

VIRGINIA COMMONWEALTH UNIVERSITY
VCU MEDICAL CENTER

BIOSAFETY MANUAL

Prepared by

The Office of Environmental Health and Safety
Chemical / Biological Safety Section
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I. ACKNOWLEDGEMENT FORM

Principal Investigators (PIs) and all personal active in research within laboratories under their charge must sign and date the following statement to demonstrate acceptance of the policies and conditions set forth in this document.

1. Principal Investigator: I am familiar with and agree to comply with the provisions of the VCU Biosafety Manual and have added information where required to address hazard conditions which are specific to the laboratory spaces under my charge. I have thoroughly discussed the content of this manual with the personnel listed below and have given them the opportunity to ask questions and voice concerns regarding their job description/work environment:

_____	_____	_____
Principal Investigator printed name	Principal Investigator signature	Date

2. Laboratory Personnel: I am familiar with and understand the potential hazards, emergency procedures, and proper use of the work methods, personal protective equipment, and engineering controls detailed within this document. My PI has provided me with further site-specific training regarding potential hazards which may present within my workplace and job description.

_____	_____	_____
Printed name	Signature	Date

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II. INTRODUCTION

A. Scope. The Office of Environmental Health and Safety (OEHS) under the auspices of the Institutional Biosafety Committee (IBC) has developed this model biosafety manual to assist principal investigators and laboratory directors in limiting staff and student exposure to biohazardous agents and to better ensure university compliance with all applicable regulations promulgated by governmental regulatory and credentialing agencies. This biosafety manual serves as the university model; through adding requested information and applicable attachments (Appendices) a document which meets the IBC mandate for development of a laboratory-specific biosafety manual can be satisfied. This manual does not address issues of radiation or chemical safety. These are covered in the university Radiation Safety Manual and the Chemical Hygiene Plan and can be accessed www.vcu.edu/oehs.

B. Regulatory Forces. The guidelines developed by the [National Institutes of Health](#) (NIH), [Centers for Disease Control and Prevention](#) (CDC), [Occupational Safety and Health Administration](#) (OSHA), and the [Virginia Department of Environmental Quality](#) (VDEQ) are key components of this biosafety manual. Compliance with the minimum conditions set forth in this biosafety manual is mandatory for all university-owned or leased facilities. All university research laboratories are strongly advised to fully review the following information offered by regulatory agency websites:

1. NIH: [Guidelines for Research Involving Recombinant DNA \(rDNA\) Molecules](#)
2. CDC-NIH: [Biosafety in Microbiological and Biomedical Laboratories 5th ed. \(BMBL\)](#)
3. OSHA: [Bloodborne Pathogens Standard](#): CFR 29 1910.1030
4. VDEQ: [Regulated Medical Waste Regulations](#)

C. Biological Safety Program at VCU

1. Principal Investigators are ultimately responsible for ensuring implementation of a comprehensive biological safety program for all laboratories under their charge. Development of a complete biosafety program requires cooperation and interaction between the following university entities:

a. [Institutional Biosafety Committee](#) (IBC). All institutions awarded NIH funding for recombinant DNA research are required to form IBCs which function in accordance with the [NIH Guidelines Research Involving Recombinant DNA Molecules](#) (NIH Guidelines). While the NIH Guidelines are specific to rDNA materials, the VCU IBC has further been charged to with the overview of all protocols containing biological hazards and *in vivo* application of chemical hazards. Failure to comply with the requirements mandated during the IBC review process may result in the suspension of research involving chemical, biological, rDNA, and/or institutional privilege to use animals.

b. [Institutional Animal Care and Use Committee](#) (IACUC). Reviews all *in vivo* research protocols to ensure ethical treatment of animals and compliance with applicable regulations. Approval from IACUC is required prior to initiating new research or altering existing *in vivo* research protocols. The approvals, concerning the *in vivo* use of hazardous materials, are awarded by the IBC in concert with the IACUC.

c. [Office of Environmental Health and Safety](#) (OEHS): Oversees the university Biological Safety Program, administers university [Select Agent Program](#), manages the university [Laboratory Safety Program](#), administers university Respiratory Protection Program, appoints an Institutional Biosafety Officer (BO) who is ultimately responsible for establishing/interpreting university biosafety policies.

OEHS staffs the "[Biosafety Office](#)" which works under the direction of the BO in the research protocol approval/registration process and performs protocol and laboratory inspections to confirm availability of proper conditions and facilities.

d. The PI must register all biohazardous agents in use within their laboratory with the IBC. The PI must [register CDC/USDA select agents](#) in *de minimus* quantities with OEHS and must submit to the IBC the research protocols and a [Memorandum of Understanding and Agreement](#) (MUA) for all proposed, new procedures that involve any *in vitro* and/or *in vivo* use of potentially biohazardous agents, rDNA, and certain cell lines ([VCU Cell Line Policy](#)). No new or related research procedures may be commenced prior to receiving approval from the IBC. Principal investigators shall submit a completed [Institutional Animal Care and Use Committee \(IACUC\) form](#) for all research protocols that involve the use of animals. **Copies of all active IBC approvals involving biohazardous/rDNA materials should be attached to Appendix A of this manual.**

f. The PI must provide, at no cost to the employee, all required training, personal protective equipment (PPE), engineering control devices, immunizations, and emergency response equipment. The PI shall ensure that manuals containing thorough/up-to-date SOPs, emergency response plans (ERPs), [Exposure Control Plans](#) (ECPs), and [Job Safety Analyses](#) (JSAs) are maintained in locations familiar to all staff within all research spaces where manipulations with biohazardous agents are performed. Principle investigators shall ensure applicable SOPs, ERPs, ECPs, and JSAs are updated annually or whenever new procedures involving biohazardous agents are performed. Laboratory staff shall receive thorough training regarding the content of the SOP/ERP/ECP/JSA manual annually and whenever new procedures are added to the laboratory regimen. **Copies of updated SOPs for all procedures involving biohazardous/rDNA materials should be attached as Appendix C to this document, a copy of the ECP should be attached to Appendix E to this manual.**

III. PRINCIPLES OF BIOSAFETY

A. Containment. The term “containment” refers to utilizing routine safe methods when handling infectious material in the laboratory. Containment is the first line of defense for reducing exposure potential to laboratory personnel and the possible contamination of the laboratory or beyond. [The Centers for Disease Control and Prevention](#) identifies the following two types of containment:

1. Primary Containment

a. Personal Protective Equipment

(1) **Gloves.** Gloves must be worn whenever manipulations involving potentially biohazardous agents or hazardous chemicals are performed. Select glove type based on specific biohazardous agents and chemical compound(s) to be handled. As required by the laboratory-specific Exposure Control Plan, two pairs of gloves may be specified to adequately protect the laboratory employee.

(2) **Safety Glasses/Goggles.** Required for all procedures involving potentially biohazardous agents. Select eye protection which provides side shielding and is ANSI-approved (bears Z-87 certification). Manipulations with the potential for splashing and/or spattering of biohazardous agents shall require the use of a face shield in addition to safety glasses or chemical splash goggles.

