware that access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments or work with cultures or specimens is in progress. Laboratory should have doors to control access.

5. Understand that the PI and/or lab supervisor must ensure that all laboratory personnel receive appropriate initial training, necessary on-going training, and supervision regarding the hazards associated with the agents involved; the necessary precautions to prevent exposures; and exposure evaluation procedures.

6. Understand that personal health status may impact an individual's susceptibility to infection or necessary medical surveillance and any conditions in this regard should be discussed with lab supervisor and healthcare personnel in Health Services as appropriate.

- Only personnel advised of the special hazards and meeting any specific entry requirements, i.e., appropriate immunizations, serum sampling, are permitted in the laboratory. Understand and follow all biosafety procedures provided by the PI and/or supervisor.
- Be aware that any possession or use of select biological agents or toxins requires special federal government registration and inspection; restricted lab access; written and strictly followed safety and security plans; personnel background checks and training; accurate records and/or reporting of agent use, transfer, loss, or destruction. Any plans for obtaining such materials must be discussed with the Biological Safety Committee and approved by the Environmental Safety Officer.
- Ensure that **when infectious agents are in use** in the laboratory, a biohazard sign is posted on the lab access door. This sign identifies the agent(s) in use, the biosafety level, any required immunizations, the PI's name and telephone number, and any PPE that must be worn in the laboratory.



7. Wash hands frequently and always after handling viable material or animals, after removing gloves, and before leaving the laboratory. A sink for hand washing is present in each laboratory.

- Know the location of a readily accessible eyewash station and safety shower.

8. Do not eat, drink, smoke, chew gum, handle contact lenses, or apply cosmetics in the laboratory. Persons wearing contact lenses in the laboratory should also wear goggles or a face shield.

9. Do not bring any food, medications, or cosmetics, into the laboratory for storage or later use. Food is stored outside the work area in cabinets or refrigerators designated specifically for that purpose.
10. Do not bring animals unrelated to experimental work into the laboratory.
11. Do not pipette by mouth; only mechanical pipetting devices are permitted.
12. Perform all procedures carefully to minimize the creation of splashes or aerosols.
13. Establish and follow policies for safe handling of sharps. Use a high degree of caution when handling any contaminated sharp item, such as needles and syringes, slides, pipettes, capillary tubes, and scalpels. Substitute plastic ware for glass whenever possible. Handle broken glassware with brush and dustpan, tongs, or forceps - not directly with hands.
14. Do not bend, shear, break, recap, or remove used needles from disposable syringes or otherwise manipulate such units by hand before disposal. Dispose of needles and syringes in the puncture resistant container provided in the laboratory for this purpose. Place full containers in an autoclave bag and sterilize before disposal in medical waste boxes.
  - Restrict needles and syringes or other sharp instruments in the laboratory for use only when there is no alternative, such as for parenteral injection. Use only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) for injection or aspiration of infectious material.
15. Use of lab coats, gowns, or other designated laboratory uniform is recommended to prevent contamination or soiling of street clothing.
  - Wear lab coats, gowns, smocks, or other provided protective garments while working with hazardous materials. When leaving the lab, remove and leave coats and other protective clothing in the lab for either disposal or laundering.
16. Wear gloves if the skin on the hands is broken or if a rash is present. Protective eyewear should be worn for procedures that involve anticipated splashes of microorganisms or other hazardous materials to the face.
  - Wear gloves when manipulating infectious materials or agents or when hands must otherwise contact contaminated surfaces. Remove and change gloves when overtly contaminated or when torn or punctured. Do not wear contaminated gloves outside the lab. Do not wash or reuse disposable gloves. Consider alternatives to latex gloves to prevent allergic response.
  - Wear appropriate face protection (goggles, mask, face shield or other splatter guard) for anticipated splashes or sprays of infectious materials to the face when agents **must** be handled outside the BSC. Persons wearing contact lenses should also wear eye protection.
17. Decontaminate equipment and work surfaces at completion of work, at the end of the day, and following spills of viable materials. If a spill occurs, cover the spill with paper towels and soak the towels with a 1 to 10 dilution of chlorine bleach or other suitable disinfectant. Allow the material to soak for approximately 20 minutes before discarding materials in biohazard bag.

