**VUMC Lab-Specific Biosafety Manual**

**Biosafety Level 2 Containment Lab**

**PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Building and Room:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Introduction**

This Vanderbilt University Medical Center (VUMC) lab-specific Biosafety Manual was developed to provide guidance on proper protocols and procedures for safe research with biohazards.The use of biohazardous materials including infectious agents and recombinant nucleic acids is regulated federally by the NIH Guidelines for Research Involving the Use of Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), and the CDC Import Permit Program.

This manual provides students, staff, and faculty at VUMC with information that is necessary to protect them and the surrounding community from possible hazards associated with the use of biohazardous agents and recombinant or synthetic DNA (r/sDNA) and RNA molecules.

VUMC is committed to a culture of safety. All faculty, staff, and students are responsible for abiding by the procedures set forth within the manual and are empowered to be an active participant in VUMC's culture of safety.

**Roles and Responsibilities**

**VUMC OCRS:** VUMC Office of Clinical and Research Safety (OCRS) Biosafety program helps to ensure that personnel are qualified to perform their jobs safely through training and documentation of technical expertise. The goal of **biological safety** is the containment of potentially harmful biological agents. Containment refers to safe methods, facilities, and equipment for managing biohazardous materials in the laboratory environment. The goal of containment is to reduce or eliminate exposure of laboratory workers, VUMC staff, and the lay community to hazardous biological agents and materials. [VUMC OCRS Biosafety Website](https://www.vumc.org/safety/bio) contains additional information to address biosafety-related concerns and needs.

**Principal Investigators (PIs):** The PIs are responsible for ensuring that all work being performed within their laboratory is performed in compliance with federal and university regulations, policies, and guidelines including the Biosafety Manual. PIs will secure approval, prior to the initiation of any research, from applicable VUMC institutional committees (e.g. IBC, IACUC, IRB) and ensure lab personnel complete and remain up to date with all training related to biological safety.

**Laboratory Staff (technicians, research assistants, post-docs, students, etc.):** Laboratory staff and students will abide by all policies and procedures set forth in the Biosafety Manual and will complete all applicable biological safety training, including the completion of annual bloodborne training every year.

**Institutional Biosafety Committee (IBC):** The IBC will meet to review and approve protocols related to all research at VUMC that involves the following: recombinant or synthetic nucleic acids, pathogens, select agent toxins, non-human primate (NHP)-derived materials, and human-derived materials.

**Risk Assessment**

Risk assessments are required for IBC approval prior to the start of each new project, addition of a new infectious agent or r/sDNA, or any other major change to a protocol. The risk assessment for each infectious agent and biohazardous material combines review of the agent/material itself, the procedures being performed, and the qualifications of personnel performing the procedures. The results of the risk assessment determine the appropriate containment level based on the combination of practices, facilities, and equipment to mitigate research risks.

The NIH has classified biological agents into four Risk Groups according to their relative pathogenicity for healthy adult humans (Risk Group 1-4). Risk group 1 agents have the lowest risk while risk group 4 agents have the highest risk.

**Risk group 2 (RG2):** Risk Group 2 agents usually cause non-life-threatening disease in healthy adults and are transmitted through the fecal-oral route, mucous membranes, and accidental scratch or puncture. Risk Group 2 agents are the most common agents to be worked with in a Biosafety level 2 (BSL2) lab, however other risk groups can potentially be handled at BSL2 as well based on the risk assessment and IBC approval.

For a full list of agents classified into Risk Groups, visit the following link: [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) Appendix B.

BSL-2 containment is appropriate for research with human-derived materials, such as blood, body fluids, and tissues when the presence of an infectious agent is unknown. Lab personnel handling human-derived materials must follow OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) precautions.