(3) **Laboratory Coats.** Protective laboratory coats, smocks, or other protective apparel designated for the work area use must be worn while working with any hazardous materials. Protective clothing must be removed before leaving the work area unless you are conducting research-related activities outside the work area (e.g., waste disposal, animal transport outside the laboratory or vivarium, stockroom pick up, maintenance activities, etc.). Individual departments may establish more stringent requirements for personal protective equipment. Non-disposable personal protective equipment items may not be taken home for laundering or laundered in public facilities (e.g., laundromats).

(4) Disposable gowns/scrubs must be utilized whenever potential for splashing of hazardous materials exists.

(5) Respirators shall be utilized whenever potential for aerosolization or other airborne biohazard exposure threat exists and cannot adequately be controlled through engineering controls. Utilization of respiratory protection devices is subject to the review and approval of OEHS under the university [Respiratory Protection Program](#). **All staff participating in the Respiratory Protection Program must be identified in Appendix D of this Biosafety Manual.**

(6) Shorts and other clothing exposing feet or legs, sandals, and other open-toed shoes are prohibited laboratory attire.

b. Engineering Controls

(1) **Biological Safety Cabinets (BSCs).** Manipulations having the potential of generating biological aerosols must be performed within certified BSCs, these may include (but are not limited to): centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption (sonication), opening containers of infectious materials with internal pressures that may differ from ambient pressures, in vivo administration of agents via intranasal or gavage procedures, and harvesting infected tissues from animals or embryonate eggs. Complete information regarding BSC certification requirements, maintenance

procedures, and classifications may be viewed at the following URL:
<http://www.cdc.gov/od/ohs/biosfty/bsc/bsc.htm> .

(2) Centrifuge safety cups must be utilized when centrifuging materials that have the potential of producing biohazardous aerosols. The safety cups will be loaded within a BSC prior to centrifuging and will be opened within a BSC following centrifuging.

2. Secondary Containment

a. Facility Construction. New or renovated research facilities where manipulations involving potentially biohazardous agents are performed and/or test animals potentially infected with biohazardous agents must be constructed to satisfy the requirements outlined in the current edition of the [BMBL](#).

b. Waste Disposal. All regulated medical waste generated within university research facilities must be disposed of through the Physical Plant Department, Customer Service Center (828-9444), and must be packaged and labeled in accordance with federal and state requirements. The total weight of individual incineration boxes may not exceed 40 lbs.

B. Standard Microbiological Practices and Techniques. The CDC has developed “biosafety levels” (BSL)/animal biosafety levels (ABSL) which specify standard operating procedures and facility requirements for work involving biohazardous agents/infected research animals. These biosafety levels range from BSL/ABSL-1 (low individual risk, low community risk), involving agents with minimal risk to normal, immunocompetent individuals and to the environment through BSL/ABSL-4 (high individual risk, high community risk), which involves biohazardous agents that are extremely dangerous to humans and/or the environment (note that research involving BSL-3 is permitted at VCU with the approval of the IBC while ABSL-3 and BSL/ABSL-4 work is not permitted at VCU). Persons working with infectious agents or potentially infected materials must be aware of potential hazards, recommended biosafety level for the agents being manipulated, and must be trained and proficient in the practices and techniques required to handle such material safely. The PI is responsible for providing or arranging appropriate training of laboratory personnel assigned to each protocol. Personnel must be advised of special hazards and shall be required to read and follow required practices and procedures. A brief outline of the requirements of BSL-1 through BSL-3 is provided below. For complete listing of the requirements of CDC BSL/ABSL refer to the [BMBL](#).

1. **Biosafety Level 1 (BSL-1)** includes agents not known to cause disease in normal, healthy adults. Use of these agents requires the use of Standard Microbiological Practices. No specific safety equipment is required and these agents can be manipulated on an open laboratory bench. A sink for hand washing must be readily available.

2. **Biosafety Level 2 (BSL-2)** agents are associated with human disease, hazard, or threat of auto-inoculation, ingestion, or mucous membrane exposure; and low aerosol-exposure risk. In addition to BSL-1 practices, the laboratory must limit access, post biohazard warning signs, follow universal "sharps" precautions, and maintain a biosafety manual containing required laboratory procedures, decontamination requirements/methods, waste disposal requirements, immunization requirements, medical surveillance requirements, etc. Safety equipment needed for BSL-2 procedures include a certified class I or II BSC or other physical containment devices used for all manipulations of agents that may cause splashes or aerosols of infectious materials. Required PPE includes laboratory coats, gloves (latex and latex alternatives, based on risk assessment, and use two pair when appropriate), face, and eye protection as needed or as specified in the laboratory in the laboratory exposure control plan. The laboratory facility must meet BSL-1 standards and have an acceptable autoclave available.

3. **Biosafety Level 2 Enhanced (BSL-2E)** are also agents that are associated with human disease, have a threat of autoinoculation, ingestion, or mucous membrane exposure as well as low aerosol-exposure threat; but do not fit the criteria for inclusion in BSL-3. However, BSL-2E requires additional precautions not found at the BSL-2 level. BSL-2E applies primarily to viral vector systems with marginally engineered safety controls (e.g., second-generation lentiviral vectors). BSL-2E practices include BSL-2 practices in addition to the minimization of sharps use, elimination of sharps wherever possible or replacement with safety-engineered devices, verification that work is strictly conducted within a certified biosafety cabinet, confirmation that laboratory access is restricted to properly trained and protected individuals, and confirmation that the laboratory has developed a laboratory-specific biosafety manual. Task-specific training is required for all staff with potential for exposure. This training should cover basic epidemiology of the agent, possible associated oncogenic risks, and a review of written standard operating procedures (SOPs) for specific tasks involving the agent. Dates of this training must be indicated on the IBC Memorandum of Understanding as well as signed records of the training (e.g., initialed attendance roster for PI and staff) must be available. Specific written SOPs shall be developed for all procedures involving the vector system including preparation/administration of doses, disposal of sharps, disinfection of surfaces/equipment, orange/red-bag disposal of waste, spill response, exposure reporting and exposure report follow-up, etc. All surfaces will be immediately disinfected with freshly prepared 10% bleach solution (one part household bleach to nine parts deionized water), 70% ethanol, or other effective disinfectant following completion of tasks involving the vector system and all laboratory coats/other laboratory protective attire and equipment used during manipulations will be removed prior to exiting the laboratory unless other required research-related activities are to be conducted outside the laboratory. Details of this effort should be documented in a central laboratory filing system.

4. **Biosafety Level 3 (BSL-3)** are indigenous or exotic agents with potential for aerosol transmission and where the disease may have serious or lethal consequences. BSL-3 practice consists of BSL-2 practices plus decontamination of all waste/laboratory clothing before laundering and special engineering and design features. The IBC has determined that baseline sera will not be collected preferring instead to collect acute and convalescent sera following suspected exposure. Safety equipment includes Class II or III BSCs used for all manipulations of the infectious agent; protective laboratory attire, gloves (type based on risk assessment), face and eye protection; and respiratory protection as needed. The BSL-3 facility must meet all BSL-2 requirements plus physical separation from access corridors, self-closing, "air lock" access, special security requirements, negative pressure conditions within laboratory, 100% exhausted air from laboratory, and nonporous/seamless laboratory surfaces.