Bench tops are impervious to water and resistant to solvents, acids, alkalis, and chemicals used for surface decontamination.

18. Work on open bench tops is permitted; use of special containment equipment such as a biological safety cabinet (BSC) is not generally required for agents assigned to BSL1.

- Work in the open laboratory is permitted, except that **a properly maintained biological safety cabinet is required whenever:**

**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** whose internal pressures may be different from ambient pressures, **inoculating animals intranasally**, and **harvesting infected tissues from animals or embryonate eggs.**

**High concentrations or large volumes of infectious agents are used.** Such materials may be centrifuged in open laboratory if sealed rotor heads or centrifuge safety cups are used, and if these rotors or safety cups are opened only in a biological safety cabinet.

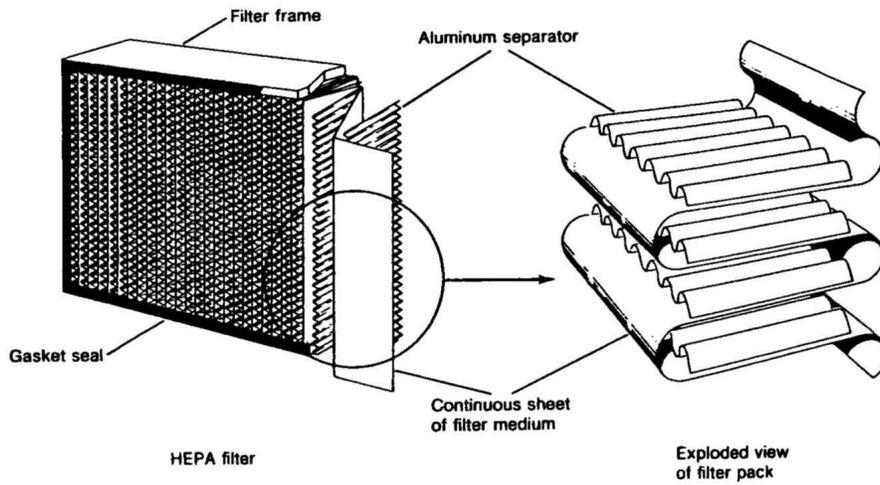
**Be aware that air sampling studies have shown that most of the common manipulations of bacterial and viral cultures in research laboratories release aerosols of viable organisms. This must be considered when evaluating need for use of the biological safety cabinet or other physical containment device.**

19. **Dispose of all regulated medical wastes (potentially biohazardous) and associated wastes as outlined in Section II F. Biological Waste Handling.** Cover containers of all cultures, tissues, specimens of body fluids, or other potentially infectious waste to prevent leakage during collection, handling, processing, storage, or transport.

## B. Biological Safety Cabinets (BSCs)

### • Types of BSCs

BSCs are classified as Class I, Class II or Class III cabinets. When properly maintained and operated, they effectively contain and capture microbial contaminants and infectious agents using HEPA (High Efficiency Particulate Air) filters. (See Figure 1.) Biosafety cabinets should not be confused with clean benches which only protect the material being worked with and are not suitable for work with infectious or toxic material. (Although clean benches, like BSCs, have HEPA-filtered air, with clean benches the air flows over the experimental material toward the user rather than being drawn away.) BSCs should also not be confused with conventional fume hoods that do not filter microorganisms.