This laboratory handles the following RG2 agents/materials: (Appendix A)

**Biosafety Level 2 (BSL2)**

**Special Practices for BSL2**

* The entrance to the laboratory must contain signage which lists hazards present in the lab, PPE required to enter the lab, and any other special precautions.
* Personnel working with potentially infectious agents must be advised of the potential hazards prior to beginning work.
* General attire for a BSL2 lab includes a shirt, long pants, and close-toed shoes.
* The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL2 agents.
* Potentially infectious materials must be placed in a durable, leak proof secondary container during storage and transport within a facility.
* Laboratory equipment should be regularly decontaminated, especially after spills or other potential contamination.
* Spills involving infectious material must be contained, decontaminated, and cleaned up by lab personnel. The personnel must be properly trained and equipped to work with infectious material.
* Animals and plants not associated with the work being performed must not be permitted in the laboratory.
* The use of cellphones or other personal electronic devices use should only occur when biohazardous material is not present.
	+ Gloves must be removed before handling cell phones or other personal electronic devices.

**Safety Equipment for BSL2**

Primary Barrier

Safety equipment including biological safety cabinets (BSCs), sealed centrifuge rotors, and other engineering controls are designed to minimize exposures to hazardous biological materials.

The Class II BSC is the principal device used to provide containment of splashes or aerosols that may be generated by procedures used in BSL2 labs. All aerosol generating procedures involving infectious materials or human-derived materials, must be conducted within a class II BSC or other approved physical containment devices (e.g., bioBUBBLE). Any work outside of a BSC is based on a risk assessment and needs to be approved by the Biosafety Officer (BSO).

**Laboratory Facilities for BSL2**

Secondary Barrier

The design and construction of the laboratory contributes to the laboratory workers' protection, by providing a barrier to protect persons outside the laboratory and persons or animals in the community from infectious agents that may be accidentally released from the laboratory. A laboratory must meet the following criteria to be certified as a BSL2 laboratory:

* Laboratory doors should be self-closing and have locks.
* Laboratory must have a sink for handwashing and maintain a supply of soap and paper towels.
* Laboratory should be designed to be easily cleaned.
	+ Non-porous floors and surfaces
	+ Carpet and rugs are not appropriate
* Lab benches must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
* Chairs must be made of a non-porous material that can be easily cleaned and decontaminated.
* BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations.
* Vacuum lines should be protected with in-line HEPA filters.
* Eyewash station must be readily available in the laboratory and checked regularly. All lab personnel should be aware of where the closest eye wash station is located.
* Relative negative pressure of laboratory (i.e. direction air flow from hallways into the laboratory) is recommended.

**Personal Protective Equipment (PPE)**

* Lab coats must be worn when working with biohazardous materials and must remain in the laboratory. They may be reusable cloth lab coats or disposable.
	+ Lab coats must be removed before leaving the laboratory area.
* Safety glasses are recommended to be worn when working in a BSL2 laboratory, especially when working with liquids.
	+ Eye and face protection such as goggles, mask, or face shield must be utilized if manipulating or handling infectious material or microorganisms outside the BSC.
	+ For high splash risks, goggles alone or safety glasses combined with a face shield can be used.
	+ It is not required if you are transporting closed containers of infectious material between storage and the BSC.
* Gloves must be worn to protect hands from working with infectious materials and other biohazards. Glove selection should be based on appropriate risk assessment.
	+ Nitrile gloves are the preferred choice given their wide range of protection and have a lower likelihood of allergies.
	+ Gloves must be changed when contaminated, glove integrity is compromised, or when otherwise necessary.
	+ Gloves must be removed, and hands washed when the work is complete. This includes all work with infectious agents and other biohazardous materials. Always remove gloves and wash hands when leaving the laboratory.
	+ Gloves must not be washed or reused.