C. RISK ASSESSMENT. "Risk" implies the probability that harm, injury, or disease may occur. In the context of microbiological and biomedical laboratories, the assessment of risk focuses primarily on prevention of laboratory-associated infections (LAIs). When addressing laboratory activities involving infectious or potentially infectious material, risk assessment is a critical exercise that assigns an appropriate biosafety level (facilities, equipment, and practices) in order to reduce exposure risk and environmental threat of laboratory staff to an acceptable minimum. The intent of this section is to provide guidance and to establish a framework for selecting the appropriate biosafety level. The PI is responsible for assessing risks in order to set appropriate biosafety levels. This process should be conducted in close collaboration with the IBC (MUA) to ensure compliance with established guidelines and regulations. Determining factors in risk assessment include:

1. *Pathogenicity* of the infectious agent pertaining to disease frequency and severity (i.e., mild morbidity versus high mortality, acute versus chronic disease). The more severe the disease, the greater the risk associated with that pathogen.

2. *Route of transmission* (e.g., parenteral, airborne, or by ingestion) with novel agents may not be definitively established. Extensive epidemiological research has indicated that agents readily

transmitted via aerosol route have caused most laboratory-associated infections making critical the consideration of aerosol transmission potential of novel agents. The greater the potential for aerosolization, the higher the risk of transmission, and correspondingly, the higher the required biosafety level.

3. *Agent stability* is a consideration that involves aerosol infectivity (e.g., from spore-forming bacteria), and an agent's ability to survive over time in the environment. Factors such as desiccation, temperature, exposure to ultraviolet light, and exposure to chemical disinfectants must be considered.

4. *Infectious dose* can vary from one to hundreds of thousands of infectious units. There is a complex interaction between pathogen and host and the resultant issues present a significant challenge even to the healthiest immunized laboratory worker and may pose a serious risk to those with lesser resistance. The laboratory worker's immune status is directly related to his/her susceptibility to disease when working with an infectious agent.

5. The *concentration* (number of infectious particles per unit volume) is important in determining risk of infection. Items to consider are the milieu containing the organism (e.g., solid tissue, viscous blood or sputum; or liquid medium), volume of concentrated material, and the laboratory activity planned (e.g., agent amplification, sonication, or centrifugation).

6. The *origin* of infectious materials is critical when preparing a risk assessment. "Origin" may refer to geographic location (e.g., domestic or foreign); host (e.g., infected or uninfected human or animal); or nature of source (potential zoonotic or associated with a disease outbreak).

7. The *availability of data* from animal studies, in the absence of human data, may provide useful information in a risk assessment.

8. The established *availability of an effective prophylaxis* or therapeutic intervention is an essential factor to be considered. The most common form of prophylaxis is immunization.

9. *Medical surveillance* ensures that the safeguards implemented produce the desired health outcomes. Medical surveillance is part of risk management and may include serum banking, monitoring employee health status, and participating in post-exposure management.

IV. BIOHAZARD DECLARATION

A. BIOHAZARD CLASSIFICATION. Biohazards are infectious agents or biologically-derived infectious materials that present a potential risk to the health of humans or animals, either directly through infection or indirectly through environmental contamination. Infectious agents have the ability to replicate and give rise to potentially large populations when small numbers are released in nature from a controlled situation. Principal investigators should indicate below any of the hazard categories which are stored or in use within laboratories under their charge. **If boxes are checked, identity and biosafety level of agents meeting classification should be listed in the space provided below each category,** additional spaces may be added if required:

Pathogens: human, animal, and plant pathogens, including bacteria, prions, rickettsia, fungi, viruses, and parasites.

Human Blood and Other Potentially Infectious Materials (OPIM): All human blood, blood products, unfixed clinical tissues, and certain body fluids (specified in OSHA 29 CFR 1910.1030).

Cells/Cell Lines: Cultured cells from humans, non-human primates, and other mammalian species and the potentially infectious agents these cells may contain. See [BMBL Appendix H](#) and the [VCU Cell Line Policy](#) for specific hazards and handling recommendations.

Allergens: (adjuvants, animal dander, latex, etc):

Toxins: (bacterial, fungal, plant, etc.):

Recombinant DNA and related products:

Clinical Specimens:

Infected animals: including live animals, animal tissues, animal bedding/waste materials, and other materials derived from known or potentially infected animals.

Select agents: including and of the select agent materials on the [CDC or USDA](#) listing.

B. UNIVERSITY BIOHAZARD POLICIES: All PIs must comply with NIH/CDC standards regarding biological hazards through:

1. Limiting laboratory access to authorized personnel.
2. Limiting unauthorized access to known or potentially biohazardous materials.
3. Limiting handling of biohazardous materials to the minimum possible amount.
4. Ensuring proper disinfection, decontamination, and/or disposal of material after usage.
5. Ensuring proper usage of appropriate safety equipment, precautions, and procedures when handling biohazardous materials.
6. Maintaining appropriate levels of identification, warning, and security during storage of the material.
7. Posting of [universal biohazard sign](#) on the outside door of each laboratory of BSL-1 and above.
8. Maintaining proper ventilation of the laboratory.
9. Keeping laboratory doors closed during operations involving biohazards.
10. Following additional standards and special practices as described in the [BMBL](#).

C. MEMORANDUM OF UNDERSTANDING AND AGREEMENT (MUA)

1. In keeping with NIH policy as implemented at the university through the IBC, PIs must complete an [MUA](#) prior to commencing new research involving biohazardous agents, rDNA, or gene therapy.
2. Completed MUAs for work involving biohazardous agents, rDNA, or gene therapy must be submitted to the IBC in advance of anticipated start-date as commencement of the proposed research project is contingent on receiving written approval from the IBC. **Copies of all active MUAs should be attached to Appendix A of this manual.**

D. MATERIAL SAFETY DATA SHEETS. Material safety data sheets (MSDSs) contain health hazard information such as infectious dose, viability (including decontamination), medical information, laboratory hazard, recommended precautions, handling information, and spill procedures. The intent of the MSDS is to provide a safety resource for laboratory personnel working with these infectious substances and ready accessibility is required by OSHA. Proper utilization of MSDSs in association with prudent work practices fosters a safer, healthier working environment. The following URL provides MSDSs for a wide array of biohazardous agents, for additional resources and assistance contact the Biosafety Inspector at 827-0353: <http://www.phac-aspc.gc.ca/msds-ftss/index.html>. **Copies of all MSDSs for all biohazardous agents and biological toxins stored or in use should be attached to Appendix B of this manual.**

E. SELECT AGENTS: In accordance with the DHHS: “[Possession, Use, and Transfer of Select Agents and Toxins; Final Rule; March 18, 2005](#)” and NIH/CDC: “Additional Requirements for the Transfer or Receiving of Select Agents” (42 CFR Part 72), all facilities which transfer, use, or store specific agents (referred to as ‘select agents’), which are considered capable of rendering substantial harm to humans are subject to strict regulatory requirements. The regulations are intended to act as a deterrent to biological terrorism through controlling access to acutely toxic and infectious “select agents.” Failure to comply with these requirements could pose significant legal penalties (mismanagement of select agents is a federal felony) to negligent individuals as well as to the university. Further information can be obtained from the [CDC Select Agent Program](#) or [VCU’s Select Agent Requirements](#) page. The complete list of Select Agents can be obtained from <http://www.cdc.gov/od/sap/docs/salist.pdf>.