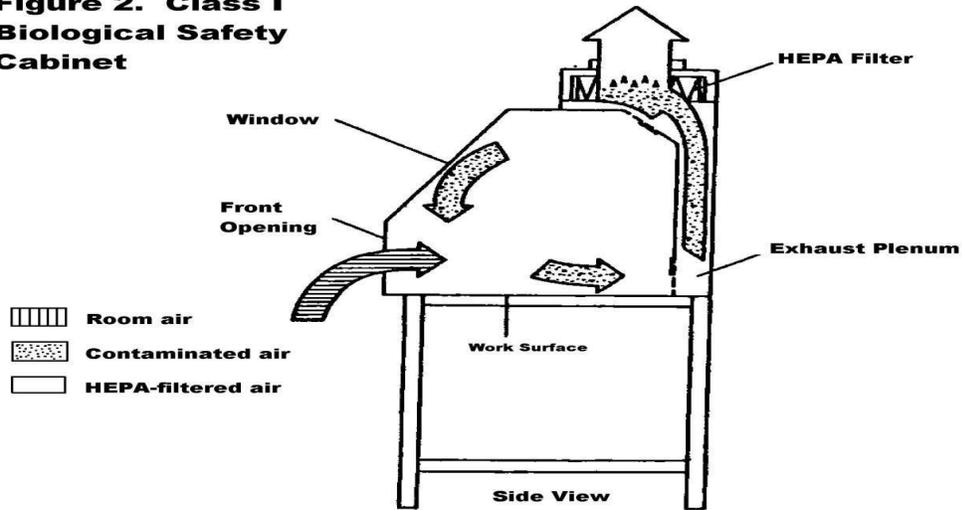


**Figure 1.** Diagram of HEPA filter. These filters are typically constructed of continuous sheets of paper-thin filter medium, pleated to increase surface area, divided by aluminum separators, and affixed to a frame.

Class I BSCs provide personnel and environmental protection, but not product protection.

(See Figure 2).

**Figure 2. Class I Biological Safety Cabinet**

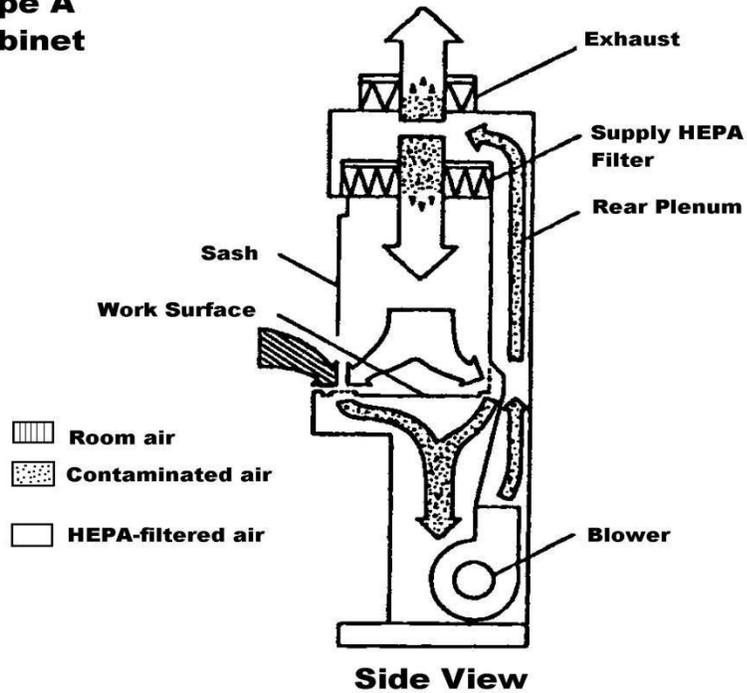




**Class II BSCs** provide personnel, environmental and product protection. (See Figure 3).

Only those which are hard ducted to the outside and provide a face velocity of 80 to 125 feet per minute should be used when working with volatile chemicals. Additionally, cabinets are not designed to prevent ignition of volatile flammable chemicals.