**Decontamination**

* + - * Reusable contaminated materials must be chemically disinfected or placed in an autoclave bin prior to autoclaving. Reusable contaminated materials include but are not limited to: used glass flasks, glass petri dishes, forceps, etc. **Do not autoclave chemicals including any disinfectants.**
* Surfaces are to be decontaminated after each use.
* Disinfectants should be specific to the agents in use.
* Ensure appropriate contact time for the disinfectant and biohazardous material(s) and follow manufacturer’s recommendations.
* Recommended disinfectants include EPA registered/approved disinfectants, freshly prepared 10% bleach, 70% ethanol (not approved for human derived materials), Lysol, Virex, and quaternary ammonia compounds. Contact OCRS Biosafety if guidance is needed for disinfectant selection.
* A list of some ready-to-use disinfectants approved for human derived materials can be found here: [disinfectant-guide.pdf](https://www.vumc.org/safety/sites/vumc.org.safety/files/public_files/bio/disinfectant-guide.pdf). You can also check whether the EPA registration number on the label of your commercial disinfectant is on [EPA’s List S](https://www.epa.gov/pesticide-registration/epas-registered-antimicrobial-products-effective-against-bloodborne) to ensure that it is an OSHA BBP compliant disinfectant.

List of lab disinfectants in use:

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| --- | --- | --- | --- |
| Disinfectant Name | Contact Time | Shelf Life | OSHA BBP Compliant? (Y/N) |
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**Storage of Biological Agents**

Signs - All areas and laboratories that contain biohazardous agents must be posted with a lab door sign that includes the universal biohazard symbol. The universal biohazard symbol must also be placed on:

* Containers of infectious materials, including waste and storage
* Refrigerators where biohazards are stored
* Incubators and/or freezers where biohazards are stored
* Equipment which may be contaminated through normal use of biohazards
* Laboratory animals (cages) which are potentially infectious

Security – the storage of biological agents should be in a secure area separate from traffic flow of the general public. Lab doors should be kept locked after hours or anytime that all of the lab members are absent.

Contact OCRS Biosafety if you need biohazard stickers.

**Biohazardous Waste**

VUMC research and clinical areas now use the Sani-Pak sterilization system to sterilize red bag biohazardous waste. In VUMC research buildings, red bag biowaste is picked up by School of Medicine Environmental Services (SOM EVS) staff in the evenings. Follow these steps to transfer biohazardous waste bags from the lab to the Sani-Pak waste container:

1. Securely close each red biohazard waste bag with 2 zip ties or a double knot
2. Place closed bags in the large Sani-Pak cart closest to your lab

**Do Not** place sharps or red sharps containers in the bags that will go into the Sani-Pak cart

Sani-Pak Carts have been placed in locations that were carefully reviewed by both SOM EVS and OCRS Biosafety. Individual labs should not move them to other locations. If you find that the cart has been moved, please contact SOM EVS at 615-322-6107 to report this problem.

When sharps containers are ¾ full, securely close them and place them in a secondary container next to the regular trash container inside your lab. If the lid does not close securely, use tape to ensure the it stays in place.

For VUMC researchers working in VU buildings, the biowaste is collected by Biowaste LLC. Please follow the biowaste instructions from VU Biosafety [Biohazardous Waste | Environmental Health and Safety (EHS) | Vanderbilt University](https://www.vanderbilt.edu/ehs/faqs/biohazardous-waste/)

**Training**

Personnel working with infectious agents or potentially infected material(s) must be advised of potential hazards and must be trained to become proficient in the practices and techniques required for handling such material safely. The PI is responsible for providing appropriate lab specific training of his/her laboratory personnel and assuring that they complete specific OCRS biosafety training listed below.

Laboratory personnel can also receive agent specific training and hazard information by reviewing [Pathogen Safety Data Sheets](https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html) published by Public Health of Canada.

Research is supervised by scientists competent in handling agents and experienced with associated procedures that require BSL2 containment.

Laboratory staff are trained in the hands-on use of lab equipment: BSC, centrifuge with safety cups, and any other laboratory equipment for the manipulation of biological agents.