1. Biomedical Research Exemption.

a. According to 42 CFR Part 72. “Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD₅₀ for vertebrates of more than 100 nanograms per kilogram body weight are exempt so long as specified [exemption quantity limits](#) for toxin(s) involved are not exceeded. National standard toxins required for biologic potency testing as described in 9 CFR Part II 3 are exempt.”

b. Legislation (“[Possession, Use, and Transfer of Select Agents and Toxins; Final Rule; March 18, 2005](#)”) states that designation of “exempt” status for institutions following September 12, 2002 be declared by DHHS/USDA on a case-by-case basis. The current exempt status for toxins at limited quantities is subject to reinterpretation and/or revision. Thus, VCU researchers must register all select agents with OEHS [Select Agent Program](#) whether of exempt or nonexempt status.

c. The National Institutes of Health advise that the [Registry of Toxic Effects of Chemical Substances \(R-TECS\)](#) tables, maintained by the National Institute for Occupational Safety and Health, be used as a guide when determining the LD₅₀ of a select agent.

d. Possession prior to 42 CFR 72. Since the new DHHS regulations include use, *possession*, and transfer of select agents, claims of exemption due to possession prior to 42 CFR 72 are no longer valid.

2. University Policy. The university must identify and track all the select agents on both campuses. The university relies upon several methods for identifying/tracking select agents such as PI registration, protocol review, and through annual laboratory inspection. Select agents are toxic at extremely low concentrations; for this reason, research involving these materials in excess of *de minimis* quantities is restricted to staff who have submitted required forms and been approved by Department of Justice, received proper training, have access to adequate work facilities, and are provided suitable personal protective equipment (PPE). The exact degree of these requirements is specified in the research protocol which must be approved by the IBC prior to initiating any procedures involving non-*de minimus* quantities of select agents or etiologic agents and/or other biohazardous materials. Additionally, work with non-*de minimis* quantities of select agents can only be carried out in laboratories specifically inspected and approved by the CDC. The National Institutes of Health/Centers for Disease Control direct facilities to deplete or destroy all select agents on site prior to disposal which includes depletion, destruction, and recycling. For additional information regarding select agents visit [OEHS’s Select Agents Requirements webpage](#).

V. RECOMBINANT DNA

A. The National Institutes of Health: ["Guidelines for Research Involving Recombinant DNA Molecules"](#) (NIH Guidelines) are designed to specify practices for constructing and handling the following agents: recombinant deoxyribonucleic acid (rDNA) molecules; and organisms and viruses containing rDNA molecules.

NIH further defines rDNA as: “. . . *rDNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above. Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed in vivo as a biologically active polynucleotide or polypeptide product, it is exempt from the NIH Guidelines. Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the NIH guidelines unless the transposon itself contains recombinant material.*”

B. University Requirements: Section III of the [NIH rDNA Guidelines](#) allocates rDNA research into six basic classifications: Section III A through F.

1. **“Nonexempt” activities:** All rDNA which falls under research Sections III.A – E is considered to be “nonexempt” (regulated by the guidelines) and **must be registered with the IBC via [Memorandum of Understanding and Agreement](#)** prior to commencing work.

a. Activities requiring NIH and IBC approval:

(1) Section III-A: Applications involving deliberate transfer of drug resistance may require preapproval from the [Office of Biotechnology Activities NIH Recombinant DNA Advisory Committee](#) (RAC) and the NIH Director submission of an MUA/IBC approval prior to commencement.

(2) Section III-B: Research involving formulation of genes for biosynthesis of highly lethal toxin molecules may require prior approval from the [NIH Office of Biotechnology Activities](#) (OBA) in addition to submission of an MUA/IBC approval prior to commencement.

(3) Section III-C: Experiments involving human subjects will require notification and approval of the RAC, OBA and submission of an MUA/IBC approval prior to commencement.

b. Experiments requiring only IBC approval prior to initiation: rDNA activities falling under Sections III, D and E may be initiated upon receiving IBC approval via submission of MUA. Experiments involving in vivo applications will require additional IBC approval/registration via completion of Appendix C of the standard [Institutional Animal Care and Use Committee](#) protocol.

2. **“Exempt” Activities:** Activities are included under Section III-F are considered to be exempt from NIH review and do not require IBC registration and approval via an MUA. **Copies of all active MUAs should be attached to Appendix A of this manual.**

3. Transgenic Species:

a. Section III-F transgenic animals: while not requiring an MUA, all import, export, and creation of **transgenic species falling** under Section III-F must be registered with the IBC via submission of a transgenic animal or transgenic plant registration form prior to commencing research. For provision of a transgenic registration form contact the [Biosafety Office](#).

b. Other Transgenic Animals: All activities involving transgenic animals which do not fall under Section III-F will require IBC approval/registration via submission of a [Memorandum of Understanding and Agreement](#). This will include all transgenic lines generated through the use of viral vectors and any other animals requiring handling at ABSL-2 or greater containment conditions.

VI. GENE THERAPY

A. Research proposals involving the deliberate transfer of rDNA into human subjects (human gene transfer) must be preapproved by the NIH [OBA](#) and [RAC](#) offices. Principal investigators shall submit their relevant information on the proposed human gene transfer experiments to NIH/OBA.

B. The IBC will be notified prior to the submission of review documents to NIH (RAC and OBA) and any other outside review agencies

C. Approval from the [Institutional Review Board](#) (IRB) is mandatory prior to engaging in research involving human subjects.

D. Approval from the IBC via submission of an [MUA](#) must be obtained prior to administering rDNA material to human subjects. **Copies of all active MUAs should be attached to Appendix A of this manual.**

E. In accordance with RAC guidelines and university policy, **genetic research involving germ line alteration(s) shall not be permissible within university facilities.**

VII. EMERGENCY PROCEDURES

Biological, Chemical, and Radiation Emergencies:

VCU and Hospital : 828-9834

Fire Emergencies:

Hospital: *50

Medical (east) campus: *50 or 828-1234

Monroe Park (west) campus: 828-1234

Medical Emergencies:

Immediate Emergencies: 828-1234

Employee Health: 828-0584

Poison Control: 828-9123

MCVH Emergency Room: 828-9000

Security Contact Numbers:

VCU Campus Police: 828-1234

MCV Hospital Security: 828-6595

VCU Communications Center: 828-1234 or 828-4357

Laboratory Contacts:

Principal Investigator contact numbers:

Other important contact numbers:

A. LABORATORY EMERGENCY POSTINGS

1. Names of responsible individuals to be contacted in case of emergencies must be posted outside of entrance doors leading into each laboratory. (A phone number for the contact individual is helpful, but optional, as long as the contact person has verified that their contact info is up to date in the VCU Employee Banner Self Serve contact section.)