**Figure 3. Class II, Type A Biological Safety Cabinet**



## **Working in a BSC**

1. Turn the cabinet on for at least 10 - 15 minutes prior to use, if the cabinet is not left running.
2. Disinfect work surface with 70% alcohol or other suitable disinfectant.
3. Consider the materials necessary for the planned work in the cabinet.
4. Place items into the cabinet so that they can be worked with efficiently without unnecessary disruption of the air flow, working with materials from the clean to the dirty side.
5. Wear appropriate personal protective equipment. At a minimum, this will include a buttoned laboratory coat and gloves.
6. Adjust the working height of the stool so that the worker's face is above the front opening.
7. Delay manipulation of materials for approximately one minute after placing the hands/arms inside the cabinet.
8. Minimize the frequency of moving hands in and out of the cabinet.
9. Do not disturb the airflow by covering any of the grillwork with materials.
10. Work at a moderate pace to prevent the air flow disruption that occurs with rapid movements.
11. Wipe the bottom and side of the hood surfaces with disinfectant when work is completed.

**NOTE:** Be very careful when using small pieces of materials such as kimwipes in the hood. These can be blown into the hood and disrupt the motor operations.

## **Certification of the BSC**

Certification is a series of performance tests on the BSC to confirm that it will provide the user and experimental material the protection for which it is designed. The air flows, filters, and cabinet integrity are checked to ensure that the cabinet meets minimum performance standards. Certification is arranged through the Environmental Health & Safety Department and provided by an outside vendor.

### **BSCs intended for user protection must be certified:**

- After they are received and installed (before use with infectious materials)
- After filter changes
- Annually

Biological safety cabinets intended only for protection of the experimental material are certified at the discretion of the Principal Investigator.

BSC decontamination can be provided by an outside vendor and needs to be done:

- Before any maintenance work requiring disassembly of the air plenum, including filter replacement
- Prior to cabinet recertification
- Before moving the cabinet to a new laboratory

## C. Decontamination

### **Definitions:**

**Decontamination** is a process or treatment that renders an instrument or environmental surface safe to handle. A decontamination procedure can be as simple as clean-up with detergent and water or as thorough as sterilization. Sterilization, disinfection, and antisepsis are all forms of decontamination.

**Sterilization** is the use of physical or chemical processes to destroy all microbial life, including highly resistant forms, such as bacterial spores.

**Disinfection** is the elimination of essentially all pathogenic non-spore forming microorganisms but not necessarily all microbial forms from work surfaces and equipment. Effectiveness is influenced by a number of factors, including: types and numbers organisms; amount of organic matter; the object being disinfected; the disinfectant being used; exposure time, temperature and concentration.

**Antisepsis** is the application of a liquid antimicrobial to skin or other living tissue to inhibit or destroy microorganisms. Examples include hand washing with germicidal solutions or swabbing skin before an injection.

### **When to Decontaminate**

All material and equipment contaminated with or containing potentially infectious agents should be decontaminated:

- Upon completion of procedures involving the use of biologically-active materials
- In the event of spills of such materials
- At least daily
- Before being washed, stored, or discarded

In most Montclair State University laboratories, decontamination is accomplished by **steam heat sterilization in an autoclave**, or by surface application of or placement in a **chemical disinfectant solution**, such as 1:10 bleach solution or its equivalent.

### **Sterilization using an Autoclave**

Autoclaving (saturated steam under pressure of approximately 15 psi to achieve a chamber temperature of at least 250°F for a designated time) is the preferred and most convenient method to rapidly destroy all forms of microbial life. However, to do this, the autoclave process must reach proper temperature and time and also prevent the entrapment of air in the bag or container of treated material.

- Material to be sterilized must come into contact with live steam.
- Bags or containers should be left open during autoclaving or water (~200ml) should be added to sealed bags to generate steam.
- Heat indicator tape should be used with each autoclave load to indicate that sterilization has been completed.