The VUMC OCRS training minimally required for all personnel working in laboratories at BSL-2 containment is outlined below: (please note additional training may be required based on risk assessment)

***Biosafety 101: Standard Microbiological Practices (SMP)****. This BSL-1 course is available online in the Learning Exchange. All PIs and lab personnel whose research involves biological materials are required to complete this course.*

***Biosafety 201: (Formerly the Principles and Practices of Biosafety course)****. This BSL-2 course is required for lab personnel who work with biological materials requiring BSL-2 containment. It is a 2-hour instructor-led course offered virtually via Teams. Biosafety 101: SMP, Biosafety Cabinet Training, and Blood Borne Pathogens for Research Labs courses must be completed before you can pre-register.*

***Bloodborne Pathogens Safety for Research labs.*** *This course meets the Bloodborne Pathogen Standard, OSHA 1910.1030. This course is* ***required*** *for all research that involves any human-derived materials and must be refreshed annually. The course* ***Bloodborne Pathogens and Infection Prevention*** *can also be used to meet this annual requirement. This course is required for all personnel who work in labs containing HDM.*

***Biosafety Cabinet (BSC) Training.*** *This course introduces the different types of BSCs with a focus on class II cabinets. It describes how to use a BSC for the containment of hazardous biological materials, including how to maintain good airflow, and how to decontaminate before and after use.*

Current training records for all lab staff: (Appendix B)

**VUMC Occupational Health Clinic (OHC)**

VUMC Occupational Health Clinic (OHC) protects faculty and staff health while they are at work through programs to monitor exposure to workplace hazards and treat work-related illnesses and injuries. The Occupational Health Clinic is located at Suite 640 in the Medical Arts Building and is open between 7:00 a.m. and 4:30 p.m. Phone: 615-936-0955.

**Medical Surveillance:**

OHC, in collaboration with the Institutional Biosafety Committee (IBC) and OCRS Biosafety reviews research registrations to assess the need for vaccination based on the CDC recommendations for agents in use and techniques outlined in the IBC registration. [Here](https://redcap.vanderbilt.edu/surveys/?s=7CXL3D8JJJ) is a link to complete the OHC Biological Risk Assessment.

Employees have the option to opt out of vaccinations and must sign a vaccine declination form that is maintained by Occupational Health. Vaccination records are maintained by Occupational Health.

**Exposures**

Exposures to biological materials can occur through percutaneous injury (needlesticks, animal bites), splashes to the mucous membranes (eyes, nose, mouth), inhalation of aerosols, and ingestion. The steps for responding to a spill or exposure involving biological materials are outlined below and are described in the IBC document found here:

[Responding to Personnel Exposures & Spills Involving Biological Materials | Office of Clinical and Research Safety (vumc.org)](https://www.vumc.org/safety/bio/responding-to-bio-exposures-and-spills)

1. Proceed to the closest sink/eyewash. Remove impacted PPE and flush the exposure site.
2. If the exposure involved broken or compromised skin, use soap and water to thoroughly cleanse the wound. (Do not use bleach or other harsh chemicals that can degrade tissues.)
3. Flush/cleanse the exposure site for 15 minutes.
4. Cover the wound with a bandage (if applicable).
5. Report to the Occupational Health Clinic or Adult Emergency Department if outside routine business hours.
	* Take any information about the source material that you have readily available along with you.
6. Notify the LAB SUPERVISOR (xxx-xxx-xxxx) and OCRS Biosafety at 615-322-0927 as soon as possible once medical follow-up actions have been initiated.
7. Fill out an research injury RedCap form: [https://redcap.vumc.org/surveys/?s=FTC8783DK7](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fredcap.vumc.org%2Fsurveys%2F%3Fs%3DFTC8783DK7&data=05%7C02%7Calexandra.elliott%40vumc.org%7C929eee97c35d4d2be17308dcd98d8195%7Cef57503014244ed8b83c12c533d879ab%7C0%7C0%7C638624449023436788%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=MOffiNLmUV45FwNWWzFHWoAvTn7mMpXSwSQDidLiUig%3D&reserved=0)

**Medical Emergencies**

Call 911 on an in-house phone or 615-421-1911 from a mobile phone. If you dial 911 from a mobile phone, you will reach Nashville Metro police and will be redirected to the Vanderbilt University Police Department (VUPD). You may also call 1-1111 from an in-house phone (615-421-1111 from external/mobile phone). These numbers are included on the VUMC Badge Buddies provided to all VUMC workforce members. Contact OCRS if you need Badge Buddies.

If necessary and possible, remove any hazardous materials from near the victim that might interfere with the response by medical personnel.

Remain with the victim until medical response personnel arrive.

If hazardous material spills or exposures are involved, follow the appropriate lab response plan including contacting OCRS (615-322-2057 business hours, 615-875-3779 after-hours).

If your laboratory has special entry/exit protocols for the protection of workers or for security purposes that could affect the response by medical personnel, contact OCRS for assistance in developing a specific response plan.

**Facility Malfunctions**

Contact Facilities Management:  [www.vumc.org/facilities](http://www.vumc.org/facilities) (615-322-2041 after-hours number) for issues related to your facility including:

Electricity loss or malfunction, plumbing issues, fire alarm issues/concerns, water leaks or intrusion, temperature/humidity issues, ventilation issues, door/lock malfunctions

For biosafety cabinet issues/concerns, contact the vendor utilized for your biosafety cabinet certifications.  You can also refer to the OCRS website ([www.vumc.org/safety](http://www.vumc.org/safety)) for a link to accredited vendors in Tennessee.

**Other Emergencies**

Each department should develop a departmental Emergency Response Sub-Plan that may contain more response procedures for a variety of other emergency situations. Contact the Emergency Preparedness department for information on and assistance in developing a Sub-Plan.

Know your codes. VUMC may announce several emergency codes. These are included on the VUMC Badge Buddies provided to all VUMC workforce members. Contact OCRS if you need Badge Buddies. You can also voluntarily sign up for emergency notifications through your electronic devices within your Workday account. Contact Emergency Preparedness for more information. Some key codes include:

* 1. Red Alert – potential fire situation.
	2. Code Black – bomb threat.
	3. Code Silver – active shooter.
	4. Yellow Alert – prepare to activate a response to a situation (example: Yellow Alert for inclement weather).
	5. Orange Alert – activate a response to a situation (example: Orange Alert for inclement weather).

Additional Resources:

1. OCRS:  [www.vumc.org/safety](http://www.vumc.org/safety)
2. VUMC Emergency Preparedness:  [www.vumc.org/emergency](http://www.vumc.org/emergency)
3. Facilities Management:  [www.vumc.org/facilities](http://www.vumc.org/facilities)
4. NIH OSP *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)
5. *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* 6th ed published by,

Centers for Disease Control and Prevention and National Institutes of Health 2021.

<https://www.cdc.gov/labs/BMBL.html>

**Appendix A – Biological Materials**

(Alternatively, the biological materials tables from IBC protocol can be copied in for Appendix A)

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| --- | --- |
| List of Materials (rDNA, human samples, infectious agents) | BSL |
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**Appendix B – Current Training for Lab Personnel**

(An alternative table can be used as long as it captures training dates)

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| --- | --- | --- | --- | --- | --- |
| **Lab Member Name** | **SMP – Bio 101** | **BSC** | **BBP (annual)** | **Bio 201** | **Works With?** |
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**Additional Recommended Documents to Keep with the Biosafety Manual**

1. A full copy of IBC registration and approval letter
2. Training certificates for lab members
3. Signature page showing that lab members have read the manual
4. SOPs specific for lab procedures
5. If available – Safety Data Sheets for biological materials
	1. Canada’s Pathogen Safety Data sheets (<https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html>)

**Required Documents to Keep with the Biosafety Manual**

1. If the lab works with animals and has an IACUC protocol, an Animal Biosafety Practices document needs to be filled out and kept with the biosafety manual.
	1. The best practices template can be found on the OCRS Biosafety website: [Biological Safety | Office of Clinical and Research Safety (vumc.org)](https://www.vumc.org/safety/bio)

Revision History

|  |  |  |
| --- | --- | --- |
| **Date** | **Description of Revision** | **Initials** |
| 10.25.22 | Initially posted | SJ |
| 12.15.22 | Removed Annual Training | SJ |
| 3.24.23 | Updated to reflect training info on website | SJ |
| 1.5.25 | Update all sections | AE |
|  |  |  |