2. A list of the significant hazards found within the laboratory must to be posted for notification of staff and emergency response personnel. The list of hazards that must be identified by signage posted at entrances to laboratories includes (but is not limited to):

a. Use/storage of biohazardous agents, acute carcinogens and toxic chemicals, radiological agents, and flammable materials.

b. Presence of strong magnetic equipment.

c. Emission of X-rays.

d. Required PPE.

e. A listing of all alarms in the laboratory and whom to contact if an alarm is sounding

3. To assist researchers in meeting posting requirements OEHS has developed fill-in-the-blank [laboratory safety](#) and [biohazard signage](#).

B. EMERGENCY EQUIPMENT

1. Verification that proper emergency equipment is provided within laboratory spaces is the responsibility of the PI. Specific emergency-response equipment requirements will depend upon the nature of research conducted within each laboratory space. Principal investigators are responsible for assessing and acquiring all necessary emergency response equipment prior to initiating new research projects. The PI must ensure that all laboratory personnel are familiar with locations and proper use of emergency equipment within their laboratory.

2. For certain hazards, respiratory protection may be required for routine and emergency operations. If respirators (including N-95 masks) are provided, the laboratory must have a written Respiratory Protection Program and all users must have been medically evaluated, fit-tested, and trained within the past twelve months to qualify for respirator use. Information about respirators and respiratory protection programs may be obtained at the following URL: <http://www.vcu.edu/oehs/chemical/resp.pdf>. **All staff participating in the Respiratory Protection Program must be identified in Appendix D of this manual.**

C. EVACUATION ROUTES: Principal investigators must ensure that staff receives adequate training regarding emergency evacuation procedures that includes the following elements:

1. Familiarization with primary and secondary (alternate) evacuation routes.

2. Awareness of alarm method(s) used to signal a building evacuation.

3. Designation of post evacuation meeting areas for laboratory staff.

4. For assistance in determining proper evacuation procedures contact the [OEHS Fire and Occupational Safety Office](#).

D. BIOHAZARDOUS MATERIAL SPILL RESPONSE PROCEDURES. Principal investigators are responsible for developing emergency response procedures and ensuring that laboratory personnel are thoroughly trained in the event of incidents involving biological and chemical spills. The essential elements of a biohazardous spill response plan suitable for addressing the two most common types of incidents encountered within university laboratories are listed below:

1. SPILL IN A BIOLOGICAL SAFETY CABINET. A spill that is confined to the interior of a properly operating biological safety cabinet (BSC) may present little or no hazard to personnel in the area. In the event of a biohazardous spill within a BSC, the following procedures shall be followed:

(1) Leave the cabinet on: while wearing gloves, spray or wipe cabinet walls, work surfaces, and equipment with suitable disinfectant as specified by the MSDS or as recommended in the [Guidelines for Disinfecting and Sterilizing in Healthcare Facilities, 2008](#) (Disinfecting Guidelines). If necessary, flood the work surface, as well as drain pans and catch basins below the work surface with disinfectant for a contact time of at least 20 minutes.

(2) Soak up disinfectant and spill with spill pad or paper towels. Drain catch basin into an appropriate container. Lift front exhaust grill and tray and wipe all surfaces. Ensure that no paper towels or solid debris are blown into the area beneath the grill.

(3) Autoclave all clean-up materials before disposal in the biohazard waste container. Wash hands thoroughly with soap and water after the clean-up procedure.

2. SPILLS IN OPEN LABORATORY AREAS. Biohazardous spills occurring in open laboratory areas pose a greater potential for exposure than spills occurring within biological safety cabinets and as such a greater degree of care and preparedness is required for safely responding to open area incidents. Essential elements of open area biohazard spill response are detailed below:

(a) When potentially biohazardous materials are spilled in open area of the laboratory evacuate the laboratory immediately to limit exposure to aerosols.

(b) Upon exiting the laboratory, warn other personnel in the area of the incident.

(c) If clothing and/or skin is known or suspected to have been contaminated during incident, proceed immediately to full immersion emergency shower or changing area providing shower suitable for personal decontamination.

(d) Remove contaminated clothing with gloved hands, folding contaminated area inward. Discard clothing in a red biohazard bag or place clothing directly in an autoclave.

(e) Thoroughly wash all potentially contaminated areas, arms, face, and hands with soap and warm water.

(f) Avoid reentry into the laboratory for at least 30 minutes to allow for the settling of aerosols potentially generated by the spill.

(g) Don appropriate PPE for cleaning operation. This must include at a minimum: gloves, eye protection, and laboratory coat. Spills involving high risk biohazardous agents with high potential for

aerosol transmission may require additional PPE including [respiratory protection](#). **All staff participating in the Respiratory Protection Program must be identified in Appendix D of this Biosafety Manual.**

(h) Cover spill gently with paper towel(s), apply disinfectant as specified in product MSDS or recommended by the [CDC Disinfecting Guidelines](#) onto adjacent surfaces working toward spill. Complete action by applying copious amount of disinfectant to actual spill area.

(i) Allow disinfectant to stand for at least 15 minutes, proceed with thorough wipe-down of spill and adjacent surface areas. Note; however, whenever sharps materials are involved, wipe down and collection of waste materials shall be conducted via mechanical means. Refer to the OEHS [Bloodborne Pathogen/Infectious Waste Management Webpage](#) for complete instructions on cleaning spills involving sharps materials.

(j) Repeat steps (h) and (i), above.

(k) If the floor and sink are affected by the spill, flush these areas with disinfectant.

(l) Dispose of all liquid and solid waste generated during spill cleanup as biohazardous waste through VCU Customer Service (828-9444).

4. Advance Planning. Advance preparation for management of a spill is an essential element of laboratory biosafety. A "spill kit" which includes necessary PPE, disinfectant, and other materials required for responding to biohazardous spills must be available in all areas where manipulations involving potentially biohazardous agents are conducted. The standard elements of a typical spill kit are detailed in Chapter VII, Section B of this manual.

5. Emergency Telephone Numbers. Whenever spills involve personal injury or biological contamination, call 8-1234 or 8- 4357 from any campus phone and request medical assistance and request that the Control Center initiate the Chemical Emergency page. Be sure to state the type of contaminant involved in the incident. The caller should remain available to brief emergency responders on the type of contamination and proper procedures for handling the material.

VIII. STERILIZATION/DECONTAMINATION

A. STERILIZATION. Sterilization is the total destruction of all viable microorganisms from a surface or given volume of gas or liquid. For protection of personal health and the integrity of research, laboratory personnel must understand this concept when working with potentially biohazardous agents and ensure proper autoclaving procedures are followed. When sterilizing glassware and other reusable instruments, autoclave operators must ensure that cycle times and temperatures are adequate and that autoclave units are functioning properly. Whenever biohazardous (regulated medical) waste materials are sterilized onsite for disposal via orange bags (domestic waste stream) the [Virginia Department of Environmental Quality - Regulated Medical Waste Regulations](#) (9VAC20-120) are applicable. Proper autoclaving procedures are detailed in Section VIII (Biohazard/Biohazardous Waste Management).