- Autoclave sterility monitoring should be conducted on a regular basis using biological indicators (such as *B. stearothermophilus* spore strips) placed among treated materials and at locations throughout the autoclave. The spores, which are more resistant to heat than most microbes, provide validation of general microbial destruction when they are effectively inactivated (250 deg. F for 13 minutes) by autoclave operation.

### **Chemical Disinfectant Use**

The most practical use of chemical disinfectants is for surface decontamination and, when used in sufficient concentration, as a decontaminant for liquid wastes prior to final disposal down the drain.

### **GENERAL RECOMMENDATIONS:**

Consult manufacturer directions to determine appropriate use and contact time for the disinfectant and the biohazards in your lab. Consider the microorganism(s) present, item(s) to be disinfected, hazard(s) associated with disinfection and application method. Some examples are listed below:

#### **Instrument Decontamination**

- Soak instruments in 70% alcohol

#### **Liquid Decontamination**

- Add liquid chlorine bleach to provide a final 1:10 dilution
- Let stand at least 20 minutes
- Discard down the drain

#### **Surface Decontamination**

- Wipe with 1:10 dilution of chlorine bleach, can also be followed with 70% Ethanol wipe

## **D. Exposure to Infectious Agents**

In the event of an exposure to an infectious agent or material, the following guidelines should be used:

#### **Intact skin**

- Remove contaminated clothing
- Vigorously wash contaminated skin for 1 minute with soap and water

### **Broken, cut or damaged skin or puncture wound**

- Remove contaminated clothing
- Flood skin with copious amounts of water and clean with soap and water. Do not rub hard or abrade the skin.
- Seek medical attention via MSU emergency services

### **Eye**

Immediately flush eyes for at least 15 minutes with water, preferably using an eyewash; if no eyewash is available, pour water on the eye(s) for 15 minutes, rinsing from the nose outward to avoid contamination of the unaffected eye.

- Hold eyelids away from your eyeball and rotate your eyes so that all surfaces may be washed thoroughly.
- Seek medical attention at MSU emergency services

### **Ingestion or Inhalation**

- Call x5222 in case of an emergency
- Seek medical attention at MSU emergency services
- Do not induce vomiting unless advised to do so by a health care provider

## **E. Biological Material Spills**

### **Spills and Preparing for Them**

In the event of a spill of biological material, the individual(s) who caused the spill is responsible for the clean-up. Montclair State University does not have a spill response team.

- Minimize the consequences of any spill of biological material by performing all work on plastic-backed liner to absorb spills
- Have a simple spill kit on hand including:
  - Chlorine bleach or some other concentrated disinfectant
  - A package or roll of paper towels
  - Autoclavable bags
  - Rubber gloves
  - Forceps for pick-up of broken glass

### **Spills Inside a Biological Safety Cabinet**

1. **LEAVE THE CABINET TURNED ON**  
While wearing gloves, spray or wipe cabinet walls, work surfaces, and equipment with disinfectant equivalent to 1:10 bleach solution. If necessary, flood the work surface, as well as drain pans and catch basins below the work surface, with disinfectant for a contact time of at least 20 minutes
2. Soak up disinfectant and spill with paper towels. Drain catch basin into a container. Lift front exhaust grill and tray and wipe all surfaces. Ensure that no paper towels or solid debris are blown into the area beneath the grill.

3. Autoclave all clean-up materials before disposal in the biohazard waste container. Wash hands and any exposed surfaces thoroughly after the clean-up procedure.

**Small Spill of Material Outside of a Biological Safety Cabinet (Spill that can be covered by a few paper towels)**

1. Wearing gloves and a lab coat, cover the spill with paper towels and gently apply disinfectant, proceeding from the outer edge of the spill to its center. Leave in place for 20 minutes.
2. Pick up the towels and discard into a biohazard container. Pick up any pieces of broken glass with forceps and place in sharps container.
3. Re-wipe the spill area with disinfectant and thoroughly wash hands after glove removal.

**Large Spill of BL2 Material (>500ml) Outside of a Biological Safety Cabinet**

1. Hold your breath and leave the room immediately.
2. Warn others to stay out of the spill area to prevent spread of contamination; post a sign stating: "**DO NOT ENTER, BIOHAZARD SPILL**", contact (name and phone #) for information".
3. Remove any contaminated clothing and put into a biohazard bag for later autoclaving.
4. Wash hands and exposed skin and inform your PI or supervisor about the spill
5. Put on protective clothing (lab coat, gloves and, if indicated, respirator, eye protection, shoe covers) and assemble clean-up materials.
6. Wait 30 minutes before re-entering the contaminated area to allow dissipation of aerosols.
7. Cover the spill with paper towels and gently apply disinfectant, proceeding from the outer edge of the spill to its center. Leave in place for 20 minutes
8. Collect all treated material and discard in a biohazard container. Pick up any broken glass with forceps and place them into a sharps container.
9. Re-wipe the spill area with disinfectant and wash hands thoroughly at completion of clean-up.

**F. Biological Waste Handling**

**Biosafety Level 1- BSL 1 (agents with minimal potential hazard to lab personnel and the environment)**

1. **All Solid waste items** which are potentially contaminated with microorganisms, tissue culture, cell culture, recombinant or synthetic nucleic acid molecules, genetically engineered organisms, or genetically engineered plants regulated by the CDC/NIH or USDA/APHIS at Biosafety Level 1 must be chemically disinfected or autoclaved prior to disposal as regular solid waste trash. Use the appropriate autoclave cycle for the waste, at a temperature of 135oC.
2. **Liquid waste items** must be chemically disinfected or autoclaved prior to drain disposal. Use the appropriate autoclave cycle for the waste type, at a temperature of 135oC.

**Biosafety Level 2 – BSL2 (agents with a moderate potential hazard to lab personnel and the environment)**

1. **Solid waste** items must be chemically disinfected or autoclaved prior to disposal as **Regulated Medical Waste (Overclassified Medical Waste)**. Use the appropriate autoclave cycle for the waste, at a temperature of 135oC and place in a Regulated Medical Waste Container box or bin after decontamination.
2. **Liquid waste** items must be chemically disinfected or autoclaved prior to drain disposal. Use the appropriate autoclave cycle for the waste type, at a temperature of 135oC.

**Regulated Medical Waste-** Wastes associated with contamination by infectious organisms or agents. These potentially infectious or biohazardous materials are defined by NJ regulations as **Regulated Medical Waste\***. **These wastes include the following:**

- All sharps, e.g. glass implements, needles, syringes, blades, etc. coming from facilities using infectious materials
- Biologically cultured stocks and plates, human blood or tissues
- Human blood or tissues

**For disposal of BSL2 Regulated Medical Wastes, the lab personnel:**

1. **Sterilize or disinfect waste materials** associated with viral, bacterial or other agents infectious to humans (by autoclave or chemical treatment equivalent to 1:10 bleach solution).
2. Place all biohazardous wastes, except for sharps, directly into the red bag-lined medical waste boxes provided by the disposal company.
3. Place sharps into labeled sharps containers which when filled are placed into the medical waste box.
4. When the Medical Waste box is filled, seal the bag liner and box and notify Environmental Health and Safety to arrange for pick-up by the disposal company.

**IMPORTANT LABELLING REQUIREMENT: Lab personnel must apply an adhesive-backed label completed with generator information to each container (such filled sharps containers) placed into the medical waste box. The vendor contracted for disposal provides such a label that has space to record Date, Building, Lab #, and Contact Person. Apply this label to all containers placed inside the medical waste box AND to the exterior of the sealed medical waste box before it is made available for pick-up by the disposal company.**

**Other wastes** generated in these facilities that are **not contaminated\*\* with biological agents or materials are not treated as biohazardous** and may be discarded in the regular trash container, with recyclables, or into other specially designated waste containers. These include such items as recyclable and non-recyclable waste glass, gloves, unused plates or tubes, fly media, etc.

\*Regulated Medical Waste - Any solid waste generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals, in the following categories: cultures and stocks (of infectious agents and associated pathological wastes, human blood and blood products, sharps (used or unused), animal waste (contaminated animal carcasses and animal bedding exposed to agents infectious in humans).

\* Non-contaminated applies to any material not having been in contact with an infectious agent. The New Jersey Regulated Medical Waste regulations define infectious agent as “any organism (such as a virus or a bacteria) capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans”.

### **Animal Bedding Waste**

All animal bedding waste is double bagged by animal care personnel and filled only to a depth and weight that will allow for effective tying of the bag by animal facility staff and for ease of handling by one person. (bag weight should not exceed 40 pounds). This will help to prevent motion injury to staff and help to prevent bags from being ripped open while being handled.

### **Animal Carcasses**

Carcasses that have been bagged and sealed in appropriate waste bins are picked up as needed for disposal by a contracted vendor coordinated through the office of Environmental Health and Safety.

**Animal waste must be evaluated by the Principal Investigator and Biosafety Officer to determine if they are potentially infectious due to the research protocol .** If they fall under Biosafety Level 2 (BSL2) animal and/or human viruses, animal bedding, carcasses, and tissue are placed in biohazard bags by the research staff. All animal bedding is autoclaved before being placed in medical waste boxes by animal care staff and disposed of in the medical waste stream. Bagged animal carcasses and tissue are placed in the appropriate freezer storage and removed by animal care staff to medical waste boxes for pick-up as part of the Regulated Medical Waste.

### **Other Permits**

**The transfer and receipt of select biological agents (See Recombinant DNA and Biosafety Policies alphabetical list of select agents and toxins) **must be registered with the CDC or USDA and comply with regulatory requirements.****

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Service (VS) regulates the importation of animals and animal-derived materials to ensure that exotic animal and poultry diseases are not introduced into the United States.

Generally, a USDA veterinary permit is needed for materials derived from animals or exposed to animal-source materials. Materials which require a permit include, animal tissues, blood, cells or cell lines of livestock or poultry origin, RNA/DNA extracts, hormones, enzymes, monoclonal antibodies for IN VIVO use in non-human species, certain polyclonal antibodies, antisera, bulk shipments of test kit reagents, and microorganisms including bacteria, viruses, protozoa, and

fungi. Exceptions to this requirement are human and non-human primate tissues, serum, and blood. They also have information on [animal products that do not require an import permit](#).

Various other animal materials which require a permit include dairy products (except butter and cheese), and meat products (e.g., meat pies, prepared foods) from countries with livestock diseases exotic to the U.S.

Import permit applications may be obtained from the [NCIE home page](#) or by writing the Import/Export Animal Products Program at:

USDA, APHIS, VS, NCIE  
Products Program  
4700 River Road, Unit 40  
Riverdale, MD 20737-1231

For further information or questions concerning import applications, please contact the Animal Products Program at Area Code (301)734-3277 or by facsimile at (301)734-8226

**The importation or domestic transfer of plant and plant pests** are also regulated by the USDA. Information may be obtained by calling 1(877)770-5990 or on the website at <http://www.aphis.usda.gov/ppq/permits/index.html>.

<sup>1</sup>The [NIH Guidelines](#) require submission of a report to the NIH of “any significant problems, violations of the *Guidelines*, or significant research-related accidents or illnesses”. The *Guidelines* also require reporting to State and local authorities any research-related accident or injury that may be hazardous to public health.

## **VII. Montclair State University Reference Policies**

- 1. Radiation Safety Policy**
- 2. Asbestos Management Plan**
- 3. Bloodborne Pathogens**
- 4. Chemical Hygiene Plan**
- 5. IACUC Policies**
- 6. IRB Policies and Procedures**
- 7. MSU general policy link: <https://www.montclair.edu/policies/university/>**