



ISMMS
BIOLOGICAL
SAFETY MANUAL
Biomedical Research Laboratories

**ISMMS Biological
Safety Program**

**ICAHN SCHOOL OF MEDICINE
AT MOUNT SINAI**
**1 Gustave L. Levy Place, New
York, NY 10029**

June 2022



Table of Contents

Tables.....	4
Table of Figures.....	4
Quick References for Biological Safety	5
Oversight of research involving biohazardous materials.....	5
Chapter 1. Introduction to Biological Safety.....	6
Non-Compliance & Disciplinary Actions	7
Chapter 2. Occupational Health and Safety Program (OHSP).....	8
Employee Health Services (EHS)	8
Vaccinations.....	8
Respiratory Protection Program	8
Bloodborne Pathogens (BBPs) Exposure Control	9
Standard Precautions.....	10
Cell and Tissue Culture Experiments.....	10
Laboratory-Acquired Infections (LAI).....	11
Laboratory Animal Occupational Health Program (LAOHP)	11
Graduate and Medical Education Requirements.....	12
Chapter 3: Biosafety Regulations & Guidelines	13
NIH Guidelines	13
Experiments Covered by the NIH Guidelines.....	13
Exempt Experiments	13
Non-Exempt Experiments	14
Poliovirus Eradication and Containment	17
Biological Select Agents and Toxins	18
Dual Use Research of Concern (DURC)	19
Chapter 4: Biological Risk Assessment.....	21
Hazardous Characteristics of an Agent.....	21
Biological Risk Assessment.....	21
Chapter 5: Pathogens and Toxins	23
Biosafety Level 1	23
Biosafety Level 2	23
Biosafety Level 3	23
Biosafety Level 4	23
Chapter 6: Vertebrate Animal Biomedical Research	26

Animal Biosafety Level 1	26
Animal Biosafety Level 2	26
Animal Biosafety Level 3	26
Animal Biosafety Level 4	26
Chapter 7: Safety Practices and Equipment	28
Standard Precautions	28
Personal Protective Equipment (PPE)	28
Laboratory Coat Program	29
Signs and Hazard Communications	29
Freezer Monitoring Program	30
Engineering controls	30
Heating, Ventilation and Air Conditioning (HVAC)	30
Centrifuges	30
Biological Safety Cabinets (BSCs)	31
Laminar Flow Cabinet	32
Downdraft tables	33
Chemical Fume Hoods	33
Vacuum Lines	34
Chapter 8: Disinfectants and Sterilization	35
Decontamination	35
Non-Ionizing Radiation	35
Vapors and Gases	35
Chemical Disinfectants	35
Sterilization	36
Steam Sterilizers (Autoclaves)	36
Dry-Heat Sterilizers	37
Chapter 9: Regulated Waste Management	38
Institutional Compliance	38
Research Laboratory Compliance	39
Uncontaminated Laboratory Glassware and Broken Glass	39
Sharps Waste	39
Chapter 10: Hazardous Materials/Dangerous Goods Shipments	41
Key Definitions	41
Dangerous Goods Classifications	41
Environmental Health & Safety (EnvH&S)	42

Permits 42

Chapter 11: Training Program..... 45

Chapter 12: Laboratory Closure & Equipment Removal or Disposal..... 47

 Lab Closeout Procedures 47

 Disposal of Used Lab Equipment 47

Chapter 13: Emergency Response Planning 49

 Natural Disasters..... 49

 Electrical Power Failure..... 49

 Water Leaks 49

 Responding to Biohazardous Spills 49

 Small spill response..... 49

 Large spill response..... 50

 Medical Emergency..... 51

 Response to Occupational Exposure 51

 Needlestick / Blood or Body Fluid Exposure (BBFE) 52

Tables

Table 1. Institutional entities providing regulatory oversight of research with biohazardous material. 5

Table 2. Listing of Exempt Experiments 15

Table 3. Experiments requiring IBC approval..... 16

Table 4. Permissible Toxin Amounts Excluded from the Select Agent Regulations (SAR)..... 18

Table 5. Scope of Research Requiring Oversight 20

Table 6. Classification of infectious microorganisms by Risk Group..... 22

Table 7. Recommended Biosafety Levels for Pathogens. 25

Table 8 Recommended Biosafety Levels for Activities in Which Infected Vertebrate Animals Are Used.. 27

Table 9. Regulatory agencies issuing permits for biohazardous materials..... 43

Table 10. training requirements for all laboratory personnel 46

Table of Figures

Figure 1. Institutional Coordination of the Biological Safety Program. 6

Figure 2. PPE reduces risk for occupational exposure to pathogens..... 28

Figure 3. Vacuum lines protected with High Efficiency Particulate Air (HEPA) filters. 34

Figure 4. Autoclave-safe red biohazard bag. 36

Figure 5. red RMW disposal bag with Mount Sinai Address (blue arrow)..... 38

Figure 6. Regulated Medical Waste Disposal Guide for Laboratories. 40

Figure 7. Category A Packaging for UN 2814 or UN 2900 (CDC)..... 44

Figure 8. Category B Packaging for UN 3373 Biological Substances (CDC)..... 44

Quick References for Biological Safety

The Icahn School of Medicine at Mount Sinai (ISMMS) maintains the highest standards for transparent and ethical conduct of research, in compliance with city, state, federal, and international guidance and regulations. Principal Investigators must have institutional approval to work with biological hazards, animals, and/or human subjects (**Table 1**). The [Research Roadmap](#) is a central hub for navigation of the Mount Sinai Health System (MSHS) research enterprise.

TABLE 1. INSTITUTIONAL ENTITIES PROVIDING REGULATORY OVERSIGHT OF RESEARCH WITH BIOHAZARDOUS MATERIAL.

Entity	Oversight	Website
IBSP	Biological safety	https://icahn.mssm.edu/research/institutional-biosafety
EnvH&S	Chemical safety	https://www.mountsinai.org/about/compliance/environmental-health-safety
IBC	rDNA or SNA, infectious agents, and Select Agents & Toxins	https://icahn.mssm.edu/research/ibc
IACUC	Research with animals	https://icahn.mssm.edu/research/iacuc
PPHS	Research with human subjects	https://icahn.mssm.edu/research/pphs

Oversight of research involving biohazardous materials

The [ISMMS Biological Safety Program](#) monitors all laboratory activities that involve biological hazards that may present a risk to the laboratory personnel, volunteers, visitors, and the environment. Registration of biomedical research conducted at Mount Sinai with the IBC, IACUC, and IRB generates a database of biohazardous material, which will help refine biosafety, biocontainment, and biosecurity at Mount Sinai.

Environmental Health & Safety (EnvH&S) promotes a safe and healthy campus environment, and oversees Laboratory Safety, Occupational Safety and Health (OSH), Radiation Safety, and shipping of dangerous goods. EnvH&S manages the laboratory safety management platform, [SECTOR](#), which aids in the development of required documentation and is used to track laboratory safety compliance.

The Laboratory Safety Committee, a [Committee of the Dean](#), is responsible for the oversight of the health and safety of employees, students, volunteers, and visitors in the biomedical research laboratories.

If your research project involves biological hazards, then approval by the IBC is required. PIs must submit IBC registrations at [eSAFETY](#).

If your research project involves animals, then approval by the IACUC is required. PIs must submit IACUC protocols at [eIACUC](#).

The Institutional Review Board (IRB), as one component of the [Program of the Protection of Human Subjects \(PPHS\)](#), is responsible for assessing and approving all research at the Medical School that is to be

conducted in human subjects. If your research project involves human subjects, then protocols must be submitted through the IRB electronic submission and application-tracking platform [RUTH](#).

Chapter 1. Introduction to Biological Safety

The safety culture of an institution is a reflection of the actions, attitudes, and behaviors of its members concerning safety. These members include the managers, supervisors, and employees in the industrial and governmental communities; and the faculty, staff, and students in the academic community. Serious chemical or laboratory incidents within an organization are often thought to be the result of a weak or deficient safety culture—a principal root cause of the incident.¹

Mount Sinai is committed to establishing and maintaining a “Culture of Safety”, which is viewed as an institutional priority. Establishing and maintaining a “Culture of Safety” results in better reproducibility and productivity of the research, and prevents laboratory incidents that may result in injury, loss of life, and loss of scientific knowledge. A “Culture of Safety” must be a fundamental part of the scientific process. Biological safety is integral to establishing and maintaining a “Culture of Safety”, and adherence to biological safety practices will ensure the safety of laboratory personnel, visitors, and the environmental. The ISMMS Biological Safety Manual contributes to the foundation upon which a “Culture of Safety” can be established. The principles of biological safety described herein apply to our research laboratories, classrooms, and clinical settings. Maintaining a culture of safety requires continuous assessment, discussion, changes, and reinforcement of policies and procedures, and responsiveness by the ISMMS Biological Safety Program.

The ISMMS Biological Safety Program coordinates with the Institutional Biosafety Committee (IBC), Institutional Animal Care & Use Committee (IACUC), Employee Health Services (EHS), Environmental Health & Safety (EnvH&S), and the Laboratory Safety Committee (LSC) (**Figure 1**). The ISMMS Biological Safety Manual was developed after careful review of pertinent federal, state, and city government regulatory documents, along with guidance documents from the Centers for Disease Control and Prevention, the National Institutes of Health, and the World Health Organization.

The ISMMS Biological Safety Manual complements the [Chemical Hygiene Plan & Clinical and Research Laboratory Safety Manual](#) developed by EnvH&S. The Chemical Hygiene Plan (CHP) applies to faculty, staff and students on all campuses engaged in the laboratory use of hazardous materials, including those covered under the Occupational Health and Safety (OSHA) Standard 29 CFR 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories (referred to as the Laboratory Standard). The ISMMS Biological Safety Manual is a living document, which is updated as necessary to address ever-changing federal, state, and city government regulations and guidance documents.

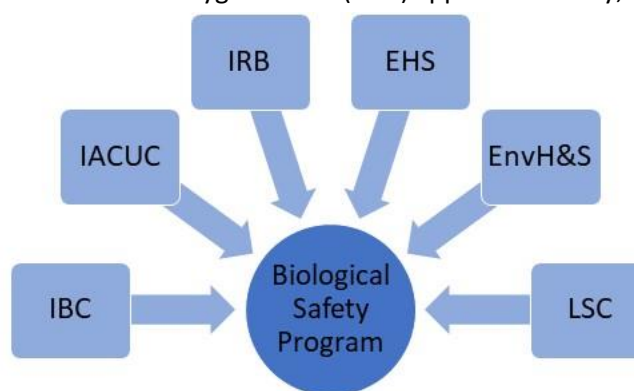


FIGURE 1. INSTITUTIONAL COORDINATION OF THE BIOLOGICAL SAFETY PROGRAM.

¹Hill Jr., R.H., et al., Creating Safety Cultures in Academic Institutions: A Report of the Safety Culture Task Force of the ACS Committee on Chemical Safety. 2012: Washington, DC. p. 63.

Non-Compliance & Disciplinary Actions

A biological safety infraction occurs when an individual(s) is negligent in following established biological safety practices and procedures described in this Biological Safety Manual or the Chemical Hygiene Plan & Clinical and Research Laboratory Safety Manual developed by EnvH&S.

Minor infringements of biological safety² are identified during routine inspections of research and clinical laboratories by Biological Safety and/or Laboratory Safety Professionals. Minor infringements of biological safety are communicated to the Principal Investigator (PI), who is given a timeframe to correct the infringement that is commiserate with the severity of the infringement.

Major deviations from biological safety practices and policies will result in a formal inspection or review by the ISMMS Biological Safety Program. If a formal inspection or review is necessary, the Director of Biosafety may obtain additional information by direct communication with the Principal Investigator (PI), laboratory personnel, or co-workers; review of laboratory procedures; IBC registrations; and/or training records. As necessary, the Director of Biosafety or other Biological Safety Professional may conduct unannounced laboratory or facility inspections. Following the inspection or review, the Director of the Biosafety Program will communicate to the PI and the designated Laboratory Safety Officer (LSO) the summary of the review and required corrective actions and response timeline. In situations where satisfactory resolution is not achieved in a timely manner, notifications will be elevated to the Laboratory Safety Committee (LSC) and department chairperson or institute director. Incidents involving exposure to recombinant DNA or synthetic nucleic acids (SNA) must be reported to the Biological Safety Officer (BSO), who must report the exposure incident to the Institutional Biosafety Committee (IBC) and the NIH Office of Science Policy.

Laboratory inspection reports are stored in the SECTOR database. All documented minor infringements or major deviations are kept on file with the ISMMS Biological Safety Program. The ISMMS Biological Safety Program will conduct annual reviews of all documented infractions to determine the type and frequency of infractions on an annual basis.

The Director of Biosafety or the LSC may suspend research activities if there is a significant threat to public health or compromise of safety and regulatory compliance. Committee enforcement or disciplinary action may include, but is not limited to, a letter of reprimand from the Director of Biosafety or the LSC Chair, mandatory retraining, a compliance inspection, and/or suspension or termination of IBC approval.

Willful or negligent violation of established biosafety practices and policies, or continuation of research activities after notification by the Director of Biosafety will be deemed research misconduct. The Research Integrity Officer will be notified for administrative review and determination of action.

Mount Sinai will protect any employee or student who reports a biosafety-related concern against retaliation and will address good faith allegations of such retaliation. Every effort will be made to protect the individual's confidentiality in accordance with Mount Sinai policy. Any individual who has biosafety-related concern may:

- Contact the Biological Safety Program by [email](#)
- Contact the Institutional Biosafety Committee (IBC) by [email](#) or by phone (212-241-0704)
- Contact the Environmental Health & Safety (EnvH&S) by [email](#) or by phone (212-241-7233 (*4SAFE))

² Minor infringements of biological safety include lapses in required biological safety training, lack of personal protective equipment, lack of required hazard communications, etc....

Chapter 2. Occupational Health and Safety Program (OHSP)

Employee Health Services (EHS)

Employee Health Services (EHS) provides services to all employees within the Mount Sinai Health System and the Icahn School of Medicine at Mount Sinai. EHS offers evaluation and treatment for work-related illnesses and injuries, performs return-to-work evaluations, administers the Workplace Accommodations Program, and administers medical surveillance programs, including testing and immunizations mandated by OSHA, New York State, New York City, and Mount Sinai.

Medical surveillance testing may be required for researchers who directly handle biohazardous materials or for laboratory visitors who are potentially exposed to biohazardous materials. Depending on the biohazardous material and the scope of research, medical surveillance testing may be required. The IBC, Biosafety, and EHS will determine optimal surveillance testing protocols. Each laboratory member must complete an Annual Health Assessment, which is reviewed by EHS to: i) assess personnel health fitness to work in the laboratory environment, ii) ensure that vaccination status against bloodborne pathogens is up-to-date, and iii) provide individual counseling as needed.

Vaccinations

Appendix G of the April 2019 *NIH Guidelines* indicates, “If a research group is working with a known pathogen for which there is an effective vaccine, the vaccine should be made available to all workers.” EHS in conjunction with the IBC, Infection Control, and Biological Safety Professionals will determine recommendation for the use of vaccinations on a case-by-case basis. Risk assessment and vaccine recommendations are based on agent, strain, scope of research, transmission routes, potential hazards associated with the procedures, and health status of the employee. EHS offers personnel working with pathogens prophylactic vaccinations when available (e.g., influenza vaccine for people involved in research on influenza viruses). Individuals that decline required vaccination must sign a declination form. EHS would follow up with counseling the employee regarding TB status, Tetanus, flu immunizations, other health reported conditions and recommend accommodations as necessary. Vaccine recommendation assessments are performed for employees working directly with pathogens. EHS may not provide vaccines to laboratory personnel or visitors who do not directly handle pathogens, and who should contact their primary care physician.

Respiratory Protection Program

The Occupational Safety and Health Administration’s (OSHA) Standard (29 CFR 1910.134, [Respiratory Protection](#)), requires Mount Sinai to develop a written Respiratory Protection Program, which describes required worksite-specific procedures and elements for required respirator use. The Respiratory Protection Program mandated by OSHA requires Mount Sinai to provide respirators that protect employees from inhalation of hazardous materials that cannot be controlled by engineering or administrative controls. Mount Sinai must provide effective annual training to employees who are required to use respirators. The Respiratory Protection Program shall be updated as necessary to reflect

those changes in workplace conditions that affect respirator use. As required by the OSHA Standard, [Respiratory Protection](#), Mount Sinai must ensure that each employee can demonstrate knowledge of at least the following:

1. Why the respirator is necessary and how improper fit, usage, or maintenance can compromise the protective effect of the respirator.
2. The limitations and capabilities of the respirator.
3. How to use the respirator effectively in emergencies, including situations in which the respirator malfunctions.
4. How to inspect, put on and remove, use, and check the seals of the respirator.
5. The procedures for maintenance and storage of the respirator.
6. How to recognize medical signs and symptoms that may limit or prevent the effective use of respirators.
7. The general requirements of the Standard.

Environmental Health and Safety (EnvH&S) policy EH-SAF11-1, *Respiratory Protection Requirements*, defines the requirements for the proper use of respirators. Respirators are issued to individuals for protection against airborne contaminant(s) and only after completion of required medical evaluation, training, and practical fit test. Respirators must not be worn for any other purpose without the knowledge and approval of the supervisor and EnvH&S.

Prior to working in areas requiring respiratory protection, employees must undergo medical evaluation by Employee Health Services (EHS) and complete fit testing for tight-fitting respirators. The employee must complete the Respirator Medical Evaluation Questionnaire (for first-time fit-test applicants) or the Periodic Medical Questionnaire (for reevaluation of existing respirator users), which is then reviewed by EHS. Based on the overall health assessment, EHS will determine fitness-for-duty and whether or not to restrict the employee from wearing respiratory protective equipment. Employees shall not be assigned to tasks requiring the use of respirators unless it has been determined by EHS and EnvH&S that the employee can perform duties while wearing the respirator and any other protective clothing. If a medical restriction is applied, the employee, his/her supervisor, and the Program Administrator are formally notified of the restriction.

EnvH&S policy EH-SAFP11-1, *Respiratory Protection Evaluation, Fit Testing, and Certification Procedure*, provides details for individuals who fail to successfully complete fit testing for N95 filtering face piece respirators, whether due to medical conditions or an inability to obtain a proper fit. Individuals who do not pass a respirator fit testing will be required to wear a powered air-purifying respirator (PAPR) on occasions where they might normally wear a filtering face piece. The PAPR is a positive-pressure alternative to the filtering face piece, usually employing a loose-fitting hood or helmet with a filtering component or blower. Because it is positive pressure, its effectiveness is not dependent upon a proper seal.

Bloodborne Pathogens (BBPs) Exposure Control

The Occupational Safety and Health Administration (OSHA) issued the [Bloodborne Pathogens Standard](#), 29 CFR 1910.1030, mandates implementation of safety measures where there is occupational exposure to blood or other potentially infectious materials (OPIM). The Bloodborne Pathogens Standard was amended by the 2000 Needlestick Safety and Prevention Act, which requires Mount Sinai to “evaluate, select, and use engineering controls (e.g., sharps with engineered sharps injury protections or needleless systems) to eliminate or minimize exposure to contaminated sharps.” The Bloodborne Pathogens

Standard addresses all bloodborne pathogens that can cause disease in humans, including hepatitis B (HBV), hepatitis C (HCV), and human immunodeficiency virus (HIV). As required by OSHA's Bloodborne Pathogens Standard, the ISMMS Exposure Control Plan (ECP) developed by the ISMMS Biological Safety Program details safeguards to protect employees and students against health hazards related to bloodborne pathogens, including use of administrative and engineering controls, personal protective equipment (PPE), employee training, medical surveillance, hepatitis B vaccinations, and other protective measures. The Mount Sinai Employee Health Services (EHS) administers the Needlestick/Blood Borne Pathogen Exposure program. The [CITI Program](#) module, *OSHA Bloodborne Pathogens*, partially addresses the training requirements established by the OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030. All ISMMS employees and students whose work involves potential exposure to HIV, HBV, HCV and other bloodborne pathogens must complete the CITI Program course, *OSHA Bloodborne Pathogens*.

Standard Precautions

The Bloodborne Pathogens Standard introduced the concept of Standard Precautions, which is an approach to infection control whereby all human blood and body fluids are treated as if known to be infectious for HBV, HCV, HIV or other bloodborne pathogens.

The application of Standard Precautions refers to the practice of administrative and engineering controls and use of personal protective equipment to prevent exposure to with bloodborne pathogens and other potentially infectious materials (OPIM). All research and clinical laboratories should have access to a biological spill kit or access to supplies for cleaning and decontaminating spills of human blood or other potentially infectious materials (OPIM). Standard Precautions applies to the handling of all soiled laundry, including laboratory coats.

Cell and Tissue Culture Experiments

Research with human or animal cells and tissues present potential laboratory hazards, including exposure to bloodborne pathogens, e.g., Hepatitis B virus (HBV), Hepatitis C virus (HCV), and Human Immunodeficiency Virus (HIV), and adventitious agents that may be present in those cells and tissues, e.g. *Mycobacterium tuberculosis*, *Streptococcus*, *herpesviruses*, etc.). Culturing of cells transformed with viral agents such as simian vacuolating virus 40 (SV40), Epstein-Barr virus (EBV), or hepatitis B virus (HBV), cells carrying viral genomic material, or tumorigenic human cells presents occupational risks to laboratory personnel. Culture of human or animal cells, which are known to contain or are suspect of containing an infectious agent should be handled at the same biosafety level as for the infectious agent. The following list of potentially infectious material must be handled at minimum with Standard Precautions and BSL-2 practices:

- All human blood, blood products, unfixed human tissue, and body fluids,
- Non-human primate blood, blood products, unfixed human tissue, and body fluids,
- All primary cell lines,
- Secondary (immortalized) cell lines,
- Cell lines exposed to or transformed by a human or primate oncogenic virus,
- Pathogen deliberately introduced or known endogenous contaminant, and
- Fresh or frozen tissue explants.

A common-sense approach to performing tissue culture experiments is to:

- Consider the cells and/or tissue as potentially infectious material,
- Use biological safety cabinets and other aerosol prevention practices, and
- Use standard microbiological practices.

Laboratory-Acquired Infections (LAI)

Laboratory-acquired infections (LAIs) refer to all infections acquired through laboratory work or laboratory-related activities with or without the onset of infections, and result from occupational exposure to pathogens. It is the joint responsibility of the Principal Investigator (PI), the designated Laboratory Safety Officer, and the laboratory staff to develop and adhere to the institutional safety protocols that are designed to reduce the risk of laboratory-acquired infections and laboratory incidents.

The predominant probable routes of laboratory-acquired infection (LAI) are:

1. Direct skin, eye or mucosal membrane exposure to an agent,
2. Parenteral inoculation by a syringe needle or other contaminated sharp, or by bites from infected animals and arthropod vectors,
3. Ingestion of liquid suspension of an infectious agent, or by contaminated hand to mouth exposure, and
4. Inhalation of infectious aerosols.³

The American Biological Safety Association, ABSA International, developed a [Laboratory-Acquired Infection \(LAI\) Database](#) to capture documented laboratory-acquired infections and relevant information, such as nature of the incident, if known, and use of personal protective equipment. Monitoring Laboratory-Acquired Infections will identify high-risk procedures that should be refined, identify additional training requirements, need for additional personal protective equipment, and/or changes to administrative or engineering controls. In 2018, Employee Health Services documented twenty-two (22) Blood and Body Fluid Exposures (BBFE), which could result in LAI.

Laboratory Animal Occupational Health Program (LAOHP)

Center for Comparative Medicine and Surgery (CCMS) staff who must tend to animals exposed to biohazardous materials are required to participate in a medical surveillance program as part of fitness-for-duty requirements prior to performing these at-risk tasks. This includes personnel who work with purposefully inoculated animals, as well as those that work with animals that may be infected with zoonotic agents not related to the research, such as non-human primates infected with Macacine herpesvirus 1. CCMS will work with Biosafety and the Employee Health Services to identify animal handlers who may be at risk for occupational exposure to biohazardous material, including infectious pathogens, while performing their duties.

Mount Sinai policy requires enrollment in the LAOHP by all faculty, staff students, and visitors who work directly with vertebrate animals, unfixed animal tissues or body fluids, and those who work in animal housing areas. As mandated by the NIH/Office of Laboratory Animal Welfare (OLAW), Employee Health Services (EHS) administers the LAOHP, which is an essential part of the overall program of animal care and use. As part of the LAOHP, Employee Health Service (EHS) reviews annual health assessments for personnel working with or caring for experimental animals within CCMS facilities. *The primary goals of the LAOHP are to:*

³ Aerosols are a serious hazard because they are ubiquitous in laboratory procedures, are usually undetected, and are extremely pervasive. Aerosols place the laboratory worker carrying out the procedure and other persons in the laboratory at risk of infection.

- *Protect individuals from work-related risks associated with exposure to animals through a program of species-specific health information, education, and risk-based medical evaluation,*
- *Protect the health of research animals from certain transmissible diseases,*
- *Be pertinent to the species with which individuals are exposed and the work they perform,*
- *Be minimally intrusive, and*
- *Be cost-effective*

In order to comply with Occupational Health and Safety (OSHA) federal regulations, Mount Sinai requires all employees potentially exposed to biohazardous materials (e.g. allergens, toxins, chemicals, pathogens, or radioactive materials) during research involving vertebrate animals to complete an annual Occupational Health and Safety Questionnaire (OHSQ) for employees with exposure to laboratory animals. The OHSQ is available online through [Sinai Central](#). The employee completes the first section of the questionnaire, Part A, which provides a risk assessment with specific queries regarding potential exposure to animal and hazardous agents. The Biological Safety Program and EHS review Part A of the OHSQ. Part B of the OHSQ is a HIPAA-compliant, confidential health assessment that captures personal health information provided by the employee, which is reviewed only by EHS medical personnel.

Review of Part A of the OHSQ by a Biological Safety Professional, and of the full document by EHS provides the basis for risk assessment and evaluation of potential health dangers for individuals exposed to animals and hazardous agents in the vivarium and in the lab. When appropriate, both EHS and a Biological Safety Professional would offer counseling and advice regarding specific ways and means to minimize risks as well as potential health consequences associated with exposure to these agents. As necessary, EHS will ensure that the vaccination status of the individual against bloodborne pathogens is current.

Investigators are required to identify in their initial Institutional Animal Care and Use Committee (IACUC) protocols all hazardous agents (chemical/biological/radiological) to be used in their studies involving vertebrate animals. The responsibility of the ISMMS Biological Safety Program is to review the proposed use of all biohazardous material and determine the hazard level. A review of the use of biohazardous materials is conducted by the Institutional Biosafety Committee (IBC) when required by federal regulations (recombinant DNA and genetically modified organisms), if research involves Risk Group 2, 3, or 4 agents (pathogens or toxins), or as requested by the IACUC. Investigators, with the advice of the Radiation and Biological Safety Professionals and/or CCMS veterinarians, must develop standard operating procedures (SOP) that describe the storage and use of biohazardous material in their laboratories. The Biological Safety Professionals review the SOPs.

Graduate and Medical Education Requirements

Students enrolled at the Icahn School of Medicine at Mount Sinai (ISMMS) have access to the on-campus [Student Health Center and Student/Trainee Mental Health Clinic](#). The Student Health Center offers physical exams, illness visits, vaccine administration, sexually transmitted infection and HIV testing, gynecologic exams, and medication refills. Graduate and Medical students must comply with the [Immunization Policy](#) outlined in the [Student Handbook and Policies](#).

Chapter 3: Biosafety Regulations & Guidelines

NIH Guidelines

The National Institutes of Health (NIH) regulate the use of recombinant DNA (rDNA) and synthetic Nucleic Acids (sNA). The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, April 2019, ([NIH Guidelines](#)) detail safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules. The Icahn School of Medicine at Mount Sinai, as an institution receiving research funds from the NIH, is subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, April 2019 ([NIH Guidelines](#)). As mandated by the *NIH Guidelines*, the Institutional Official has appointed an Institutional Biosafety Committee (IBC) to ensure that the research that the Institution conducts or sponsors complies with the *NIH Guidelines*, regardless of the source of funding. Following the NIH Guidelines is the responsibility of all investigators at Mount Sinai and not solely that of investigators that are funded by NIH. The IBC provides additional evaluation of protocols involving human subjects or animals.

Each Mount Sinai Principal Investigator (PI) who uses or possesses Recombinant DNA or synthetic Nucleic Acids (sNA), biohazardous agents/pathogens, and/or biological toxins must register his/her research with the IBC. The IBC registration must describe all biohazards, experimental procedures, and safety protocols associated with the research program. This policy applies to all independent Principal Investigators. Collaborators may not "piggy-back" on another Principal Investigator's IBC registration. Postdoctoral or Clinical fellows, graduate or undergraduate students, technicians, scientists are covered by the registrations of their PI. The Principal Investigator (PI) is ultimately responsible for the registration, training, and safe handling of biohazardous materials handled by their personnel.

Experiments Covered by the NIH Guidelines

Exempt Experiments

The *NIH Guidelines* specify several categories of rDNA/sNA molecules. One of the most important categories is the Exempt category. Experiments that qualify for this category do not require registration with the Institutional Biosafety Committee. Section III, Category F of the *NIH Guidelines* outlines the criteria to exempt experiments from the *NIH Guidelines*. **Table 2** summarizes the recombinant or synthetic nucleic acid molecules that are exempt from the *NIH Guidelines* and do not require registration with the Institutional Biosafety Committee. However, other federal and state standards of biosafety may still apply to such research. For example, the Centers for Disease Control and Prevention (CDC)/NIH publication *Biosafety in Microbiological and Biomedical Laboratories*, Fifth edition.

Section III-E covers experiments that require IBC notice simultaneous with initiation. This section covers experiments involving the formation of Recombinant or Synthetic Nucleic Acid Molecules containing no more than two-thirds of the genome of any eukaryotic virus. This section also covers BSL-1 experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of Recombinant or Synthetic Nucleic Acid Molecules, or nucleic acids derived therefrom, into the germ-line (i.e. transgenic rodents).

Non-Exempt Experiments

If the experiment does not fall within one or more of the exempt categories (**Table 6**), then you must obtain approval of the research by the IBC. **Table 3** summarizes the types of experiments using recombinant DNA (rDNA) and synthetic nucleic acids (sNA) that require regulatory approval.

Section III-A covers experiments that require NIH Director approval and IBC approval before initiation. The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (such that the transfer of a drug resistance trait compromises the ability to control disease agents in humans, veterinary medicine, or agriculture) requires NIH Director approval.

Section III-B covers experiments that require NIH Office of Science Policy (OSP) and IBC approval before initiation. Deliberate formation of recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD₅₀ of less than 100 nanograms per kilogram body weight (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, and *Shigella dysenteriae* neurotoxin).

Section III-C covers experiments involving the deliberate transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into one or more human research participants (i.e. Human Gene Transfer studies).

Section III-D covers experiments that require IBC approval before initiation. This section covers:

- Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems;
- 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;
- 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;
- Experiments involving whole animals;
- Experiments involving more than 10 liters of culture; and
- Experiments involving influenza viruses.

TABLE 2. LISTING OF EXEMPT EXPERIMENTS

Are the nucleic acids designed to: (1) neither replicate nor generate nucleic acids that can replicate in any living cell, and (2) not integrate into DNA, and (3) not produce a toxin that is lethal for vertebrates at an LD ₅₀ of less than 100 nanograms per kilogram body weight?	Yes	Section III-F-1
Are the nucleic acids not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes?	Yes	Section III-F-2
Do the nucleic acids consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature?	Yes	Section III-F-3
Do the nucleic acids consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host, or when transferred to another host by well-established physiological means?	Yes	Section III-F-4
Do the nucleic acids consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host?	Yes	Section III-F-5
Do the nucleic acids consist entirely of DNA segments from different species that exchange DNA by known physiological processes ⁴ , though one or more of the segments may be a synthetic equivalent?	Yes	Section III-F-6
Do the genomic DNA molecules contain a transposable element that does not contain any recombinant and/or synthetic DNA?	Yes	Section III-F-7
Do the nucleic acids present a significant risk to health or the environment (see Section IVC-1-b-(1)-(c), Major Actions), as determined by the NIH Director following appropriate notice and opportunity for public comment. See Appendix C, Exemptions under Section III-F-8 for other classes of experiments, which are exempt from the NIH Guidelines.	No	Section III-F-8

⁴ See Appendices A-I through A-VI, *Exemptions under Section III-F-6--Sublists of Natural Exchangers*, for a list of natural exchangers that are exempt from the *NIH Guidelines*.

TABLE 3. EXPERIMENTS REQUIRING IBC APPROVAL.

Experiment	Section	Approval requirements
Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine or agriculture.	(III-A-1)	Require NIH Director approval and IBC approval before initiation.
Cloning of DNA, RNA or synthetic nucleic acid molecules encoding toxins lethal to vertebrates at an LD ₅₀ of <100 ng/kg body weight.	(III-B-1)	Require NIH Office of Science Policy (OSP) and IBC approval before initiation.
Transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules into human research participants.	(III-C-1)	Require IBC approval prior to initiation.
Risk Group 2, Risk Group 3, Risk Group 4 or Restricted Agents used as Host-Vector Systems.	(III-D-1)	Require IBC approval before initiation.
DNA from Risk Group 2, Risk Group 3, Risk Group 4 or Restricted Agents cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.	(III-D-2)	Require IBC approval before initiation.
Infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems.	(III-D-3)	Require IBC approval before initiation.
Whole animals, including transgenic animals.	(III-D-4)	Require IBC approval before initiation.
Large-scale DNA work.	(III-D-6)	Require IBC approval before initiation.
Influenza virus.	(III-D-7)	Require IBC approval before initiation.
Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus	(III-E-1)	Require IBC Notice Simultaneous with Initiation
Experiments Involving Transgenic Rodents	(III-E-3)	Require IBC Notice Simultaneous with Initiation

Poliovirus Eradication and Containment

Three wild-type strains of poliovirus (WPV) circulated among humans: WPV Type 1, Type 2, and Type 3. People need to be protected against all three types of the virus in order to prevent polio disease and the polio vaccination is the best protection. Due to the success of polio vaccination programs with live attenuated polio vaccines (OPV) and inactivated polio vaccines (IPV), the United States has been polio-free since 1979. Due to the success of global polio vaccination programs, WPV Type 2 was declared eradicated in September 2015, and WPV Type 3 was declared eradicated in October 2019. WPV Type 1 continues to circulate in regions outside the United States.

Laboratories and other facilities that handle or store poliovirus or material potentially contaminated with poliovirus pose a risk for the re-introduction of poliovirus in the United States. Poliovirus containment is critical to minimize the risk of the virus getting into the environment and causing harm.

Toward the goal of global eradication of wild-type strains of poliovirus, the World Health Organization developed the Global Action Plan (GAPIII)⁵ that describes implementation of poliovirus safe-handling and containment measures to minimize the risks of a facility-associated reintroduction of virus into the polio-free community. In January 2018, the U.S. Department of Health and Human Services established The US Poliovirus National Authority for Containment of Poliovirus (NAC), located in the Centers for Disease Control and Prevention, Center for Preparedness and Response. The NAC is responsible for implementing GAPIII in the United States.

Currently, poliovirus type 2 (PV2), which includes wild poliovirus (WPV), vaccine-derived poliovirus (VDPV), or oral polio vaccine (OPV) infectious materials (IM), are subject to GAPIII containment. Other potentially infectious material (OPIM) includes stool or respiratory specimens that originate from areas with a high prevalence of poliovirus. Laboratories storing poliovirus OPIM containing poliovirus are encouraged to reevaluate the scope of research with these viruses, implement inventory control, and/or destroy any unneeded materials. If you are currently working with poliovirus or materials that may contain poliovirus contact the ISMMS Biological Safety Program.

⁵ WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use. World Health Organization. 2015. http://polioeradication.org/wp-content/uploads/2016/12/GAPIII_2014.pdf

Biological Select Agents and Toxins

The Federal Select Agent Program (FSAP) is jointly comprised of the Centers for Disease Control and Prevention/Division of Select Agents and Toxins (CDC/DSAT) and the Animal and Plant Health Inspection Service/Agriculture Select Agent Services (APHIS/AgSAS). The FSAP oversees the possession, use and transfer of biological select agents and toxins (BSAT), which have the potential to pose a severe threat to public, animal or plant health or to animal or plant products. The possession, use and transfer of BSAT are governed by three codes of federal regulation that are collectively referred to as Select Agent Regulations (SAR), which evolved from the 1996 Antiterrorism and Effective Death Penalty Act, the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001, and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

If the amount of toxin under the control of a Principal Investigator (PI), treating physician or veterinarian, or commercial manufacturer or distributor does not exceed, at any time, the amounts indicated in **Table 4**, then the indicated toxin is not subject to the Select Agent Regulations (SAR)^{6,7}.

TABLE 4. PERMISSIBLE TOXIN AMOUNTS EXCLUDED FROM THE SELECT AGENT REGULATIONS (SAR).

Permissible Toxin Amounts	
HHS Toxins	Amount
Abrin	1000 mg
Botulinum neurotoxins	1 mg
Short, paralytic alpha conotoxins	100 mg
Diacetoxyscirpenol (DAS)	10,000 mg
Ricin	1000 mg
Saxitoxin	500 mg
Staphylococcal Enterotoxins (Subtypes A, B, C, D, and E)	100 mg
T-2 toxin	10,000 mg
Tetrodotoxin	500 mg

Mount Sinai is registered with the FSAP. A Principal Investigator (PI) that intends to possess, use, or transfer any BSAT must contact the Responsible Official for the Select Agents and Toxins Program to

⁶ The Select Agent Regulations require the Principal Investigator use “due diligence” when transferring an amount of an HHS select toxin otherwise excluded under the Regulations. This provision requires the Principal Investigator to take reasonable actions to ensure that the recipient:

- Is eligible to receive the select toxin (Principal Investigator, treating physician or veterinarian, or commercial manufacturer or distributor).
- Has a legitimate need (i.e., reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such select toxins.

⁷ The Principal Investigator must maintain accurate inventory records of the select toxin, including the transfer of unregulated amounts of the toxin.

discuss potential amendment of the institutional registration with the FSAP. Experiments involving Select Agent and Toxins must be reviewed and approved by the [Mount Sinai IBC](#).

Dual Use Research of Concern (DURC)

The United States Government (USG) defined a subset of biomedical research that has the greatest potential for generating information that could benefit or threaten public health, i.e. Dual Use Research of Concern (DURC). The United States Government (USG) defined DURC as “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.” In March 2012, the USG issued a policy for institutional oversight of life sciences dual use research of concern (March 2012 DURC Policy)⁸, which articulated the practices and procedures that Mount Sinai must implement to ensure that DURC is identified at the institutional level and the risk mitigation measures that Mount Sinai must implement as necessary.

DURC policies apply to a subset of 15 biological agents and toxins that are considered Biological Select Agents and Toxins that are regulated by the Federal Select Agent Program. Additionally, DURC policies apply to seven (7) categories of experiments. **Table 5** outlines the scope of biomedical research requiring DURC review. If the scope of research proposed by a Principal Investigator (PI) involves one or more of the pathogens or toxins and falls within a category of experiments listed in **Table 3**, then the PI must complete and submit a [DURC Questionnaire](#) to the Mount Sinai IBC.

Principal Investigators (PIs) conducting research involving pathogens and toxins subject to the USG Policy on DURC must complete training on Dual Use Research for Concern (DURC). The [CITI Program](#) training module, [Dual Use Research of Concern \(DURC\) \(ID 16263\)](#), overviews the DURC policy and the responsibilities of individuals conducting research involving pathogens and toxins that are subject to the USG Policy on DURC.

⁸ The United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern, March 29, 2012, <http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf>.

TABLE 5. SCOPE OF RESEARCH REQUIRING DURC OVERSIGHT

Pathogens and Toxins		
Avian influenza virus (highly pathogenic)	Ebola virus	Rinderpest virus
<i>Bacillus anthracis</i>	Foot-and-mouth disease virus	Toxin-producing strains of <i>Clostridium botulinum</i>
Botulinum neurotoxin ⁹	<i>Francisella tularensis</i>	Variola major virus
<i>Burkholderia mallei</i>	Marburg virus	Variola minor virus
<i>Burkholderia pseudomallei</i>	Reconstructed 1918 Influenza virus	<i>Yersinia pestis</i>
Categories of Experiments		
Enhances the harmful consequences of the agent or toxin		
Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification		
Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies		
Increases the stability, transmissibility, or the ability to disseminate the agent or toxin		
Alters the host range or tropism of the agent or toxin		
Enhances the susceptibility of a host population to the agent or toxin		
Generates or reconstitutes an eradicated or extinct infectious agent or toxin listed above		

⁹ For the purposes of this Policy, there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential.

Chapter 4: Biological Risk Assessment

Hazardous Characteristics of an Agent

The three principal hazardous characteristics of an infectious agent are its capability to infect and cause disease in a susceptible human or animal host, its virulence as measured by the severity of disease, and the availability of preventive measures and effective treatments for the disease. Other hazardous characteristics of an infectious agent include probable routes of transmission of laboratory infection, infective dose, stability in the environment, host range, and its endemic nature. The NIH Guidelines and the World Health Organization (WHO) Laboratory Biosafety Manual describe four similar risk group classifications based on the principal hazardous characteristics and the route of transmission of the infectious agent (**Table 6**). Risk group classifications correlate with but do not equate to biosafety levels. A risk assessment will determine the degree of correlation between an agent's risk group classification and biosafety level.

Biological Risk Assessment

The investigator must make an initial risk assessment based on the Risk Group (RG) of an agent (**Table 4**). Although risk assessment is ultimately a subjective process, biological risk assessment is an important responsibility for directors and principal investigators of microbiological and biomedical laboratories. The Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC), ISMMS Biological Safety Program, and Environmental Health & Safety (EnvH&S) share in this responsibility. Risk assessment is a process used to identify the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in a person's exposure to an agent, the likelihood that such exposure will cause a LAI, and the probable consequences of such an infection.

The information identified by risk assessment will provide a guide for the selection of appropriate biosafety levels and microbiological practices, safety equipment, and facility safeguards that can prevent LAIs. Laboratory directors and principal investigators should use risk assessment to alert their staffs to the hazards of working with pathogens and to the need for developing proficiency in the use of selected safe practices and containment equipment. Successful control of hazards in the laboratory also protects persons not directly associated with the laboratory, such as other occupants of the same building, and the public.

TABLE 6. CLASSIFICATION OF INFECTIOUS MICROORGANISMS BY RISK GROUP.

Risk Group	NIH Guidelines, April 2019^{10,11}	World Health Organization Laboratory Biosafety Manual¹²	Risks
RG-1	Agents that are not associated with disease in healthy adult humans.	A microorganism that is unlikely to cause human or animal disease.	No or low individual and community risk
RG-2	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.	A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock, or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.	Moderate individual risk, low community risk
RG-3	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.	A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.	High individual risk, low community risk
RG-4	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available	A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.	High individual and community risk

¹⁰ The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, April 2019, ([NIH Guidelines](#))

¹¹ Appendix B, Classification of Human Etiologic Agents on the Basis of Hazard, of the NIH Guidelines summarizes biohazardous agents within each risk group classification.

¹² World Health Organization. (2004). *Laboratory biosafety manual*, 3rd ed. World Health Organization. <https://apps.who.int/iris/handle/10665/42981>

Chapter 5: Pathogens and Toxins

Biomedical research activities involving infectious microorganisms and laboratory animals are categorized into four biosafety levels that provide increased degrees of protection to personnel, the environment, and the community. Appendix G of the April 2019 *NIH Guidelines* describes four physical biocontainment levels for organisms containing recombinant or synthetic nucleic acid molecules and to reduce the potential for exposure of laboratory employee and visitors, persons within public corridors, and the environment to organisms containing recombinant or synthetic nucleic acid molecules. The BMBL, Sixth Edition, defines the microbiological practices, and administrative and engineering controls required for each laboratory biosafety level. Special microbiological practices enhance worker safety, environmental protection, and address the risk of handling agents requiring increasing levels of containment. **Table 7** summarizes the biosafety levels for biomedical research laboratories that are authorized at Mount Sinai.

Appendix K of the April 2019 *NIH Guidelines* specifies physical containment guidelines for large-scale (greater than 10 liters of culture) research or production involving viable organisms containing recombinant or synthetic nucleic acid molecules. Appendix K defines four biosafety levels of large-scale physical containment (also referred to as Good Large-Scale Practice): BSL1-Large Scale, BSL2-Large Scale, and BSL3-Large Scale.

Biosafety Level 1

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and 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.

Biosafety Level 2

Biosafety Level 2 builds upon BSL-1 and is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling pathogens 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 are conducted in BSCs or other physical containment equipment.

Biosafety Level 3

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through inhalation route exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents and must be supervised by scientists competent in handling pathogens and associated procedures. Engineering controls, e.g. directional airflow, are required.

Biosafety Level 4

Biosafety Level 4 is required for work with dangerous and exotic agents that pose a high individual risk of life-threatening disease, aerosol transmission, or related agent with unknown risk of transmission. Agents with a close or identical antigenic relationship to agents requiring BSL-4 containment must be handled at

this level until sufficient data are obtained either to confirm continued work at this level or to move to a lower biosafety level.

Mount Sinai does not operate Biosafety Level 4 laboratories. Refer to the BMBL, Sixth edition, for additional information on BSL-4 facilities and practices.

TABLE 7. RECOMMENDED BIOSAFETY LEVELS FOR PATHOGENS.

BSL	Agents	Practices	Safety Equipment (Primary Containment)	Facilities (Secondary Containment)
1	Not known to consistently cause disease in healthy adults	Standard Microbiological Practices	None required	Open bench top sink required
2	Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practices plus: Limited access Biohazard warning signs "Sharps" precautions Biological Safety Manual defining any needed waste decontamination or medical surveillance policies	Primary barriers = Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPEs: laboratory coats; gloves; face protection as needed	BSL-1 plus: Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL-2 practice plus: Controlled access Decontamination of all waste Decontamination of lab clothing before laundering Baseline serum	Primary barriers = Class I or II BSCs or other physical containment devices used for all open manipulations of agents; PPEs: protective lab clothing; gloves; respiratory protection as needed	BSL-2 plus: Physical separation from access corridors Self-closing, double-door access Exhaust air not recirculated Negative airflow into laboratory
4	Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission	BSL-3 practices plus: Clothing change before entering Shower on exit All material decontaminated on exit from facility	Primary barriers = All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure personnel suit	BSL-3 plus: Separate building or isolated zone. Dedicated supply and exhaust, vacuum, and decontamination systems; Other requirements outlined in the text

Chapter 6: Vertebrate Animal Biomedical Research

Laboratory animal facilities (e.g. vivaria) are a special type of laboratory. As a general principle, the biosafety level (facilities, practices, and operational requirements) recommended for working with pathogens in vivo and in vitro are comparable. The physical environment of the animal room and the animals present unique biohazardous risks. Animals may generate aerosols, they may bite and scratch, and they may be infected with a zoonotic agent. The concurrent application of Biosafety Levels and Animal Biosafety Levels are determined by a protocol driven risk assessment. **Table 8** summarizes the animal biosafety levels for biohazardous agents that are authorized at Mount Sinai.

Animal Biosafety Level 1

Animal Biosafety Level 1 is suitable for work involving well-characterized agents that are not known to cause disease in immunocompetent adult humans, and present minimal potential hazard to personnel and the environment.

Animal Biosafety Level 2

Animal Biosafety Level 2 builds upon the practices, procedures, containment equipment, and facility requirements of ABSL-1. ABSL-2 is suitable for work involving laboratory animals infected with agents associated with human disease and pose moderate hazards to personnel and the environment. It also addresses hazards from ingestion as well as from percutaneous and mucous membrane exposure.

Animal Biosafety Level 3

Animal Biosafety Level 3 involves practices suitable for work with laboratory animals infected with indigenous or exotic agents, agents that present a potential for aerosol transmission and agents causing serious or potentially lethal disease. ABSL-3 builds upon the standard practices, procedures, containment equipment, and facility requirements of ABSL-2. The ABSL-3 laboratory has special engineering and design features.

Animal Biosafety Level 4

Animal Biosafety Level 4 is required for work with animals infected with dangerous and exotic agents that pose a high individual risk of life-threatening disease, aerosol transmission, or related agent with unknown risk of transmission. Agents with a close or identical antigenic relationship to agents requiring ABSL-4 containment must be handled at this level until sufficient data are obtained either to confirm continued work at this level, or to re-designate the level. Animal care staff must have specific and thorough training in handling extremely hazardous, pathogens and infected animals.

Mount Sinai does not operate Animal Biosafety Level 4 laboratories. Refer to the BMBL, Sixth edition, for additional information on ABSL-4 facilities and practices.

TABLE 8 RECOMMENDED BIOSAFETY LEVELS FOR ACTIVITIES IN WHICH INFECTED VERTEBRATE ANIMALS ARE USED.

BSL	Agents	Practices	Safety Equipment (Primary Containment)	Facilities (Secondary Containment)
1	Not known to consistently cause disease in healthy human adults.	Standard animal care and management practices, including appropriate medical surveillance programs.	As required for normal care of each species.	Exhaust air not recirculated Directional air flow recommended Handwashing sink recommended.
2	Associated with human disease. Hazard: percutaneous exposure, ingestion, mucous membrane exposure.	ABSL-1 practices plus: Limited access Biohazard warning signs Sharps precautions Biological Safety Manual Decontamination of all infectious wastes and of animal cages prior to washing.	ABSL-1 equipment plus primary barriers: containment equipment appropriate for animal species; PPE: laboratory coats, gloves, face, and respiratory protection as needed.	ABSL-1 facility plus: Autoclave available Handwashing sink available in the animal room. Mechanical cage washer used.
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious health effects.	ABSL-2 practices plus: Controlled access Decontamination of clothing before laundering Cages decontaminated before bedding removed Disinfectant footbath as needed.	ABSL-2 equipment plus: Containment equipment for housing animals and cage dumping activities Class I or II BSCs available for manipulative procedures (inoculation, necropsy) that may create infectious aerosols. PPE: appropriate respiratory protection.	ABSL-2 facility plus: Physical separation from access corridors Self-closing, double-door access Sealed penetrations Sealed windows Autoclave available in facility.

Chapter 7: Safety Practices and Equipment

The Principal Investigator (PI) bears ultimate responsibility for the health and safety of all laboratory personnel working under their authority (including visiting scientists, fellows, volunteers, temporary employees, visitors and students) or within their research facilities. The Principal Investigator (PI) must also ensure that his or her laboratory implements sufficient security measures and procedures to prevent unauthorized access to biohazardous materials. Each Principal Investigator (PI) must develop site-specific policies and procedures that safeguard all biohazardous materials, regardless of risk group, from unauthorized removal.

Standard Precautions

The concept of Standard Precautions is to treat all blood and other body fluids, tissues, and cells as if they were known to be infectious for bloodborne pathogens (BBPs). Standard Precautions includes adhering to principles of standard microbiological practices, which provide the safety controls needed to protect laboratory staff, visitors, and the environment from contamination in the event that biohazardous agents are accidentally released from primary containment. Standard microbiological practices also prevent organisms present in the laboratory environment from contaminating the biomedical research. Both objectives are important, but the first objective is primarily important for the safety of the laboratory staff and visitors, while the second objective is primarily important for the quality of the research.

Standard microbiological practices include frequent handwashing, no mouth pipetting, no food or drink in the lab, proper disposal of biohazardous/medical waste, and use of engineering controls and Personal Protective Equipment (PPE). Engineering controls include items such as biosafety cabinets, ventilation systems, sealed buckets and rotors for centrifuges, etc.

Personal Protective Equipment (PPE)

Environmental Health and Safety (EnvH&S) Policy, EH-LAB3-1, *Mandatory Lab Attire and Personal Protective Equipment*, defines the minimal acceptable attire and personal protective equipment (PPE) for entering and working in a biomedical research or clinical laboratory. Minimum PPE for all laboratories includes a laboratory coat (or equivalent) and closed toed shoes. Additional PPE may be required based off a hazard assessment. The policy applies to anyone, including staff, their supervisors, visitors, and students, entering the research or clinical laboratory.

Personal protective equipment (PPE) is a necessary part of laboratory safety in addition to engineering controls (i.e., laboratory ventilation and biological safety cabinets) and good work practices. PPE such as gloves, lab coats, eye protection, face shields or other protective equipment must be selected and used as appropriate. When properly selected and used, PPE can be effective in minimizing individual exposure (**Figure 2**). Face protection (goggles, mask, face shield, or other splatter guard) should be used for anticipated splashes or sprays when biohazardous material must be handled outside of the BSC.

Disposable gloves must be discarded when overtly contaminated and removed when work with infectious materials is completed or when the integrity of the glove is compromised. Laboratory personnel should



FIGURE 2. PPE REDUCES RISK FOR OCCUPATIONAL EXPOSURE TO PATHOGENS.

not wash or reuse disposable gloves should, or touch “clean” surfaces (keyboards, telephones, etc.) while wearing potentially contaminated disposable gloves. Alternatives to powdered latex gloves should be available. Laboratory personnel follow good hand hygiene practices and wash hands following removal of disposable gloves.

Each Principal Investigator (PI) or designated Laboratory Safety Officer must complete the Laboratory Hazard Assessment Tool (LHAT) within [SECTOR](#), which identifies personal protective equipment (PPE) requirements for identified hazards in the research or clinical laboratory. The LHAT should be reviewed and submitted at least annually, or when new hazard is introduced to the laboratory. All laboratory staff must review and digitally sign the LHAT.

Laboratory Coat Program

Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn at all times while in the laboratory as required by EnvH&S Policy (EH-LAB3-1), *Mandatory Lab Attire and Personal Protective Equipment*. Laboratory staff should remove protective clothing before leaving for non-laboratory areas, e.g., cafeteria, library, and administrative offices). Reusable laboratory coats must never be taken home to be laundered. To assist with safety, compliance and reduce risk, research staff must take soiled laboratory coats to Linen Services for cleaning. Disposable laboratory coats must not be washed or reused. Used disposable PPE should be discarded as Regulated Medical Waste.

Signs and Hazard Communications

The Biological Safety Program and Environmental Health & Safety (EnvH&S) will jointly inspect all biomedical research and clinical laboratories. As outlined in the BMBL, Sixth Edition, Principal Investigators must post a sign incorporating the universal biohazard symbol at the entrance to the laboratory when pathogens are present.

1. The door posting must indicate:
 - a. The laboratory’s biosafety level,
 - b. The name of the Principal Investigator (PI) or the designated Laboratory Safety Officer
 - c. Telephone number, and
 - d. Required procedures for entering and exiting the laboratory.

Appendix G-II-C-2-e of the *NIH Guidelines*, April 2009, indicate that “when organisms containing recombinant or synthetic nucleic acid molecules or experimental animals are present in the laboratory or containment module, a hazard warning sign incorporating the universal biosafety symbol is posted on all laboratory and animal room access doors.” Similarly, 1910.1030(g)(1)(ii)(A) of the OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030, requires that PIs post signs at the entrance to HIV and HBV Research Laboratory and Production Facilities that indicate:

- The universal biohazard symbol,
- Name of the Infectious Agent,
- Special requirements for entering the area, and
- Name, telephone number of the laboratory director or other responsible person.

Red-orange coded biohazard labels must be placed on equipment used for material designated for BSL-2 containment or higher; this includes human and NHP cells, tissue, and blood/bodily fluids. Examples of

equipment include storage freezers, refrigerators, incubators, any other laboratory equipment used with BSL-2 or -3 agents; shipping containers; medical waste containers; or any surface, which may be reasonably anticipated to be contaminated by biohazardous materials. Biohazard labels are available through EnvH&S, or can be acquired directly from a vendor (e.g. Fisher Scientific, VWR).

Freezer Monitoring Program

Each Principal Investigator (PI) should establish a Freezer Monitoring Program that provides real-time information and alerts about the status of critical freezers and refrigerators. Establishment of a Freezer Monitoring Program at the department level could be a cost-effective approach that ensures uniform monitoring services. Depending on the system capability, some devices monitor the performance of freezers and provide indications of potential issues with the compressors. Each Principal Investigator (PI) should establish an emergency contact list of key individuals, who can be notified of freezer issues via phone, text, or email.

Principal Investigators should establish inventory control practices for all biohazardous material stored within freezers. Knowledge of the freezer inventory of biohazardous material is essential for the Principal Investigator (PI) and/or EnvH&S to complete comprehensive risk assessments of laboratory activities, refinement of training requirements of laboratory personnel, and maintaining an accurate database of biohazardous material at Mount Sinai, which will help refine biosafety, biocontainment, and biosecurity.

Engineering controls

Engineering controls include design and construction of the biomedical research and clinical laboratory or facility. Engineering Controls help prevent the accidental release of an agent from the laboratory and help create a safe laboratory environment.

Heating, Ventilation and Air Conditioning (HVAC)

Building ventilation should provide research laboratories with at least six (6) air changes per hour (ACH) of fresh conditioned air. Directional airflow is dependent on the operational integrity of the laboratory's heating, ventilation, and air conditioning (HVAC) system. HVAC systems require careful monitoring and periodic maintenance to sustain operational integrity. Loss of directional airflow compromises safe laboratory operation and biocontainment capability of the laboratory or facility.

Newly constructed BSL-2 research and clinical laboratories should have inward airflow, which directs airflow from clean public corridors into research laboratories with higher hazard. Inward directional airflow keeps odors, dusts, and vapors out of public corridors and other public areas. BSL-3 biocontainment laboratories must operate with sustained directional airflow that draws air into the laboratory from clean areas towards potentially contaminated areas.

High-level biocontainment (BSL-3) facilities should have High Efficiency Particulate Air (HEPA) filter housings with gas-tight isolation dampers, decontamination ports, and/or bag-in/bag-out (with appropriate decontamination procedures) capability. The HEPA filter housing should allow for leak testing of each filter and assembly. The filters and the housing should be certified at least annually.

Centrifuges

Centrifuges should be equipped with a solid cover and have a safety interlock that prevents the operator from opening the cover until the centrifuge has come to a complete stop. Use of centrifuges presents physical hazards to the operator. Use of biohazardous materials presents additional exposure hazards due to potential aerosolization of biohazardous materials. Centrifuges used for biohazardous materials must be placarded with a biohazard label. Sealed tubes, sealed rotors, or safety buckets must be used when centrifuging infectious pathogens. Ensure that O-rings or gaskets of safety buckets and rotors in place and in good condition with no signs of wear and tear or deformities before use. Logbooks must be maintained for each high-speed centrifuge and rotors. Rotors should not be used beyond the life spans recommended by the manufacturer. Centrifuges should be cleaned with an appropriate disinfectant recommended by the manufacturer after each use for biohazardous materials.

The laboratory should establish a preventative maintenance plan for each centrifuge. A qualified service technician should certify high-speed centrifuges and/or centrifuges used in BSL-3 laboratories annually.

Biological Safety Cabinets (BSCs)

A biological safety cabinet (also called biosafety cabinet) is an enclosed, ventilated environment for safely handling biohazardous materials containing or potentially contaminated with infectious pathogens. BSCs are among the most effective, as well as most used primary containment devices in biomedical research laboratories working with pathogens.

BSCs are available in three types (Classes I, II, and III) that have different performance characteristics and limitations¹³. The type of BSC required for biomedical research depends on the area of biomedical research, the type of procedures conducted, and need for product sterility versus need for personal protection against biohazardous material.

A properly maintained Class I BSC, when used in conjunction with standard microbiological practices, provides primary biocontainment for the safe manipulation of low to moderate risk pathogens requiring Biological Safety Level-1 or -2 biocontainment. Class I BSCs are not suitable for applications requiring sterile techniques.

Class II BSCs provide High Efficiency Particulate Air (HEPA)-filtered air flowing down over and across the work surface (i.e. vertical laminar airflow). Class II BSCs are suitable for work using pathogens requiring Biosafety Level 1, 2 or 3 biocontainment. The Class II BSC is designed with an inward airflow of at least 75 linear feet per minute (lfpm), and a downward, vertical laminar airflow. The dual airflow pattern provides an air curtain barrier that protects the user from the biohazardous materials and protects materials within the cabinet from contamination originating outside the cabinet. Both supply air and exhaust pass through HEPA filters. Exhaust air is HEPA-filtered prior to discharge within the laboratory, or discharge through a ducted ventilation system to the external environment. Class II BSCs are classified into two subcategories, A and B, based on design configuration, construction, air flow velocities and exhaust systems used.

A Class II, Type A1 BSC must maintain a minimum average inflow velocity of 75 lfpm through the sash opening. A Class II, Type A1 cabinet is suitable for work with pathogens in the absence of volatile or toxic chemicals and radionuclides. Class II Type A BSCs may exhaust HEPA-filtered air back into the laboratory (100% recirculation) or may exhaust HEPA-filtered air outside through a thimble canopy connection¹⁴.

¹³ Refer to the *BMBL*, Sixth edition, Appendix A, [Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets](#).

¹⁴ A thimble is a canopy hood with design dimensions that allow the discharge from the BSC to be captured efficiently and transported through a duct system, while allow sufficient make-up air from the laboratory to enter

A Class II, Type A2 BSC must maintain a minimum average inflow velocity of 100 fpm through the sash opening. A Class II, Type A2 BSC may exhaust HEPA-filtered air back into the laboratory (100% recirculation) or may exhaust HEPA-filtered air outside through a thimble canopy connection. A Class II, Type A2 BSC with canopy connection is suitable for research involving biological agents treated with minute quantities of hazardous chemicals. A Class II, Type A2 BSC may be used with tracer quantities of radionuclides that do not interfere with the work if the radionuclides are recirculated in the down flow air.

A Class II, Type B1 or B2 BSCs must maintain a minimum average inflow velocity of 100 fpm through the sash opening.

- A Class II, Type B1 BSC has HEPA-filtered down flow air composed mostly of uncontaminated recirculated inflow air. Some of the contaminated air is recirculated within the BSC while most of the contaminated air is exhausted through a HEPA filter prior to discharge through a dedicated duct that vents outside. Class II, Type B1 BSCs are suitable for work involving minute quantities of toxic chemicals and tracer amounts of radionuclides required as an adjunct to microbiology applications as long as the work is done in the directly exhausted rear portion of the cabinet.
- A Class II, Type B2 BSC has HEPA-filtered down flow air drawn from the lab or the outside air (no air is recirculated from the cabinet exhaust). All contaminated air is exhausted through a HEPA filter without recirculation in the cabinet or return to the lab (100% Exhaust). Class II, Type B2 BSCs are suitable for work involving biological agents treated with hazardous chemicals and radionuclides required as an adjunct to microbiology applications.

BSC HEPA filters require replacement when a qualified individual has determined that the airflow is no longer sufficient and filter load has reached capacity. HEPA filters must be decontaminated before removal by a qualified service technician.

A qualified service technician must certify a BSC upon:

1. Initial Installation: A new BSC must be installed and certified to ensure the unit operates as designed by the manufacturer.
2. Relocation: Relocating a BSC may break the HEPA filter seals, damage the HEPA filters, or cause physical damage to the cabinet components.
3. Major Repair: Replacement of HEPA filters or blower motor requires recertification that the unit operates as designed by the manufacturer.
4. Annual verification schedule¹⁵: Each BSC should be tested and certified at least annually to ensure the unit operates as designed by the manufacturer.

Class III BSCs are totally enclosed, ventilated cabinets that offer the highest degree of personal and environmental protection from infectious aerosols as well as protection of research materials from microbiological contaminants. Class III BSCs are not frequently used at Mount Sinai.

Laminar Flow Cabinet

Laminar flow hoods are designed to provide HEPA-filtered unidirectional airflow to a sterile working environment to prevent contamination of cell culture or other sterile biological samples. Because of the

simultaneously so that the system is not starved for air. This duct system has a terminal fan and usually an additional HEPA filter before the fan.

¹⁵ On December 11, 2014, the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) released the policy statement, BSL-3/ABSL-3 HVAC and Facility Verification. This policy statement requires that BSL3 laboratory HVAC HEPA filters, if present, have been certified annually as part of the annual BSL-3/ABSL-3 facility verification process.

outward airflow, laminar flow cabinets do not provide protection against biohazardous materials. HEPA filters require replacement when the airflow is no longer sufficient, and filter load has reached capacity. Laminar flow hoods must be tested and certified at least annually.

Downdraft tables

Downdraft tables are workstations with built-in ventilation that pulls air, odors, vapors, and aerosols down and away from the surface and the worker's face. They are used primarily for animal necropsies, surgeries, perfusions, and dissections. Downdraft tables also capture dust, vapors, or other contaminants making these tables suitable for change out of rodent cages. HEPA filters require replacement when the airflow is no longer sufficient, and filter load has reached capacity.

Chemical Fume Hoods

Chemical fume hoods, when used properly, limits exposure of laboratory personnel to hazardous or toxic fumes, vapors or dusts. They protect workers by:

- Containing vapors, dusts, gases, and fumes generated within the hood, and removing them as air flows into the hood and then out via the laboratory exhaust system
- Contributing to laboratory ventilation as air flows through the hood
- Shielding the worker with a clear sliding window, called a sash, that contains aerosols and prevents injury from splashes, fires, or minor explosions that may occur inside the hood

Chemical fume hoods have limitations:

1. They are not designed for use with biohazardous materials.
2. They are not intended for use with heated perchloric acid (specialty fume hood is required).
3. Chemical fume hoods may be equipped with flat or rounded sills or airfoils, which direct the flow of air smoothly across the work surface. Sills should not be removed or modified. Objects should never be placed on these sills, as the inward airflow may be insufficient to capture any material released from containers placed on the sills. Objects placed on the sill may prevent the quick and complete closure of the sash during an emergency response.
4. Modern fume hoods may have recessed work surfaces or spill containment berms that are designed to contain minor liquid spills. Objects should not be placed on the sides of the recessed work surfaces or spill containment berms.
5. All air-borne contaminants exhausted by unfiltered chemical fume hoods are released directly into the atmosphere.

Laboratory staff should inspect chemical fume hoods prior to use to ensure normal operation. If a digital display is available, the face velocity should read 80 – 120 fpm. If a fume hood is operating outside of this range, it should be marked as “out of service” and must not be used. Deficiencies should be immediately reported to Facilities & Engineering for correction.

Chemical fume hoods must be annually inspected for functionality and condition by Engineering. An annual certification sticker should be placed on the front of each fume hood indicating the inspection results. If the chemical fume hood in your lab has not been annually certified, immediately contact Facilities & Engineering for correction.

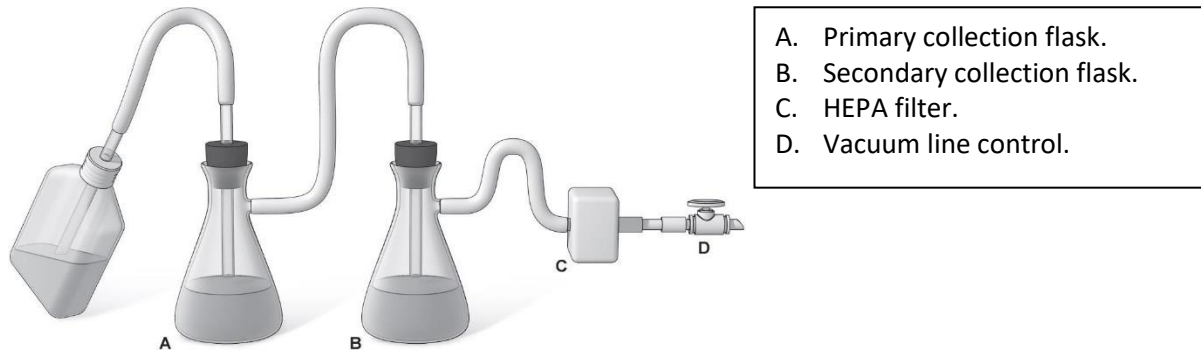


FIGURE 3. VACUUM LINES PROTECTED WITH HIGH EFFICIENCY PARTICULATE AIR (HEPA) FILTERS.

Vacuum Lines

Vacuum systems (both centralized and stand-alone pumps) are commonly used to help researchers filter reagents and dispose of waste. Vacuum lines should be protected with in-line High Efficiency Particulate Air (HEPA) filters, or their equivalent (**Figure 3**). HEPA filters must be replaced as needed. Liquid disinfectant traps may be required to prevent contamination of the vacuum system.

Chapter 8: Disinfectants and Sterilization

Decontamination

Non-Ionizing Radiation

Ultraviolet (UV) radiation is a form of non-ionizing radiation. UV radiation (UV) from a 254 nanometer (nm) wavelength “germicidal” UV-C light source is used to control airborne microorganisms and to decontaminate surfaces. UV-C lamps typically have an average lifespan of 9,000 hours and should be replaced on an annual basis.

Biological Safety Cabinets (BSCs) are commonly equipped with a “germicidal” UV-C light source to decontaminate the work surface. Poor penetrating power, relative humidity, temperature, air movement, cleanliness, age and overuse of the light source, and long exposure time limit the effectiveness of this form of decontamination. The “germicidal” UV-C light source should not be used as the primary means to decontaminate the work surface of the BSC. The effectiveness of the “germicidal” UV-C light source should be checked with a photometer equipped with a sensor to measure 254nm UV wavelength light.

Vapors and Gases

From a practical point of view, formaldehyde, beta-propiolactone and ethylene oxide are not routinely used in laboratory sterilization practices. These types of sterilant are used in hospitals and commercial facilities where closed systems controlling temperature, humidity, and concentration are required to achieve sterilization using these agents.

Biological safety cabinets are decontaminated using paraformaldehyde heated to decomposition to release formaldehyde gas. This procedure should be performed only by personnel trained in this procedure due to the explosive nature of formaldehyde.

Of the types of types of sterilant listed above, Ethylene Oxide (ETO) has wide use as an alkylating agent with very broad biocidal activity including spores and viruses. Because of its toxicity and potential carcinogenicity, it is not used today.

Instruments and optics that may be damaged by other sterilization methods, rooms, buildings and air-handling systems in particular are also sterilized using these types of sterilant. These types of sterilant are extremely toxic and are regulated under OSHA and EPA regulations.

As a final note, the desired result for any treatment is to arrive at a significant reduction in the numbers of infectious entities (several orders of magnitude or logs of reduction), with the final result that there is no longer a risk of acquiring an infection while handling the materials after treatment. Complete sterility with the exception of media preparation and the disposal of some highly pathogens, is not required for the disposal of infectious waste.

Chemical Disinfectants

Selection of chemical disinfectants is based on several factors:

- What is the target organism that you wish to inactivate?
- What are the physical characteristics of the surface, which will be disinfected?
 - Porous surfaces may absorb disinfectants.

- Some disinfectants may corrode metal surfaces.
- What is the duration of the contact time between the disinfectant and the target organism?
 - High concentrations of biological organisms may require longer contact times.

Although physical methods are often superior to chemical disinfection/sterilization, it is not practical to autoclave or subject many items to high heat, especially if the items can be damaged through repeated exposure to heat. Treatment of inert surfaces and heat labile materials can be accomplished with disinfectants, provided that the following factors are considered: concentration of active ingredient, duration of contact between disinfectant and item to be disinfected, pH, temperature, humidity, and the presence of organic matter or soil load. The interplay of these factors will determine the degree of success in accomplishing either disinfection or sterilization. In all situations, review the manufacturer's recommendations for correct formulation and use of the chemical disinfectant. Do not attempt to use a chemical disinfectant for a purpose for which it was not intended.

The best way of ascertaining the suitability of a disinfectant against a particular agent is to challenge that agent with the disinfectant at the manufacturer's recommended concentration, or several concentrations to establish a kill curve. In general, this is not necessarily due to a large body of literature available on many disinfectants, and the manufacturer's own test results, which can be obtained in many cases.

Additional guidance on chemical disinfectants:

- Listing of EPA-registered disinfectants
 - <https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants>).
- Guideline for Disinfection and Sterilization in Healthcare Facilities (2008):
 - <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf>
- Centers for Disease Control and Prevention listing of chemical disinfectants
 - <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/disinfection-methods/chemical.html>

Sterilization

Steam Sterilizers (Autoclaves)

Autoclaving at a temperature of 121°C (steam under pressure) at 20 psi is one of the most convenient and effective means of sterilization available. Care must be taken to ensure that the steam can circulate around articles to provide even heat distribution. The success of the sterilization is very time-dependent in liquid media, with large volumes requiring longer periods of time to reach the effective temperature within the media itself. Additionally, there should be no void spaces in the load that could insulate the contents against the steam, which could prevent the transference of heat to the contents resulting in failed sterilization. Red autoclave-safe biohazard bags should not be confused with red Regulated Medical Waste (RMW) bags (**Figure 4**).

For dry material, small amounts of water (50 to 75 mL per 30-gallon bag) should be included inside the autoclave bag to ensure sufficient



FIGURE 4. AUTOCLAVE-SAFE RED BIOHAZARD BAG.

moisture content within the load to allow for heat transference and distribution.

Steam sterilizers should be installed and certified by a qualified individual to ensure the unit operates as designed by the manufacturer¹⁶. It is recommended to validate and document the killing efficiency of the autoclave by completing a test cycle with a Diack sterilization monitor or commercially available biological indicator (*Geobacillus stearothermophilis* or *Bacillus atrophaeus* (formerly *Bacillus subtilis* var. niger)). This is critically important if the autoclave is used for the sterilization of pathogenic cultures. Autoclave tape can be used to indicate whether a specific temperature was reached for sterilization of glassware or media before use. If required, the autoclave log sheets and logbooks should be completed for each cycle.

Dry-Heat Sterilizers

There are two types of dry-heat sterilizers. The static-air, or oven-type, sterilizer uses heating coils in the bottom of the unit cause the hot air to rise inside the chamber via gravity convection. The forced-air, or mechanical convection, sterilizer uses a motor-driven blower to circulate heated air within the chamber for more efficient heat transfer to the contents. Common time and temperature settings for sterilization with dry-heat sterilizers are 170°C (340°F) for 60 minutes, 160°C (320°F) for 120 minutes, and 150°C (300°F) for 150 minutes. Dry-heat sterilizers are effective for sterilizing glassware, or other non-porous heat conductive materials. Dry-heat sterilizers are not effective for sterilizing organic and inorganic materials that can act as insulation and are unsuitable for heat labile materials.

Dry-heat sterilizer should be installed and certified by a qualified individual to ensure the unit operates as designed by the manufacturer. The dry heat sterilizer validation process consists of accurately measuring the temperature at critical points within the sterilization chamber throughout the sterilization process. In clinical settings, validation of a dry heat sterilization cycle is required by regulatory agencies to ensure that all items that are required to be sterile or pyrogen-free are consistently and reliably sterilized to reduce the chance of introducing or spreading an infectious microorganism or pyrogen. It is recommended to validate and document the killing efficiency of the dry-heat sterilizer by completing a test cycle with a commercially available biological indicator containing spores of *Bacillus atrophaeus*. If required, the autoclave log sheets and logbooks should be completed for each cycle.

¹⁶ On December 11, 2014, the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) released the policy statement, *BSL-3/ABSL-3 HVAC and Facility Verification*. This policy statement requires that BSL3 laboratory decontamination systems (i.e. autoclave, room decontamination systems, digesters, liquid effluent systems, etc.) have been confirmed to be operating correctly and are certified annually as part of the annual BSL-3/ABSL-3 facility verification process.

Chapter 9: Regulated Waste Management

Mount Sinai generates different types of waste, including regulated medical waste (RMW), municipal solid waste, radioactive waste, industrial non-hazardous waste, construction and demolition debris, and domestic sewage and wastewater. This chapter covers management of Regulated Medical Waste (RMW), also known as 'biohazardous' waste or 'infectious medical' waste, including collection, transport, and final disposal by an authorized solid waste management facility.

Institutional Compliance

The New York State Department of Health (NYS/DOH)¹⁷ and the New York State Department of Environmental Conservation (NYS/DEC)¹⁸ jointly administer New York State's Regulated Medical Waste (RMW) Program. The RMW Program has oversight for proper storage, treatment and disposal of medical waste produced by hospitals, residential health care facilities, diagnostic and treatment centers and clinical laboratories. The NYS/DEC has oversight authority for all storage, treatment and destruction processes located on-site of facilities not under DOH jurisdiction.

The NYS/DEC defines RMW as biohazardous material generated from research, production and testing of biologicals or health care such as:

- Infectious animal waste
- Human pathological waste
- Human blood and blood products
- Needles and syringes (sharps)
- Cultures and stocks (microbiological materials)
- Other infectious waste (e.g. materials contaminated with pathogens such as Hemorrhagic Fever viruses)

Biohazardous waste generated at Mount Sinai includes all laboratory waste that may contain or may have been contaminated by biohazardous material. All biohazardous waste must be disposed of in red RMW bags marked with the biohazard symbol and printed with the institutional address (**Figure 5**). Red RMW bags should not be confused with red autoclave-safe biohazard bags (**Figure 4**). Red RMW bags must be packaged in single-use (e.g., corrugated boxes) or reusable rigid (e.g., plastic) or semi-rigid, leak proof containers before transport to a designated secure storage or collection area within Mount Sinai for transport and final disposal by an authorized solid waste management facility. Building Services manages collection and storage of RMW at Mount Sinai.



FIGURE 5. RED RMW DISPOSAL BAG WITH MOUNT SINAI ADDRESS (BLUE ARROW).

¹⁷ New York State Department of Health (NYS/DOH) [Regulated Medical Waste oversight](#).

¹⁸ New York State Department of Environmental Conservation (NYS/DEC) [Regulated Medical Waste oversight](#).

Research Laboratory Compliance

Principal investigators and laboratory directors are responsible for the health and safety of all laboratory personnel working under their authority (including visiting scientists, fellows, volunteers, temporary employees, visitors and students) or within their research facilities.

Research and clinical laboratory personnel are responsible for proper handling and disposal of biohazardous waste to prevent infection of personnel (laboratory workers, custodians, etc.), laboratory visitors, and release to the environment. **Figure 6** provides a reference for handling of Regulated Medical Waste (RMW). At a minimum, all biohazardous waste must be labeled with the universal biohazard symbol and the word 'Biohazard' as illustrated in **Figure 4**. Additional details that indicate the type of waste (such as "sharps" or "liquid waste") and origin of the waste is recommended. Disposable personal protective equipment and other contaminated waste must be appropriately contained and decontaminated prior to disposal as municipal waste. All cultures, stocks, and other potentially infectious materials should be decontaminated using an effective method before disposal.

Areas used to store regulated and non-regulated medical waste and recyclables must be kept clean and free of clutter to allow easy access to all waste containers.

Containers used to store RMW must be red in color or be labeled with the words "Regulated Medical Waste" or "Infectious Waste" or use the Universal Biohazard symbol. RMW containers must be kept in restricted areas, which limit exposure to the public. The storage containers must be kept covered and clean.

Uncontaminated Laboratory Glassware and Broken Glass

Laboratory personnel should collect uncontaminated laboratory glassware and broken glass in rigid containers (separate from other waste) that will prevent cuts and punctures to personnel. Containers should be labeled "broken glass." Broken glass is to be disposed of as ordinary trash.

Sharps Waste

The OSHA Bloodborne Pathogens Standard requires disposal of regulated medical waste containing contaminated sharps into containers which are: a) closable, b) puncture-resistant; c) leak-proof; and d) labeled and/or color-coded in accordance with the Standard [29 CFR 1910.1030(d)(4)(iii)(A)].

All sharps must be discarded into a sharps container after use. Sharps containers are either wall mounted or free standing and are identified by a biohazard label.

"Sharps" applies to any item having rigid corners, edges or protuberances capable of cutting or piercing, including, but not limited to, all of the following:

- Discarded medical/research articles that may cause puncture or cuts
- Needles, syringes, tubing, scalpel blades, disposable razors, and suture needles
- Broken glass/plastic items, such as Pasteur pipettes and blood vials contaminated with medical waste





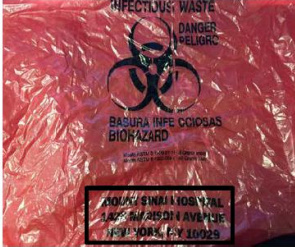

BSL	Lab Waste Material	Initial Step	Immediate Work Area Container	Processing and Collection
BSL2 or Higher Agents (e.g. Lentivirus, Adenovirus)	Non-Sharps <i>Examples include:</i> <ul style="list-style-type: none"> • Kimwipes • Pads • Gloves • Intact plastic ware 	Use Autoclave Bag as liner for container 	For Example: Designated Container in Tissue Culture Room 	<ol style="list-style-type: none"> 1. Trained / designated staff process autoclave bag in an autoclave. 2. Place treated autoclave bag into an outer red bag preprinted with Mount Sinai address. 3. Request pickup via Building Services (buildingservices@mountsinai.org)
	Sharps <i>Includes any glass, metal, or plastic instruments or items that have the potential to cut, puncture, scratch, or abrade skin.</i>	Decontaminate BSL2 or higher sharps inside BSC with disinfectant (bleach)  *(Representative Method) Decontamination of BSL1 and human material sharps is not required before disposal in sharps container.	Place sharps into a Stericycle sharps container:  8 gallons 17 gallons <ul style="list-style-type: none"> ➤ Decontaminated BSL2 or higher sharps ➤ Non-decontaminated BSL1 and human material sharps 	Request pickup via Stericycle / Building Services <ul style="list-style-type: none"> • buildingservices@mountsinai.org • For Stericycle Technicians, call (212) 241-1300; enter pager #4639 or #4640
<ul style="list-style-type: none"> • BSL1 Agents (e.g. E. Coli K12, mouse cells) • Human Material (not known to be infectious) 	Non-Sharps <i>Examples include:</i> <ul style="list-style-type: none"> • Kimwipes • Pads • Gloves • Intact plastic ware 	Use Standard Red Bag preprinted with Mount Sinai Address as liner for container 	For Example: Designated Container in Tissue Culture Room or by laboratory bench 	Request pickup via Building Services (buildingservices@mountsinai.org)

FIGURE 6. REGULATED MEDICAL WASTE DISPOSAL GUIDE FOR LABORATORIES.

Chapter 10: Hazardous Materials/Dangerous Goods Shipments

Transport of Hazardous Materials/Dangerous Goods off campus requires training and certification prior to shipping. The U.S. Department of Transportation (DOT) and the International Air Transport Association (IATA) regulate shipping of Hazardous Materials/Dangerous Goods. The IATA Dangerous Goods Regulations govern air transport of Hazardous Materials/Dangerous Goods worldwide.

Key Definitions

- Dangerous goods are substances that when transported are a risk to health, safety, property or the environment.
- Hazardous materials are chemical substances that if released or misused can pose a threat to the environment or personal health.
- Infectious substances are substances that are known or are reasonably expected to contain pathogens.
- Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents, such as prions, which can cause disease in humans or animals.

The IATA Dangerous Goods Regulations (DGR) require that any individual involved in the transport of Hazardous Materials/Dangerous Goods must be trained, tested, and certified. A record of training must be created for each employee involved in preparing, packaging, or transport of dangerous goods. The record of training must be retained for each employee throughout his or her employment and for 90 days following termination of employment.

Mount Sinai personnel can complete the Collaborative Institutional Training Initiative Program ([CITI Program](#)) training module, *Shipping and Transport of Regulated Biological Materials*, for initial training on packaging or shipping diagnostic and clinical human or animal specimens, human or animal pathogens, and other regulated biohazards. Completion of the CITI training does not remove the institutional requirement to have packages inspected and approved by Environmental Health and Safety (see below).

Dangerous Goods Classifications

Category A infectious substances are capable of causing permanent disability or life threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. Category A infectious substances have two shipping names: “Infectious substances, affecting humans” (UN 2814) or “Infectious substances, affecting animals” (UN 2900). Infectious substances meeting these criteria, which cause disease in humans or both in humans and animals, must be assigned to UN 2814. Infectious substances, which cause disease only in animals, must be assigned to UN 2900. Shipment of Category A infectious substances requires special shipping systems in which the hazardous material is tripled packaged (**Figure 7**). Category A packages must be prepared by an individual certified in packaging dangerous goods class 6.1 infectious substances, and must be compliant with IATA Packing requirements.

Category B infectious substances generally are not capable of causing permanent disability or life threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. Category

B includes infectious substances transported for diagnostic or investigational purposes. UN3373 Biological Substance, Category B can be human or animal material including (but not limited to) blood and its components, tissue, tissue fluids or body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention. Shipment of Category B infectious substances requires special shipping systems (**Figure 8**). Category B packages must be prepared by an individual certified in packaging dangerous goods class 6.1 infectious substances, and must be compliant with IATA Packing requirements.

The Department of Transportation and IATA classify dry ice as a “miscellaneous” hazard, Class 9. Dry ice releases a large volume of carbon dioxide gas as it sublimates.

Environmental Health & Safety (EnvH&S)

All packages of Hazardous Materials/Dangerous Goods must be reviewed and approved by Environmental Health and Safety (EnvH&S) prior to shipment. Members of the EnvH&S team maintain the IATA/DOT certifications required to pack hazardous materials and dangerous goods shipments. EnvH&S will ensure all research and clinical packages are packaged, marked and labeled in accordance with applicable local, state and federal regulations. The PI or designee must submit a completed *HazMat Shipping Approval Form* to AskEHS@mssm.edu at least 24 hours prior to the expected shipping date for Category A or Category B packages. The PI must complete the EnvH&S [Export Checklist](#) if controlled biologics are shipped anywhere outside the United States (including Canada). EnvH&S must be contacted before any export-controlled biological material or toxin is shipped abroad so that an export license can be obtained. The HazMat Shipping Approval Form and the Export Checklist can be downloaded from the [Environmental Health & Safety](#).

Laboratories may arrange shipment of Category B packages if the individual involved in preparing and packaging of dangerous goods is compliant with IATA training requirements for Division 6.2, *Infectious Substances*. Training certification for Division 6.2, *Infectious Substances*, is valid for two years or until regulatory changes are implemented and must be retaken at that time if needed. EnvH&S must inspect and approve Category A packages before they are received by the transportation courier.

Permits

Importation of a package of infectious material into the United States must have an importation permit approved by the Centers for Disease Control and Prevention (CDC) or by the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) (**Table 9**). Organisms, such as mosquitoes, that might transmit infectious diseases to other humans are called vectors. Importation of vectors may require permits from the CDC or the USDA. It is important to obtain a permit prior to requesting an etiologic specimen from a source outside the United States. The Institutional Biosafety Committee may request that the Principal Investigator (PI) indicate the source of any pathogens used in experiments at Mount Sinai during the review process.

TABLE 9. REGULATORY AGENCIES ISSUING PERMITS FOR BIOHAZARDOUS MATERIALS.

CDC Import Permit Program (IPP)	USDA/APHIS import permits
https://www.cdc.gov/cpr/ipp/index.htm	https://www.eauth.usda.gov/home
<p>Materials requiring permits include:</p> <ul style="list-style-type: none"> • Infectious biological agents capable of causing illness in humans • Materials known or reasonably expected to contain an infectious biological agent • Vectors of human disease (such as insects or bats) 	<p>Materials requiring permits include:</p> <ul style="list-style-type: none"> • Animal and Animal Products • Biotechnology, including genetically engineered organisms considered to be regulated articles • Plants, Organisms, and Soil • Veterinary biologics, including vaccines, antisera, diagnostic kits, and other products of biological origin.

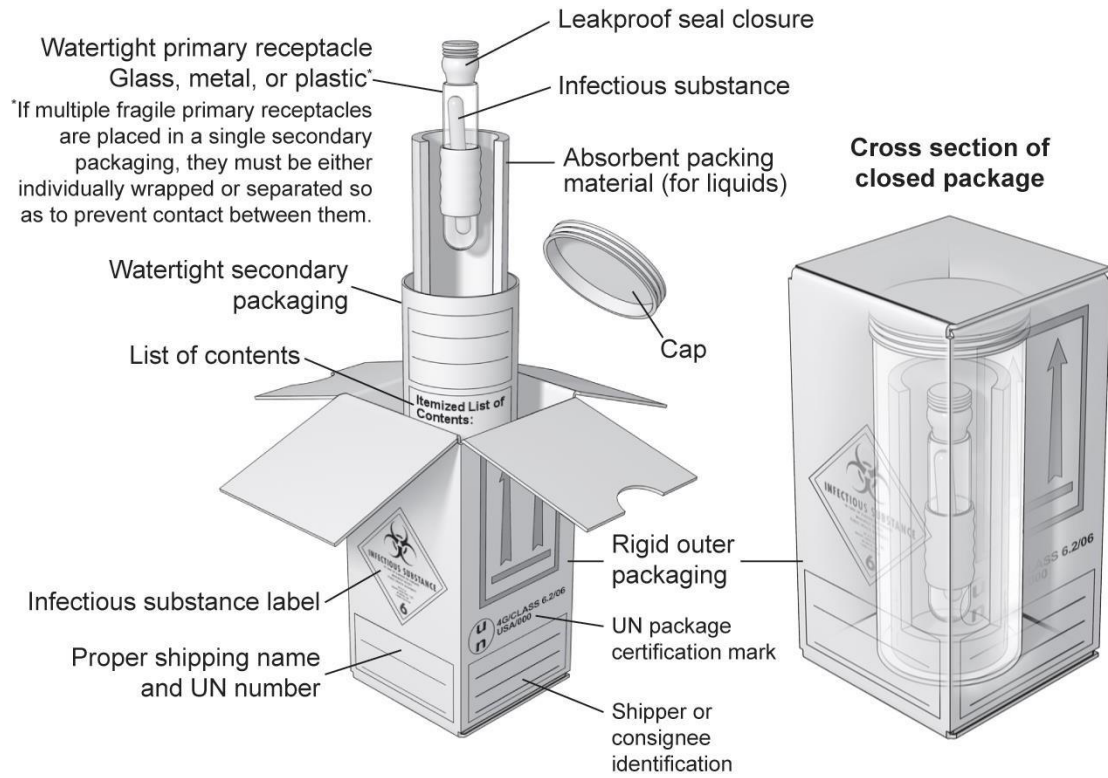


FIGURE 7. CATEGORY A PACKAGING FOR UN 2814 OR UN 2900 (CDC).

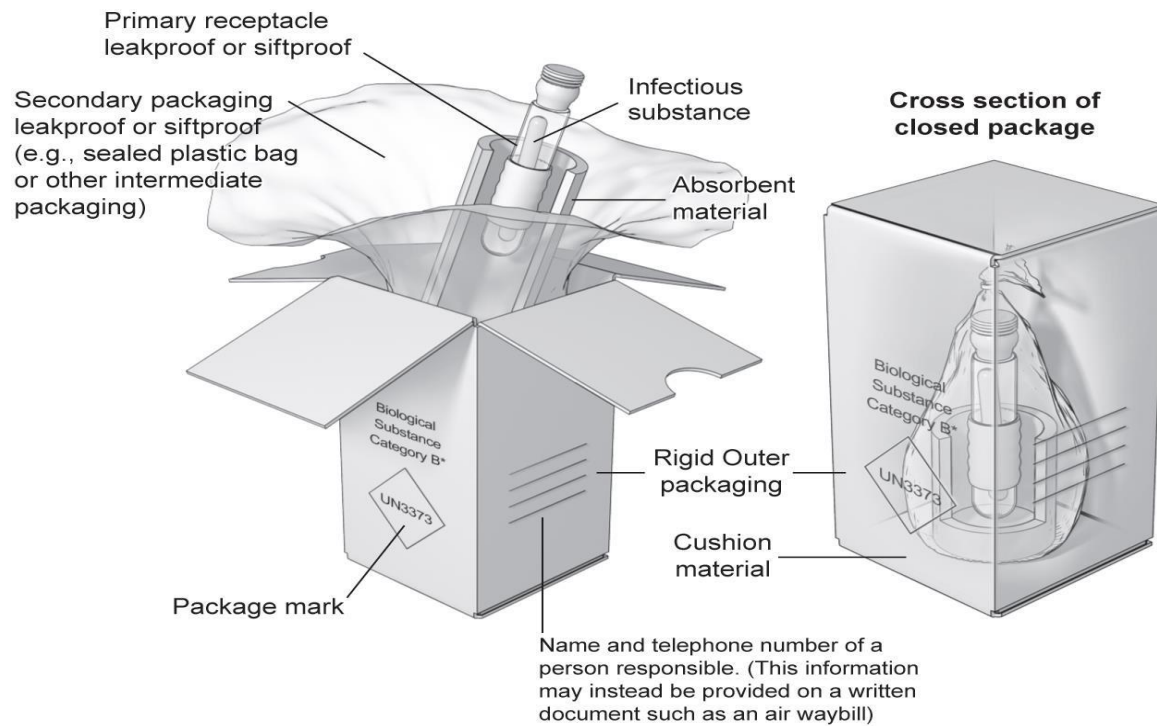


FIGURE 8. CATEGORY B PACKAGING FOR UN 3373 BIOLOGICAL SUBSTANCES (CDC).

Chapter 11: Training Program

Principal Investigators (PIs) are responsible for the health and safety of their laboratory personnel. The PI may delegate safety duties to the Laboratory Safety Officer (LSO), but the PI must ensure that all laboratory members are compliant with institutional safety requirements.

The Laboratory Safety Committee (LSC) redesigned the training requirements that ISMMS researchers must take before beginning to work in a research laboratory. The [Research Roadmap](#) outlines these [training requirements](#). All Principal Investigators and members of the research staff must complete the Core Training Requirements series that includes the required training Biosafety Course Overview, Risk Management: Work Practices, Risk Management: Personal Protective Equipment, Laboratory Hazardous Waste Management, and Hazard Communication. All Basic Sciences Research investigators and members of the research staff that are actively involved in biomedical research with potentially biohazardous materials must complete the required training Biomedical Research series that includes Laboratory-Acquired Infections, Biohazard Risk Assessment, Medical Surveillance, Risk Management: Emergency and Spill Response, Risk Management: Engineering Controls. Supplemental training may be required for all individuals completing specific tasks in a laboratory (research or clinical; biological or chemical). ISMMS researchers must complete these training requirements within the Collaborative Institutional Training Initiative Program ([CITI Program](#)). Training completion records are incorporated daily into [SECTOR](#), a cloud-based compliance and safety inspection management program. EH&S presents the training compliance report to the LSC. **Table 10** summarizes the training requirements for all laboratory personnel. Training must be entity-specific with individual training requirements based on the scope of the biomedical research and the needs of the individual handling the biohazardous material. EnvH&S monitors compliance with the Laboratory Safety Training Requirements.

The OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030, requires initial training of employees at the time of initial assignment of roles and duties that may result in occupational exposure, and annual training of all employees within one year of previous training. The CITI Program series, *OSHA Bloodborne Pathogens*, partially addresses the training requirements established by the OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030. The CITI Program, *OSHA Bloodborne Pathogens*, series consists of seven (7) lessons covering:

- OSHA Bloodborne Pathogens Standard (ID 13902)
- Hepatitis B Virus (HBV) Vaccination (ID 13903)
- Labels and Engineering Controls (ID 13904)
- Universal Precautions and Work Practices (ID 13913)
- Emergency Response Procedures (ID 13914)
- Safe Sharps Devices (ID 13946)
- Work Safely with Sharp Instruments (ID 13899)

TABLE 10. TRAINING REQUIREMENTS FOR ALL LABORATORY PERSONNEL

Basic Sciences Training Curriculum	Platform	Regulatory Agency	Frequency	Biological Safety Training										Laboratory Safety			
				Animal Users	Bloodborne Pathogens	Autoclave Users	BSL-3 Studies	Respirator Users	rDNA & Synthetic Nucleic Acids	Nano-Technology	Shipping of Regulated Biological Materials	Fume Hood Users	Work with Radiation	Work with Lasers	Dark room Users	Access to Emergency Equipment	
New Employee Initial Training	C	OSHA, EPA, FDNY	Initial	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Core Training-Biosafety Course Overview	C	OSHA	Annual	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Core Training-Risk Management: Work Practices	C	OSHA	Annual	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Core Training-Personal Protective Equipment	C	OSHA	Annual	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Core Training-Laboratory Hazardous Waste Management	C	EPA, DEC	Annual	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Core Training-Hazard Communication	C	OSHA	Annual	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Biomedical Research-Laboratory-Acquired Infections	C		Triennial	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Biomedical Research-Biohazard Risk Assessment	C		Triennial	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Biomedical Research-Medical Surveillance	C		Triennial	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Biomedical Research-Risk Management: Emergency and Spill Response	C		Triennial	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Biomedical Research-Risk Management: Engineering Controls	C		Triennial	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Animal Users	C		Triennial	X													
OSHA Bloodborne Pathogens	C	OSHA	Annual		X												
Autoclave Safety	C	OSHA	Triennial			X											
BSL-3/BSL-3 Biocontainment Research	C	OSHA	Triennial				X										
Respiratory Protection Program	P	OSHA	Annual					X									
Recombinant DNA & Synthetic Nucleic Acids	C	NIH	Triennial							X							
Nanotechnology	C	OSHA	Triennial								X						
Shipping and Transport of Regulated Biological Materials	C	IATA	Triennial									X					
Proper Use of Chemical Fume Hoods	P	FDNY	Initial										X				
Initial Radiation Safety for Researchers	P	OSHA	Initial											X			
Laser Safety	P	OSHA	Annual												X		
Compliant Management of Dark Rooms	P	OSHA, EPA, FDNY	Initial													X	
Eyewashes and Safety Showers	P	OSHA	Initial														X

*Online training through CITI Program (C) or PEAK (P)
 †Regulatory Agency:
 Occupational Safety and Health Administration (OSHA)
 National Institutes of Health (NIH)
 Environmental Protection Agency (EPA)
 Department of Environmental Conservation (DEC)
 Fire Department of the City of New York (FDNY)
 International Air Transport Association (IATA)

Chapter 12: Laboratory Closure & Equipment Removal or Disposal

The *Leaving ISMMS* website of the [Research Roadmap](#) provides guidance for Principal Investigators (PIs) on the [exit process](#) for leaving Mount Sinai. Principal Investigators (PIs) with active research projects who end their employment with ISMMS, whether through resignation, retirement or termination must complete the PI Exit Checklist, available on the *Leaving ISMMS* website, and submit it to Sponsored Projects Accounting (SPA). As part of the exit process, the PI of a biomedical research laboratory that uses and stores biohazardous materials must notify the Biological Safety Program prior to terminating work to ensure that the laboratory has been decontaminated and that all biological materials have been secured or properly disposed. This will allow the Biological Safety Officer (BSO) to consult with the PI and perform a walkthrough of the laboratory to provide recommendations on the most expeditious way to prepare for the move and the final termination of the biohazardous work in the laboratory. Contact the Chemical Hygiene Officer and refer to the Chemical Hygiene plan for information on how to properly remove chemicals from your laboratory.

Lab Closeout Procedures

- The Principal Investigator (PI) is responsible for proper disposal of biohazardous material or transfer of the biohazardous material to another PI, who is authorized to handle such material.
- A certified professional must decontaminate biological safety cabinets (BSCs). The outer surfaces must be cleaned with a suitable disinfectant.
- The PI should submit to the Biological Safety Program a [Certificate of Decontamination](#) for any major laboratory equipment that has been contaminated with biological agent(s) that will be discarded or transferred to another PI. The Certificate of Decontamination must indicate the make, model, and serial number of the major piece of laboratory equipment.
- Freezers containing biohazardous material should be emptied and the surfaces should be decontaminated with a suitable disinfectant. Biohazardous material must be decontaminated by autoclaving or dispose as Regulated Medical Waste (RMW).
- Liquid nitrogen storage equipment must be emptied and biohazardous material decontaminated by autoclaving or dispose as Regulated Medical Waste (RMW).
- Any biohazard labels must be removed from surfaces of equipment, i.e., freezers, centrifuges, BSCs, etc. The outer surface of all equipment and any work surface must be decontaminated with a suitable disinfectant.
- The Principal Investigator (PI) must account for all biohazardous material stored outside the laboratory, i.e., shared walk-in cold room, Freezer Farm Dean's CoRE, etc.
- Biohazardous waste containers (i.e. such as used sharps containers) must be disposed of and the biohazardous waste storage areas cleaned with a suitable disinfectant.
- The PI must remove the biohazard posting from the entrance to the laboratory.

Disposal of Used Lab Equipment

Laboratory equipment, such as cell/tissue culture incubators, refrigerators and freezers, used in research with biohazardous material must be decontaminated prior to disposal or release to surplus property. The Principal Investigator (PI) should submit a Certificate of Decontamination of the equipment to the

Biological Safety Program. The Certificate of Decontamination must indicate the make, model, and serial number of the piece of equipment. Laboratory equipment that was used in research with chemicals and/or radioactive materials should be decontaminated as required by EnvH&S policy.

- Remove all biohazardous materials from the equipment.
- Remove all biohazard labels from the surface of the equipment.
- Equipment surfaces should be decontaminated with a suitable disinfectant.
- Liquid nitrogen storage equipment must be emptied in accordance with EnvH&S policy.

Laboratory staff should not access internal compartments of equipment for decontamination. If the internal compartments of a piece of equipment are grossly contaminated with biohazardous material, then secure and label the equipment as being potentially biohazardous. Contact the Biological Safety Program for a biosafety assessment of the equipment.

The Biological Safety Program will review the certificate of decontamination. If certificate of decontamination acceptable, then the Biological Safety Program will issue a permit that indicates the equipment is safe for disposal or transfer to surplus inventory. The permit should be affixed to the outer surface of the piece of equipment.

Once approved by Biosafety, contact ehswaste@mountsinai.org to begin the disposal procedure. Some laboratory equipment (incubators, centrifuges, etc.) can be recycled as electronic waste, while large equipment (freezers, fridges) will need to be disposed as bulk waste.

Chapter 13: Emergency Response Planning

Natural Disasters

New York City and the Mount Sinai Hospital System have experienced annual occurrences of hurricanes, tropical storms, blizzards, and Nor'easters. These weather events are types of natural disasters that can significantly impact normal operations of the Mount Sinai Health System. However, these types of weather events can be predicted. Research laboratories should develop plans in preparation for severe weather. The research community should activate these plans to safeguard valuable biological materials when Emergency Management issues and advanced warning of pending severe weather. These plans should identify “essential biomedical research” that is essential in nature and cannot be safely and expeditiously halted in response to an incident that has potential to have a significant and long-lasting impact on school operations. The term “essential biomedical research” applies to research that must continue in support of ongoing clinical trials and activities required to maintain essential research resources or meet time-essential commitments to external sponsors. Examples of valuable biological materials in biomedical research include, but are not limited to, biological select agents and toxins, primary cell stocks, animal lines. Essential biomedical research also includes longitudinal studies and instruments with specific handling and monitoring requirements.

Electrical Power Failure

Although Mount Sinai experiences infrequent disruption of electrical power, individual pieces of laboratory equipment frequently malfunction. Electrical power failures occur without notice.

- Consider where your biological materials are stored and what equipment contains such materials.
- Assess whether critical freezers are connected to backup power.
- Assess whether sensitive equipment is connected to uninterruptible power supply (UPS).
- Be familiar with the location of dry ice to protect sensitive freezer inventory.
- Connect critical freezers to a freezer monitoring system with alarm notifications.

Water Leaks

Mount Sinai plumbing includes low- and high-pressure water supply lines that infrequently rupture. An active fire response results in pooling or runoff of large volumes of water. Responding to these incidents in a safe manner requires assessment.

- Is anyone injured by the incident?
- Are there biohazardous or radioactive material in the area?
- Are research animals present in the area?
- Has water reached critical research material?
- Is the electrical power still on?

Responding to Biohazardous Spills

Small spill response

Under the direction of the Principal Investigator (PI), laboratory personnel can respond to small biohazardous spills (less than 500 mL) with disposable pads, paper toweling and chemical disinfectants. Laboratory personnel should review the CITI Program module, *Risk Management: Emergency and Spill Response* (ID 13459), of the Biomedical Research (Biosafety) training series for guidance on responding to small biological spills. Laboratory personnel should wear appropriate personal protective equipment (PPE), i.e., gloves, disposable laboratory gown, disposable shoe covers, respiratory protection, and eye protection, and use tongs or forceps to apply the disinfectant-soaked towels technique to respond to small biological spills.

For biological spills outside of the BSC, place a dry towel or pad over the spilled material and absorb as much spilled material as possible. These towels or pads can be autoclaved and disposed of in red bags. Place a towel or pad soaked in disinfectant directly over the spill area and allow sufficient contact time for the disinfectant to neutralize any organisms present. Place dry pads or toweling over the wet ones and carefully remove and contain for disposal.

Biological spills within a biological safety cabinet (BSC) pose little aerosol hazard to lab personnel. Surface decontaminate the BSC with 1/100 dilution of hypochlorite (bleach) solution, or other hospital-grade disinfectant. Do not open internal surfaces of the biological safety cabinet (BSC) without prior decontamination of the cabinet. Exposure to viable infectious organisms within these areas could result. This procedure should be performed only by certified individuals knowledgeable in NSF and NIH decontamination procedures.

Each biomedical research laboratory handling human or non-human primate blood or body fluids should maintain a biological spill response kit that is easily accessible within the research laboratory. The biological spill response kit should include:

- Disposable solid-front fluid-resistant gown
- Disposable face shield or splash goggles
- Disposable shoe covers
- Nitrile gloves*
- Halyard[®] Fluidshield[®] N95 Filter Respirator
- Absorbent paper towels
- Two (2) Biohazard waste bags to contain contaminated towels and PPE
- Small disposable broom with dustpan or forceps or tongs for picking up broken glass or other sharps.
- Sharps container
- A laminated copy of the biological spill response and cleanup procedures

*The spill response kit should contain two (2) pairs of nitrile gloves if this PPE is not easily accessible in the area.

Large spill response

Laboratory personnel should not handle large biohazardous spills (greater than 500 mL). Laboratory personnel should:

1. Immediately check for injury and/or contamination,
2. Exit the laboratory,
3. Notify Mount Sinai Security (*60 campus phone) immediately!

Personal decontamination and follow-up medical treatment should be performed as soon as practical. Contaminated clothing must be removed and autoclaved with no exceptions. As necessary, contaminated personnel may use emergency chemical showers or take a personal shower and wash all exposed areas with germicidal surgeon's scrub or soap and water. Contaminated items may be decontaminated or discarded at the discretion of the Biosafety Officer.

No one should enter the contaminated laboratory until authorized by the Emergency Responders or the Biosafety Officer. Emergency Responders should not enter contaminated laboratory until a minimum of 30 minutes time has elapsed after the spill to allow airborne particulates to settle.

Medical Emergency

When working with biohazardous material, consider what information would be helpful to those responding to any incidents, including providing medical assistance. Be sure to discuss possible exposure to human pathogens or other potentially infectious materials (OPIM).

- Call Mount Sinai Security (*60 campus phone) for emergencies.
- Be familiar with who is certified for Basic life support (BLS).
- Be familiar with the location and usage of the nearest automated external defibrillator (AED).
- Be familiar with the location of first aid supplies.
- Be familiar with the location of Employee Health Services and the Emergency Department

Response to Occupational Exposure

All exposures to biohazardous material, including chemical exposures, blood and body fluid exposures (BBFE), and needle sticks, must be reported to a Biological Safety Professional immediately.

Employee Health Services standard, EHS- D 16.0, *Occupational Exposure to Blood/Body Fluids*, defines the Mount Sinai policy for responding to blood and body fluid exposures (BBFE):

Employees who sustain an exposure to blood or body fluids (BBFE) are evaluated for post-exposure prophylaxis (PEP) immediately upon arrival in Employee Health Service (EHS) or the Emergency Department (ED) when EHS is closed. Employees at remote locations should seek immediate care at the nearest ED and follow up with EHS.

ISMMS Students who sustain an injury on the Mount Sinai Hospital campus report to the Jack Martin Fund Clinic in lieu of EHS during business hours and the ED after hours and on weekends. ISMMS students on campuses other than MSH should report to EHS or the ED.

Agency staff, EMT staff and students on other MSHS campuses, visiting students (including medical, nursing and/or PA students), and research laboratory volunteers report to the ED if they sustain an exposure to blood or body fluid.

Needlestick / Blood or Body Fluid Exposure (BBFE)

1. **WASH** the area with soap and water.
 - a. If mucous membrane exposure (eyes, nose, mouth), then **FLUSH** with water.
2. **REPORT** to supervisor/nurse manager or Principal Investigator (PI) of research lab.
3. **Notify EHS:** Monday – Friday 8:30 am – 4:30 pm, at 646-951-7223 or 57691.
 - a. At other times, notify the Nursing Administrator on duty (dial “0” for page operator MSH).
4. **REFER the EXPOSED** person for immediate medical evaluation and care:
 - a. **Note:** The current process for referral of the exposed individual for medical evaluation is unchanged.
 - b. **Staff & Volunteers:** Employee Health Service, 19 East 98th Street, 2nd floor (Monday-Friday, 8:30am to 4:30pm) or Emergency Department (at other times)
 - c. **Medical Students:** Jack Martin Fund Clinic, 17 East 102nd Street (Monday – Friday 9am – 4pm) (212-824-7395 or 57395)
 - d. **Other Students/Non-Employees/Agency or Travel Staff:** Emergency Department or employer-designated provider for follow-up care.
5. The **EXPOSED person takes:**
 - a. Employee Accident/Injury Report signed by supervisor to the medical evaluation.
6. **SOURCE ASSESSMENT** done by provider in conjunction with EHS or Nursing Administrator:
 - a. May include review of medical record and/or interview source patient about HIV, Hepatitis B and Hepatitis C status.
 - b. If known HIV positive, active Hepatitis B, or other high-risk source may alert Infectious Disease MD on call.
7. **SOURCE PATIENT:** Laboratory tests to be ordered by provider in conjunction with EHS or Nursing Administrator:
 - a. Every patient needs (1) GOLD (1) GREEN (1) PEARL TOP TUBE.
 - i. Hepatitis B surface antigen (HBsAg) **Gold Top Tube**
 - ii. Hepatitis C antibody (anti-HCV or HCV Ab) **Gold and Pearl Top Tube**
 - iii. HIV rapid antibody (HIV Ab) test* **Green Top Tube**
 1. HIV verbal consent with chart documentation.
 2. Anonymous HIV test for source that is unable to consent.
 - iv. If known HCV positive HCV RNA Quant **Pearl Top Tube**
 - v. If known HIV positive HIV Viral Load **Lavender Top Tube**

***Potentially infectious body fluids** include blood, cerebrospinal fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, synovial fluid, semen, vaginal secretions, any visibly bloody fluid, and unfixed tissues.

Employee Health Services Policy

(Effective 2/28/18)