B. DECONTAMINATION: Decontamination is the process whereby viable microorganisms are removed from solutions, surfaces, or materials by filtration, heating, radiation, or chemical removal. A freshly prepared dilution of household bleach is a frequently employed, and is a quite effective decontaminant for a number of biological agents. Researchers should, however, refer to the agent/product MSDS and the [CDC Disinfecting Guidelines](#) whenever determining appropriate disinfectants. If bleach is selected, OEHS recommends use of a bleach-water 10% solution (i.e., one part household bleach to nine parts water) prepared daily. Decontaminants are an essential component of an emergency spill response kit. Spill kits are required in all labs conducting research involving potentially biohazardous agents. A listing of the required elements within a spill kit includes:

1. A sufficient reserve to produce at least four liters of 10% bleach solution or other suitable decontaminant. Even in un-opened original containers, undiluted bleach can lose its potency over time; therefore, concentrated bleach held on hand for spill decontamination should be rotated every six months.
2. Absorbent materials, such as absorbent pads, vermiculite, or disposable towels for containing and treating spills.
3. Spray/mist bottles for disinfectant application.
4. "Red bags" for receiving biohazardous waste generated during spill response or for overpacking leaking containers.
5. Leak-proof, puncture-resistant, closable, and properly labeled containers for receiving contaminated broken glass and other sharps materials.
6. Protective clothing, and equipment including:
 - a. Liquid impermeable disposable coveralls (e.g., Tyvek[®]).
 - b. Eye protection gear, including splash resistant safety glasses and face shields.
 - c. Gloves suitable for protection from biological/chemical hazards. Be aware that glove materials are variably resistant to chemical penetration and degradation; therefore, the glove material must be appropriate for the chemical against which it is intended to provide a barrier.
 - d. Rubber boots, and/or foot covers.
 - e. *Protective breathing devices such as N-95 respirators.

*For certain hazards, respiratory protection may be required for routine and emergency operations. If respirators are to be provided, the laboratory must have a written Respiratory Protection Program which addresses all aspects of an OSHA-compliant respiratory protection program. Information about respirators and respiratory protection programs may be at the following URL: <http://www.vcu.edu/oehs/chemical/resp.pdf>.

7. Forceps, broom, heavy-duty brush, and dustpan (for spills involving sharps materials).
8. Extra clothing to replace items contaminated during spill/cleanup (scrubs, e.g.).

IX. BIOHAZARD/BIOHAZARDOUS WASTE MANAGEMENT

A. Regulated Medical Waste: The [Virginia Department of Environmental Quality - Regulated Medical Waste Regulations](#) (9VAC20-120) and university policy designate the following seven classes of regulated medical (i.e., biohazardous, infectious) waste:

1. Cultures and stocks of microorganisms and biologicals. Discarded cultures, stocks, specimens, vaccines, and associated items likely to have been contaminated with organisms potentially pathogenic to healthy humans.
2. Human blood/blood products, other potentially infectious material (OPIM), and animal blood/blood products. This includes wastes consisting of human and animal blood/blood products (includes serum, plasma, etc.) and items contaminated by *significant* amounts human and animal blood/blood products. “Significant” quantities of blood are present whenever materials render visible release of liquid or dried blood upon being subjected to wringing and/or typical handling procedures. Under this definition, materials stained with small quantities of embedded blood/blood products do not require disposal as RMW.
3. Tissues and other anatomical waste. This includes all human anatomical wastes and all human tissues, organs, body parts, or body fluids.
4. Sharps materials. Includes all discarded needles and scalpels (regardless of contamination potential), any other sharps materials likely to be contaminated with pathogenic organisms, and all sharps used in patient care and veterinary practice.
5. Intentionally infected animal carcasses, body parts, urine, feces, bedding, and related waste. This applies when source animals are known or suspected to be infected with organisms potentially pathogenic to healthy humans.
6. Residues, soils, liquids, and other debris resulting from cleanup of a spill of any regulated medical waste.
7. Solid waste contaminated by, or mixed with regulated medical waste.
8. Other Regulated Biological Materials: In accordance with NIH standards, all rDNA/gene therapy waste that may have potentially come into contact with rDNA molecules or gene therapy waste) must be considered biohazardous waste. Surgical instruments and other reusable materials should be sterilized in accordance with the [CDC Disinfecting Guidelines](#) and applicable hospital policies prior to reuse.

B. Proper Management and Disposal Procedures: All of the above listed materials shall be considered biohazardous (regulated medical waste) and shall be managed/disposed of as detailed below. Proper disposal procedures can be obtained from <http://www.vcu.edu/oehs/chemical/biosafe/bbp.pdf>.

C. Sharps Materials: All needles, scalpels, blades, scissors, and other laboratory instruments that pose laceration or puncture hazards will be managed and disposed of as “infectious sharps” regardless of whether they have come into contact with infectious (biohazardous) in accordance with all applicable federal and state regulations and university guidelines.

1. Management and disposal requirements for infectious sharps include the following elements:

a. Infectious sharps materials must be placed in an approved container. Approved infectious sharps containers must have the following properties:

(1) Containers must be rigid and puncture resistant.

(2) Containers must be leak resistant on sides and bottom.

(3) Containers must be capable of being readily (without coming into contact with sharps materials) closed and securely sealed properly prior to disposal.

(4) Containers must be clearly marked with the following labeling; "BIOHAZARD: INFECTIOUS SHARPS".

b. Fingers/hands must never be placed inside sharps containers. In the unlikely event that an item would have to be retrieved or dislodged from a sharps container, forceps or another mechanical device must be utilized.

c. Sharps containers must not be overfilled: sharps materials must fit completely into the container; portions of sharps materials shall not be allowed to protrude from the top of the vessel. When containers are approaching full, seal them securely and replace with new (empty) sharps containers.

d. Upon filling, infectious sharps containers must be securely sealed and placed inside red bag/incineration box units for disposal via VCU Customer Service (828-9444).

e. Needles and other sharps materials must not be recapped unless deemed essential to research project by PI. Where alternative means are not available, needle recapping may be performed under the following conditions:

(1) Recapping of needles may be conducted only by the use of mechanical devices or one-handed scoop technique under the approval of the IBC. Principal investigators wishing to include needle recapping in research protocols are required to complete/submit a [needle recapping waiver form](#). Upon IBC approval, a copy of the waiver form should be maintained in the laboratory exposure control plan and/or biosafety manual. Waivers are valid for three years from date of issue and must be re-submitted if the need persists beyond three years.

(2) Needles, scalpels, and other mounted sharps materials may not be removed from mountings or remounted.

f. Breaking, bending, or shearing of needles is strictly prohibited.

g. All employees involved in incidents with known or potentially infectious sharps materials shall report immediately to Employee Health for medical evaluation. [VCU HR Employee Health](#)

h. All sharps-related injuries shall be recorded in a sharps injury log which must be obtained from Employee Health.

i. The model university [exposure control plan](#) can be downloaded at the following from the OEHS webpage.

2. Pipette tip disposal:

a. Pipette tips with the potential for contamination with infectious materials will be handled by either of the two following means:

(1). Direct disposal into an incineration box which has been double-lined with red bags. Both bags must be individually sealed to prevent possible leakage of residual fluid. Tips with potential for retaining significant amounts of fluids should be handled as indicated below.

(2). Disinfection in bleach solution (daily prepared stock at 10% or greater concentration) with minimum contact time of 30 minutes, and disposal as “noninfectious broken glass” (refer to line IX.C.3)

b. Pipette tips with no potential for contamination with potentially infectious materials: discarded tips must be discarded as “noninfectious broken glass” (refer to line IX.C.3).

3. “Non-Infectious Broken Glass” includes all broken glassware which has not come into contact with potentially infectious agents. These materials may include such items as: glassware broken during or after cleaning, glassware broken while containing noninfectious materials (water, buffers et. al.), broken coffee cups, broken soda bottles etc. Glass Pasteur pipettes, pipette tips, glass and plastic serological pipettes, test tubes, flasks and petri dishes which have not come into contact with potentially infectious agents may also be classified as non-infectious broken glass, if handled accordingly as detailed below:

a. Place all noninfectious broken glass items into puncture resistant containers (e.g. sturdy cardboard/fiberboard box) which has been lined with plastic bag (do not use a red or orange bag).

b. Do not fill above the top of the box, when approaching full, seal box and wrap box with several strips of packing or duct tape.

c. Clearly label box "NONINFECTIOUS BROKEN GLASS" (use an indelible black marker or other clearly visible permanent pen type).

d. Dispose of noninfectious broken glass box through housekeeping (or place in regular "domestic" trash dumpster).

D. UTILIZATION OF REUSABLE CONTAINERS FOR STAGING BIOHAZARDOUS MATERIALS. Regulated medical waste materials including red-bagged material and orange-bagged materials prior to autoclave sterilization may be conveyed and/or staged in reusable containers or carts under the following conditions:

1. The waste in containers must be fully packaged in compliance with VDEQ and DOT requirements (within suitable red bags). Discrete packages of waste and the reusable container must each be labeled in accordance with DEQ requirements.

2. Immediately following each time that a reusable container is emptied and prior to being reused, it must be thoroughly cleaned, rinsed, and effectively sanitized with a hospital grade disinfectant effective against mycobacteria. The area in which this is done shall be considered a regulated medical waste staging area; therefore, it must be regularly sanitized and placed under restricted access during times when disinfectant is in use.

3. Unloading of large-volume reusable carts and containers must be accomplished through mechanical means that do not involve manual handling of bags or packages. Mechanical means may consist of tipping floors, chutes, snares, and other simple mechanisms.

4. Unloading of small-volume containers such as pails or trashcans must be performed with proper personal protective equipment (gloves, lab coat, safety glasses, etc.) utilizing techniques which minimize handling of red/orange bags and while avoiding contact with bag contents.

X. SHIPPING OF BIOHAZARDOUS MATERIALS

A. Regulatory Requirements. Materials in commerce deemed to have a reasonable potential for being contaminated with infectious agents are classified as “Dangerous Goods.” Shipment of dangerous goods is regulated primarily by the United States DOT although several other federal agencies (USDA, CDC, OSHA, etc.), international organizations (United Nations, [World Health Organization](#), International Air Transport Association (IATA), etc.), and foreign governments also have requirements which apply to the shipment of dangerous goods under certain circumstances.

B. University Policy. As indicated in the section above, employees who participate in the packaging, shipping, receiving, transportation, or otherwise handle packages containing dangerous goods must receive comprehensive training and possess an up-to-date certification. Detailed information regarding packaging, shipping, and labeling requirements for dangerous goods (infectious materials, diagnostic specimens, dry ice, etc.) training/certification opportunities and related topics may be reviewed at the following OEHS websites:

1. [Dangerous Goods: General Information Page](#): Overview of regulatory requirements and university policies.
2. [Dangerous Goods: Hot Topics Page](#): Provides updates on regulatory changes and other current events affecting the research community.
3. [Dangerous Goods: Training Information](#): Dates/locations of upcoming training and certification classes.

C. Contact the OEHS Dangerous Goods Program: For arrangement of dangerous goods safety training and/or assistance with questions/problems involving the packaging, shipping, receiving, labeling, or other dangerous goods issues, contact OEHS at 828-1392.

D. Accredited Staff: Laboratory personnel who have been certified for shipping/receiving of Dangerous Goods via the OEHS platform presentation or other approved course should be listed below (note: certification must be renewed every two years):

1. _____ Certification expires: _____
2. _____ Certification expires: _____
3. _____ Certification expires: _____
4. _____ Certification expires: _____
5. _____ Certification expires: _____
6. _____ Certification expires: _____

XI. TRAINING REQUIREMENTS. The OSHA [Bloodborne Pathogens Standard](#) and [Laboratory Safety Standard](#) specify that employers (PIs, laboratory managers, and other supervisory staff) are responsible for ensuring that employees are trained regarding the hazards associated with their job descriptions. University laboratories conducting research involving known or potentially biohazardous agents must meet the following training requirements:

A. Orientation Training. Supervisors must ensure that all new employees attend orientation training upon beginning employment. For additional information regarding orientation refer to the [Fire and Occupational Safety webpage](#).

B. General Laboratory Safety Training. The Office of Environmental Health and Safety has developed [laboratory safety training modules](#) to assist in the training process. Six modules are currently available for the VCU research community:

1. *General Laboratory Core*
2. *Physical Hazards Training*
3. *Carcinogens Training*
4. *Chemical Hygiene Officer Training*
5. *Animal Biosafety Training*
6. *General Biosafety Training*

Laboratory supervisors may choose which of the six modules are applicable to each job description; however, all laboratory workers are strongly encouraged to complete the core laboratory safety module. Tests provided with the interactive modules are to be reviewed by the supervisor to ensure that staff members have mastered the training material. Graded tests should be maintained on file by the supervisor to serve as documentation of completion of training. Verification of staff participation should be provided below:

1. _____ Module numbers completed: _____
2. _____ Module numbers completed: _____
3. _____ Module numbers completed: _____
4. _____ Module numbers completed: _____
5. _____ Module numbers completed: _____
6. _____ Module numbers completed: _____
7. _____ Module numbers completed: _____
8. _____ Module numbers completed: _____

C. Hazard Communication Training: The OSHA [Hazard Communication Standard](#) requires that general laboratory safety training be complemented with job-specific/hands-on safety training. Supervisors must ensure that employees are made aware of all hazards associated with their job and other hazards present within the work area. Thorough hazard communication training includes incorporation of the record keeping elements described in Section XI.

D. Special Training Requirements: Laboratory staff working under special conditions may require additional training and/or certifications. Examples of duties requiring special training would include:

1. Preparing/receiving dangerous goods shipments (refer to Section IX)
2. Work in BSL-3 or greater biological containments (refer to Section III)
3. Work involving select agents (refer to Section IV.E.)
4. Issuance of respiratory protection in order to reduce exposure to biological and/or chemical hazards will require participation in the university [Respiratory Protection Program](#). **All staff participating in the Respiratory Protection Program must be identified in Appendix D of this Biosafety Manual.**

XII. RECORDKEEPING REQUIREMENTS

A. Standard Operating Procedures (SOPs) Manual. **Laboratory SOPs for procedure involving biohazardous and rDNA materials should be attached in Appendix A of this manual.**

Standard Operating Procedures (SOPs) must be developed for all laboratory procedures that involve known or potentially biohazardous agents. Laboratory staff must be trained annually in regards to each SOP or whenever new procedures are added to the work regimen. Required elements of an SOP include:

1. Descriptive title defining purpose of operation.
2. Preparation and revision dates.
3. Identification of department/laboratory for which SOP is applicable.
4. Brief statement of purpose.
5. Indication of potential undesirable outcomes.
6. Identification of regulatory standards that apply to procedures.
7. Listing by category of all materials, tools, and equipment required to complete SOP – it is critical that all safety equipment be identified (required PPE, BSCs, etc.).
8. Listing of environmental conditions, time constraints, or other factors which may have a negative impact on the execution of the SOP.
9. An overview of the sequence of the SOP describing major functions and anticipated/potential health and safety and environmental impact.
10. Definitions of terms.
11. Prominent display of warnings and cautions prior to description of each task with potential danger involved.
12. Listing of all tasks included within SOP in sequential order.

B. Biological Material Safety Data Sheets. In addition to the inventories of MSDSs compiled for hazardous chemicals, all laboratories performing research with known or potential biohazardous agents must maintain a comprehensive collection of MSDSs for each biohazardous agent. Questions or concerns regarding acquisition of MSDSs of biohazardous materials should be directed to the Biosafety Inspector at 827-0353.

C. Job Safety Analysis (JSA). OSHA requires that supervisors prepare assessments (JSAs) of safety issues relating to the workplace and work activities identifying the range of hazards and determining whether existing precautions are adequate. If existing safety precautions are not adequate, appropriate corrections must be identified and implemented. Supervisors are further required to explain and discuss the completed JSA with employees and to maintain the JSA within the laboratory. OEHS has developed a [model JSA form](#) to aid supervisors in the fulfillment of this requirement. This form must be updated annually or as conditions warrant.

D. Exposure Control Plan (ECP): In accordance with the requirements of the [OSHA Bloodborne Pathogen Standard](#), laboratories performing research where there is a potential occupational exposure to bloodborne pathogens are required to develop and maintain an ECP. The Office of Environmental Health and Safety has developed a [model university ECP](#) which provides a uniform policy for protection of university personnel who, as part of their job function, face reasonably anticipated exposure to bloodborne pathogens. **If an ECP is required, a copy of the completed document should be attached to Appendix E of this manual.**

E. Sharps Injury Log: In accordance with the requirements of the OSHA Bloodborne Pathogens Standard, laboratories performing research involving known or suspected bloodborne pathogens must document all incidents involving potential employee exposure via sharps injury. University sharps injury logs must be obtained from Employee Health whenever sharps-related incidents occur. Information requested on the sharps injury log form must be completed by the injured worker's supervisor and reviewed/signed by the injured worker. Completed and signed forms must be submitted to Employee Health with a copy maintained within the laboratory of affected employee.

F. Medical Surveillance Program: Principal investigators must retain on file records of all occupational monitoring, medical examinations, vaccination/vaccination declination, and required medical treatment records for all employees involved tasks with risk for exposure to biohazardous agents. Medical surveillance records must be maintained on file for the duration of employment plus 30 years.

G. Engineering Control Devices and Safety Equipment Testing/Certification. Laboratories must arrange for testing services required for maintaining certification of all engineering control devices and safety equipment necessary for achieving compliance with regulatory requirements. An abbreviated list of equipment requiring regular testing and/or certification includes:

1. Biological safety cabinets utilized for procedures involving BSL-2 or greater biohazardous agents: annual testing/certification required.
2. Biological glove box units utilized for procedures involving BSL-2 or greater biohazardous agents: annual testing/certification required.
3. Directional flow/negative pressure ventilation of laboratories operating under BSL-3 conditions: annual verification of suitable conditions required.
4. [Chemical fume hoods](#): annual testing provided by OEHS.
5. Autoclave units utilized for onsite treatment of biohazardous waste: monthly testing and regular documentation required (see section VIII.B).

H. Respiratory Protection Program: Research involving certain toxic chemicals and/or biohazardous agents may require that respiratory protection be provided for employees involved in routine tasks or potential emergency response operations. If respirators are provided, the laboratory must implement a written [Respiratory Protection Program](#) that is fully compliant with 29 CFR 1910.134.

I. Dangerous Goods Shipping Records: All shippers declarations and waybills related to the shipment of any dangerous goods materials must be retained in the laboratory's central files for a minimum of two years post shipment.

J. Additional Records/Documents: Although the primary focus of this section is the identification of biosafety-related record keeping requirements, PIs and laboratory directors must be

aware that they are also responsible for complying with the recordkeeping requirements of a broad range of other environmental and safety programs including: [chemical safety](#), [radiation safety](#), and [fire/occupational safety](#).

APPENDIX A: Institutional Biosafety Committee (IBC) Approvals

Attach copies of all active protocols involving biohazardous and/or rDNA materials and corresponding IBC approvals. This should include all IACUC protocols requiring completion of Appendix C (*in vivo* use of chemical, biological, and rDNA hazards), Memoranda of Understanding and Agreement (MUAs), Needle Recapping Waivers, and any other documents conveying IBC instruction/interpretation.

APPENDIX B: Material Safety Data Sheets (MSDSs)

Attach an agent/product-specific MSDS copy for each biohazardous agent and/or biological toxin in use with in the laboratory. All biological toxins (even if covered under this biosafety manual) must also be addressed in the laboratory Chemical Hygiene Plan (CHP). If an MSDS is not available for specific agents/toxins provide whatever hazard information is available.

APPENDIX C: Laboratory SOPs

Attach Laboratory Standard Operating Procedures (SOPs) for all Tasks Involving Biological Hazards and Recombinant DNA materials.

APPENDIX D: Respiratory Protection Program

Laboratory personnel who are issued respiratory protective equipment (including N-95 masks) are required to participate in a [Respiratory Protection Program](#) which includes medical evaluation, proper use training, and fit-testing. All staff who are issued a respirator must receive medical clearance and fit-testing annually. Contact the [Biosafety Office](#) if you need assistance with the development of this program. Laboratory personnel who have completed respiratory protection program requirements should be listed below, along with training/fit-testing date, and type of respirator(s) approved to wear:

Name _____

Initial fit-testing/training date _____

Annual fit-testing renewal _____

Respirator type(s) approved to utilize: _____

Name _____

Initial fit-testing/training date _____

Annual fit-testing renewal _____

Respirator type(s) approved to utilize: _____

Name _____

Initial fit-testing/training date _____

Annual fit-testing renewal _____

Respirator type(s) approved to utilize: _____

Name _____

Initial fit-testing/training date _____

Annual fit-testing renewal _____

Respirator type(s) approved to utilize: _____

Name _____

Initial fit-testing/training date _____

Annual fit-testing renewal _____

Respirator type(s) approved to utilize: _____

APPENDIX E: Exposure Control Plan

In accordance with the OSHA [Bloodborne Pathogens Standard](#) (CFR 29 1910.1030) personnel with reasonable potential for occupational exposure to bloodborne pathogens (BBPs) must be included in an [Exposure Control Plan](#) (ECP). Principal investigators performing research involving bloodborne pathogens should attach a completed [Exposure Control Plan](#) which includes all personnel with reasonable potential for exposure to BBPs here: