# VUMC Institutional Biosafety Committee (IBC) Policy:
# Biosafety Level 2 with Enhanced Practices (BSL-2+) for Basic Research Applications

## Background

Risk Group 2 agents are those which are associated with human disease that is rarely serious and for which therapies and vaccines exist. Risk group 2 agents may be found in lab research operations that work with infectious microorganisms, as well as those that work with human or animal-derived body fluids, tissues and cells. In general, Biosafety level 2 (BSL-2) is the containment standard of practice for biological materials that may harbor a Risk Group 2 agent. For materials that may harbor a Risk Group 3 agent (i.e., one associated with serious or lethal human disease for which medical interventions may be available; high individual risk but low community risk), BSL-3 containment will be required if the agent is transmitted via inhalation or when required by health authorities. However, there are times when specific Risk Group 2 or 3 agents (or materials that could contain these) may be handled at BSL-2 using enhanced practices in order to further limit the potential for personnel exposure and ensure a greater level of biosecurity. This containment level is often referred to as BSL-2+. Specific basic research examples warranting BSL-2+ containment include:

- Some use of HIV, HBV or HCV, or patient samples containing these (see Attachment A)
- Use of any biological agent that requires BS2+ containment in accordance with a federal or state health authority permit (i.e., USDA APHIS, CDC, etc.)
- Use of any emerging infectious agent as determined by the Biosafety Officer & IBC Chair with input from the Principal Investigator

This document outlines the minimum standard of practice to be followed when lab activities have been approved by the entity's Institutional Biosafety Committee (IBC) for BSL-2+ containment. Additional requirements may apply based on individual agent/activity circumstances. These will be outlines in the Principal Investigator's IBC registration and/or Biosafety Manual.

## BSL-2+ Containment Administrative/Operations Oversight

A designated oversight person must be identified for all research activities being conducted under BSL-2+ containment conditions. In the case of activities taking place in a lab assigned only to a Principal Investigator (PI), this person should be identified by the PI, and should be someone who is knowledgeable and proficient in performing the tasks required for the BSL-2+ activities. If the space is a core or shared lab, the designated oversight person should be the Lab Manager (or equivalent) for the space. (For other scenarios, the Biosafety Officer will assist the PI in identifying a designated oversight person.) The designated oversight person must assure that all personnel working on the BSL-2+ activities adhere to the practices outlined in this document as well as the biosafety manual prepared for the activities requiring BSL-2+ containment, and/or the shared facility that operates at BSL-2+ for all activities.

**Additionally, no materials requiring BSL-2+ containment may be transferred to another lab without prior notification to, and approval by, the IBC via the Biosafety Officer.** This notification is necessary in order to assure that permit restrictions are not violated. It is also necessary to assure the receiving lab has the facilities and biosafety support structure in place to work safely with these materials before these materials are in hand.

## Biosafety Manual

A biosafety manual must be prepared for BSL-2+ activities (or lab facilities that operate at BSL-2+ for all operations). This document should be made available to all BSL-2+ authorized lab personnel both electronically and in hard copy. The manual must include:

- This policy document

- Pathogen safety data sheets/agent summary statements for all agents requiring BSL-2+ containment
- Technical procedures involving manipulation of infectious agents/samples
- Lab-specific biocontainment procedures including:
    - Biosafety equipment acquisition and use (see Attachment B for a template)
    - Autoclave operation
    - Inventory/activity logging
    - Spill and exposure response
    - Additional procedures based on risk assessment
    - Authorized personnel roster and training/proficiency records

This manual will be reviewed (and that review documented) at least annually by the designated oversight person to assure that information is current and complete. OCRS Biosafety can assist with annual review upon request.

**BSL-2+ Trainees**

Trainees must meet the following criteria to be approved to train for BSL-2+ activities:

- Be included on an IBC registration with an approved BSL-2+ activity/protocol
- Complete all applicable medical surveillance requirements
- Complete Principles & Practices of Biosafety training (or equivalent); if the activities involve bloodborne pathogens (BBP) materials, BBP training must also be completed through OCRS Biosafety
- Have a mentor assigned who can evaluate proficiency performing tasks associated with BSL-2+ work
- Review the biosafety manual and sign an acknowledgment regarding the expected standard of practice

Once these actions have been completed, the trainee may enter the BSL-2+ lab for training with their assigned mentor. The training and proficiency testing (qualification) process should include:

1. Mentor demonstrates procedure to trainee
2. Trainee assists mentor in performing aspects of procedure as appropriate as training progresses
3. Trainee demonstrates proficiency by performing procedure for mentor to observe

In the case of a new protocol to be performed by a lab group not previously approved for BSL-2+, a mentor should be sought who has experience working with agents/activities similar to those planned. Contact OCRS Biosafety for assistance in identifying prospective mentors.

Once the trainee has demonstrated proficiency in all tasks associated with BSL-2+ work, and this has been documented by the mentor and designated oversight person, the trainee may be cleared for independent access and work in accordance with the lab's operational policies. See the "Personnel Onboarding & Qualification" procedure in Attachment C for more information. In the event that a person has fulfilled the qualifications to work independently, but they have not worked at BSL-2+ for over one year, they must complete a BSL-2+ lab practices reorientation with the designated oversight person. Additionally, the BSO must be consulted to determine if task performance requalification is necessary before resuming independent work.

**BSL-2+ Lab Visitor Management**

For the purposes of this document, a lab visitor is any person other than BSL-2+ authorized lab personnel or trainees. Principal Investigators who do not perform bench work and OCRS personnel are not considered lab visitors if they will enter or be present in the BSL-2+ area for observation purposes only.

Labs that operate at BSL-2+ should be maintained in a restricted access state (i.e. card key, pin lock) at all times. Lab visitors should be kept to a minimum. If lab visitors must be present, this must be cleared with the designated oversight person ahead of time. Visitors must be provided with BSL-2+ visitor awareness training and escorted by a person approved for independent BSL-2+ work. Guidance and examples of training forms for research-related visitors as well as lab support visitors are available in Attachment D.

**BSL-2+ Facilities/Engineering Controls Requirements**

Lab areas where BSL-2+ activities will be conducted are expected to meet the following criteria in order to effectively achieve the intent of enhanced containment practices:

1. The BSL-2+ activity space must have a door. The door must be kept closed and posted while BSL-2+ activities are underway.
2. The BSL2+ lab space must negative air flow with respect to surrounding areas.
3. A sink and properly maintained eyewash need to be available within the BSL-2+ activity space. This is necessary to support the intent of keeping materials requiring BSL-2+ practices contained within that space in the event of an exposure.
4. A functional autoclave that can be used for waste treatment needs to be readily accessible (preferably nearby on the same floor) to the BSL-2+ activity space.
5. A biosafety cabinet (BSC) with a current NSF 49 certification must be available in the BSL-2+ space for any manipulations of the materials requiring BSL-2+ containment. When used routinely for BSL-2+ activities, the BSC working surface should be disassembled and cleaned at least annually (preferably just prior to annual recertification).
6. Incubators (if required for BSL-2+ activities) should be available within the BSL-2+ space. If the incubator is "common use", a dedicated area (or shelf) for materials requiring BSL-2+ containment should be used. Primary containers should be placed (and stored) in appropriate secondary containers when outside the BSC.
7. Other processing equipment needed to support BSL-2+ activities (such as centrifuges) should be located within the BSL-2+ activity space whenever possible. Safety cups or sealed rotors are required for centrifugation of any materials requiring BSL-2+ containment.
8. A properly maintained biological spill kit must be available within the BSL-2+ activity space.

**BSL-2+ Personal Protective Equipment (PPE) Requirements**

To provide primary protection in the event of any spill in the lab, personnel who enter BSL-2+ spaces (whether activities are underway or not) are expected to wear attire that completely covers their legs and feet. Minimum personal protective equipment (PPE) required for handling materials requiring BSL-2+ containment includes the following:

- Wraparound fluid-resistant disposable gown
- Two pairs of fluid-resistant disposable gloves
- Safety glasses required if contacts are worn; strongly recommended for all

Additional PPE requirements may be assigned when determined by risk assessment or by PI preference. These requirements will be included in standard operating procedures section of the Biosafety Manual as necessary.

**BSL-2+ Biocontainment Practice Requirements**

All BSL-2 containment practices should be followed and are not specifically stated here in order to reduce redundancy. However, the practices specifically outlined here are expected to be followed by personnel carrying out BSL-2+ activities in order to provide effective containment of the materials requiring BSL-2+ containment:

1. Glass devices or containers must not be used if non-glass alternatives are available and technically feasible.
2. Sharp devices should not be used unless necessary; consult with OCRS Biosafety before implementing the use of a sharp device.
3. The door must be closed and posted with BSL-2+ signage when BSL-2+ activities are underway. (This signage will be prepared and provided by OCRS Biosafety.) Only personnel who are approved for BSL-2+ activities should enter the space while such activities are underway.

4. The sink and eyewash must be verified as functional and accessible before BSL-2+ work starts.
5. Disinfectants must be EPA-registered for destruction of the agent, or deemed effective for destruction of the agent based on scientific literature (if the agent is not HIV, HBV, or HCV).
6. All solid biohazardous wastes must be collected inside the BSC; serological pipettes must be collected separately inside the BSC.
7. Collected biohazardous wastes must be removed from the BSC at the conclusion of procedures if the space is used for activities other than BSL-2+ activities. If the lab is dedicated for the BSL-2+ activities, wastes may be stored in the BSC only if the collection receptacles are closed and the outside of the collection containers are properly disinfected at the conclusion of procedures.
8. Whenever feasible, solid biohazardous wastes must be biologically inactivated by autoclave prior to submitting these to Environmental Services or an outside biohazardous waste contractor for terminal treatment and disposal. (If this is not feasible, waste treatment and handling procedures must be determined in conjunction with OCRS Biosafety before BSL-2+ work is initiated.) The general procedure for autoclave treatment of solid wastes is as follows (to be performed by BSL-2+ personnel only):

    a. If wastes have minimal moisture content, 50 ml of water should be added to the bag before closure. Bags should be closed using a rubber band, zip-tie or single knot. Bags should be surface-disinfected and placed in a tray for removal from the BSC and transport to the autoclave.
    b. Wastes must be autoclaved such that the bag contents are exposed to saturated steam conditions for at least 15 minutes. This can be verified by running a simulant test pack or "test bag" with the biowaste bags. A "test bag" can be prepared by placing nonhazardous simulant materials (such as paper towels or nonhazardous lab plastics) in an autoclaveable biohazard bag and placing a loosely sealed conical within that contains a chemical integrator strip or a biological indicator. These products, as well as simulant test packs, are available through manufacturers like Propper, Steris and 3M. (Contact OCRS Biosafety for assistance in identifying a product if needed.) The "test bag" should be closed in the same manner as the bags containing biohazardous waste.
    c. Following autoclave treatment, verify that the load was effectively sterilized based on the results from the "test bag" per the manufacturer's instructions. If sterility was not achieved, repeat the autoclave treatment cycle. If sterility was achieved, place the waste in the designated pickup container. Log all autoclave runs and results, and maintain these in accordance with lab SOPs.

Reminders: Do not autoclave liquid wastes that have been treated with a disinfectant as this may create hazardous conditions. Disinfectant-treated liquid wastes may be discharged to the sanitary sewer via the lab sink unless otherwise specified by a permit. If you generate other "mixed waste" (i.e., biologically contaminated waste containing a particularly hazardous chemical such a guanidinium thiocyanate), contact OCRS for guidance regarding collection and disposal.

9. When working in the BSC, no items (including gloved hands) may be removed from the BSC unless these are surface-disinfected first. (Any exception must be reviewed with OCRS Biosafety before implementation.)
10. At the conclusion of procedures, all items in the BSC must be thoroughly surface-disinfected, even if the item will be stored in the BSC. (Storage of items inside the BSC is not recommended, but may be warranted.)
11. Incubators or processing equipment where the materials requiring BSL-2+ containment will be left unattended must be posted with the name of the agent and responsible lab contact if the area is not dedicated to the BSL-2+ activities.

12. Processing equipment must be disinfected at the conclusion of procedures to reduce the potential for cross-contamination of lab materials and personnel exposure to contaminated surfaces.
13. PPE worn for BSL-2+ activities must be removed before exiting the BSL-2+ area. Hands must be washed after PPE removal and before leaving the BSL-2+ area.
14. Stock materials requiring BSL-2+ containment must be stored in a manner that prohibits personnel other than the approved lab users from gaining access to these materials.
15. An inventory listing of materials (i.e., what is in possession and where it's located) requiring BSL-2+ containment must be generated and maintained. The inventory should be verified at least quarterly when the materials are not actively in use. An activity log to document use and surveillance activities is strongly recommended.
16. In the event that a spill, exposure or "near miss" (unexpected event that could have led to exposure) occurs during the course of BSL-2+ work, lab personnel must report this immediately to the PI and/or designated responsible person for the BSL-2+ area. The Biosafety Officer must be informed as soon as possible in order to determine if reporting requirements apply and to determine whether procedural changes are warranted.

**Related Documents**

All forms in the attachment section will be made available to designated oversight personnel when a lab or PI is approved for BSL-2+ activities. Links to relevant OCRS Biosafety Program documents include:

Researcher's Tool: Profile Your Infectious Agent

IBC Policy: Best Practices for Use of Human-Derived Materials and Bloodborne Pathogens in Basic Research Applications

IBC Policy: Responding to Personnel Exposures & Spills Involving Biological Materials

Maintain, Move or Transfer a Class II Biological Safety Cabinet (BSC)

**Policy Endorsement & Revision**

This policy was originally endorsed by the Vanderbilt University (VU) and Vanderbilt University Medical Center (MC) Institutional Biosafety Committees (IBCs) on 8/22/2017.

The VU and MC IBCs approved revision of the document to reflect the current name of the Biosafety Program's home department (OCRS) on October 27, 2020.

The MC IBC approved revision of the document to remove references to Vanderbilt University and to update contact information on December 12, 2023.

# Risk Assessment of Research Activities involving HIV & Human Clinical Materials from HIV-infected Sources

Research activities involving the potential for personnel exposure to human immunodeficiency virus (HIV) are commonplace in a biomedical research environment such as Vanderbilt University. Activities may range from manipulation of human clinical specimens collected for any number of clinical or biomedical research analysis purposes, through culturing and concentration of the virus itself. The foundation of practices for handling these materials in a manner that is safe for lab workers as well as the immediate environment where these materials are manipulated and stored can be found in the OSHA Bloodborne Pathogens (BBP)Standard (29 CFR 1910.1030) and the CDC/NIH "Biosafety in Microbiological & Biomedical Laboratories"(BMBL), 5th edition. These documents address many aspects and scenarios associated with containment of HIV exposure risk in a research setting. However, three specific items warrant further consideration and risk assessment to determine appropriate containment practices for Vanderbilt's research activities. These include:

1. What Vanderbilt labs fall under the definition of a research laboratory in the context of the BMBL? The OSHA BBP Standard specifically states that the section of the regulations for research and production labs (1910.1030(e)) does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. However, in a research environment such as Vanderbilt, there are occasions where clinical specimens are being manipulated by clinical research personnel in a basic research lab that is subject to the provisions of the BMBL.
2. What containment practices should be used for handling human clinical specimens that may contain a high concentration of HIV in a research lab setting? This category of materials is not specifically addressed in either of the standards.
3. What constitutes large scale volume of virus in a research lab setting? This is not defined in either standard but is cited in both standards as a scenario that warrants BSL-3 (or equivalent) containment.

On August 7, 2013, VEHS Biosafety coordinated a risk assessment meeting with stakeholders including members of the Institutional Biosafety Committee (IBC) and faculty from Department of Medicine, Chemistry, Pathology, Microbiology & Immunology and Pediatric Infectious Diseases. The objective of the meeting was to discuss these questions in-depth and formulate a recommendation for assignment of containment practices for research activities involving HIV exposure risk at Vanderbilt.

The background documents used as the basis for the risk assessment discussion are on file with VEHS Biosafety and are available for review upon request.

**What Vanderbilt labs fall under the definition of a research laboratory in the context of the BMBL?**

Because Vanderbilt is a diverse mixture of clinical and research activities and facilities, it is sometimes difficult to discern where patient care activities end and research begins. In the case of human clinical trials, there is some element of both. The Vanderbilt IBC purview includes review and endorsement of containment practices for research use of human-derived materials and thus, defining what that means is essential for providing guidance to those who may need to be registered with and approved by the IBC.

The consensus of the assembled group was that work with human clinical specimens would fall under the BMBL research laboratory definition (and therefore under the purview of the IBC) if:

1. manipulation of human clinical specimens was taking place in a space designated as a research lab by Vanderbilt, and
2. the lab was not subject to human clinical accreditation standards (CAP, JCAHO, etc.).

As such, these activities should be carried out in compliance with the BMBL BSL-2 containment criteria (at a minimum), as well as the general provisions of the OSHA Bloodborne Pathogens Standard. Registration with

the IBC is also expected in order to assure compliance for funding and regulatory agencies.

**What containment practices should be used for handling human clinical specimens that may contain a high concentration of HIV in a research lab setting?**

The virology subject matter experts involved in the assessment concurred that a clinical specimen known or estimated to contain $10^8$ PFU/ml HIV (or greater concentration) would warrant containment practices outline for research laboratories under the OSHA BBP Standard (19010.1030(e)), commensurate with BSL-2 with BSL-3 practices. This concentration is not likely to be present in clinical specimens under most circumstances. However, in the unique scenario where this level could be encountered, the group consensus was that such specimens should be handled using the same containment practices that apply to research laboratories that manipulate lab scale quantities and concentrations of HIV.

**What constitutes a large scale volume of virus in a research lab setting?**

The virology subject matter experts concurred that a large scale volume of virus would be one that exceeds 1 liter containing a $10^8$ PFU/ml HIV (or greater concentration). An operation that would be manipulating this amount of virus is likely to be commensurate with a "production facility" as is referenced by the OSHA BBP Standard. Under that standard, production laboratories are required to use containment practices that are synonymous with BSL-3 as outlined in the BMBL. The group is not aware of research data supporting that HIV would be transmissible via aerosols to personnel outside of the lab environment in the case of a catastrophic release (i.e., centrifuge malfunction). Therefore, they concurred that work with lab scale quantities and concentrations that do not meet the large scale definition can be done safely using BSL-2 with BSL-3 practices.

*The table below summarizes the group's recommendations for containment related to HIV & Human Clinical Materials from HIV-Infected Sources.*

| **BMBL Containment level** | BSL-2 | BSL-2 with BSL-3 Practices | BSL-3 |
|---|---|---|---|
| **OSHA BBP Standard applicable sections** | General provisions (i.e., "universal precautions") | 1910.1030(e) requirements for research labs | 1910.1030(e) requirements for research labs & production facilities |
| **HIV-containing/suspect materials description** | Human clinical specimens that are not known or estimated to contain virus in excess of $10^8$ PFU/ml HIV (or greater concentration) manipulated in a Vanderbilt research lab. | Human clinical specimens that are known or estimated to contain virus in excess of $10^8$ PFU/ml HIV (or greater concentration)manipulated in a Vanderbilt research; lab scale work with HIV (i.e., not to exceed 1 l at $10^8$ PFU/ml HIV (or greater concentration). | Large scale work with HIV (exceeds 1 liter containing a $10^8$ PFU/ml HIV (or greater concentration)). |

*Note: Work with HIV in conjunction with recombinant DNA was not included in this discussion. Containment recommendations for those scenarios are outlined in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, and the IBC would use that resource for considering containment practices for those scenarios.*

**Biosafety Equipment Acquisition & Use Summary BSL-2+ LAB LOCATION:_____**

| BSL-2+ Operational Profile | |
|---|---|
| **Item** | **Lab-Specific Response** |
| **Which lab areas are included in the BSL-2+ operations?** | |
| **Who is the designated responsible person and what is their contact number?** | |
| **Which BSC's are designated for BSL-2+ work?** | |
| **Which incubator (and which area within) is designated for BSL-2+ materials?** | |
| **Where is the biosafety signage stored that needs to be posted when BSL-2+ is underway (If not a BSL-2+ dedicated area)?** | |
| **Where is the sink and eyewash located within the BSL-2+ space?** | |
| **Where is the biological spill kit located within the space?** | |
| **Where is the autoclave located for biohazardous waste treatment?** | |
| **How will waste be transported to the autoclave if located outside the immediate lab area?** | |

| Personal Protective Equipment (PPE) | |
|---|---|
| **Item** | **Lab-Specific Response** |
| **What is the product name & ordering number for the wraparound gown to be used?** | |
| • **What use restrictions apply (i.e., when must it be replaced, how must it be stored if reused, etc.)?** | |
| • **How does one acquire a new gown?** | |
| **How can fluid-resistant disposable gloves be acquired?** | |
| **How can safety glasses be acquired?** | |
| • **What use restrictions apply (i.e., how can they be cleaned, stored; when should they be replaced, etc.)?** | |
| **Where are splash goggles stored for use?** | |
| • **When must these be worn?** | |
| • **What use restrictions apply (i.e., how can they be cleaned, stored; when should they be replaced, etc.)?** | |
| **Is any other PPE required? If yes, what is it, where is it, and when does it need to be used?** | |

| Disinfection & Biohazardous Waste | |
|---|---|
| **Item** | **Lab-Specific Response** |
| **What surface disinfectant will be used for BSL-2+ work? What is the contact time?** | |
| • **What are the hazards (MSDS should be available in biosafety manual)?** | |
| • **If the product is not ready-to-use, how do you prepare it? What's the shelf-life of the prepared solution?** | |
| **If liquid waste will be generated, what disinfectant product will be used in collection vessels and in what ratio?** | |
| **Where/how should chemically-treated liquid biowaste be discharged?** | |
| **Where can one find autoclaveable biohazard bags for use?** | |
| **Where can one find secondary containers for transport/storage of waste bags or liquid waste vessels?** | |
| **If serological pipettes will be used, what should these be collected in?** | |
| **What load verification method is used for autoclave treatment? (Details regarding waste bag preparation and autoclave treatment should be fully outlined in the lab's Autoclave Treatment SOP.)** | |
| **Where are treated solid wastes to be placed for pickup, terminal treatment and disposal?** | |

| Other Lab-Specific Biocontainment Items | |
|---|---|
| **Item** | **Lab-Specific Response** |
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Document prepared (or updated) by/date: _____

# BSL-2+ Personnel Training & Qualification Record

**BSL-2+ Designated Oversight Person:** Use this document to record all relevant actions and qualifying events required for the individual named to be approved for independent BSL-2+ work as defined by the lab's Biosafety Manual. Maintain all completed records with the Biosafety Manual for regulatory review purposes. Please notify the BSO whenever a person has been added to, or removed from, the roster of BSL-2+ authorized lab personnel.

| Personnel Information | Trainee Eligibility Requirements | Date completed | Verified by (initials) |
|---|---|---|---|
| Name: | Biosafety 101:SMP | | |
| Job Title: | Principles & Practices of Biosafety | | |
| Phone & email: | Biosafety Cabinet Training | | |
| PI: | BBPs for Lab Personnel | | |
| Assigned mentor: | Biosafety Manual Read | | |
| Agents to be worked with & scope of activities to be performed: | Biosafety Manual Q&A with Designated Oversight Person | | |
| | Addition to IBC registration | | |
| | Medical surveillance enrollment (if applicable) | | |

**PROFICIENCY ACKNOWLEDGMENT**

_____ has satisfactorily completed all lab-specific procedural training (listed and documented on Page 2 of this form). He/she has been observed to be proficient in carrying out all procedures as outlined in the lab's Biosafety Manual.

_____ _____

Name of Designated Oversight Person Signature & Date

_____ _____

Name of Lab Mentor Signature & Date

**BSL-2+ AUTHORIZED LAB PERSONNEL CODE OF CONDUCT ACKNOWLEDGMENT**

I agree to follow all technical and biosafety procedures as outlined in the lab's Biosafety Manual. I understand that my privileges to work on BSL-2+ projects may be revoked if I fail to follow these procedures.

_____ _____

Name of BSL-2+ Authorized Lab Personnel Signature & Date

## LAB-SPECIFIC HANDS-ON PROCEDURAL TRAINING AND PROFICIENCY DETERMINATION

The assigned mentor & BSL-2+ designated oversight person should list all relevant technical SOPs needed to perform planned activities. When possible, technique training should be performed using noninfectious simulant materials. If the trainee has prior experience with a procedure/technique, they may be evaluated for proficiency after at least 1 observation is completed.

| Name of lab SOP | Observation 1 (DATE/INITIALS) | Observation 2 (DATE/INITIALS) | Observation 3 (DATE/INITIALS) | Proficiency verified (DATE/INITIALS) |
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| Biosafety equipment acquisition and use | | | | |
| Autoclave treatment of biowaste | | | | |
| Inventory/activity logging | | | | |
| Spill & exposure response | | | | |

# Vanderbilt BSL-2 with Enhanced Practices (BSL-2+) Entry Training For Research Visitors

*This form is intended for a laboratorian who needs to visit the BSL-2+ lab to observe a procedure but will not be performing any procedures themselves. This form is <u>not</u> intended for those who are in the process of gaining approval to become a BSL-2+ trainee.*

| | |
|---|---|
| Name (print): | Date(s) of Entry: |
| Department/Entity: | Lab to be Entered: |
| Purpose for Lab Entry: | |

**Why is training required? What specific restrictions apply?**

"All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements" according to the Centers for Disease Control and Prevention/the National Institutes of Health's "*Biosafety in Microbiological and Biomedical Laboratories*".

Lab activities and areas that operate in accordance with BSL-2+ practices do so in order to further limit the potential for personnel exposure to infectious agents and ensure a greater level of biosecurity. Specific practices that apply to research visitors entering the lab include:

- Do not enter the lab if you are sick or have any concerns related to your immune status (see acknowledgment below);
- You must wear attire that completely covers your legs and feet while in the lab;
- You must be escorted by a person who is approved for independent BSL-2+ work; please stay with this person for the duration of your necessary time in the lab;
- Do not handle any lab materials while in the lab;
- Follow all biosafety procedures as instructed by your escort.

<u>Risk of Materials Present and Personal Health Status</u>
Labs designated as BSL-2+ perform all work with biological materials inside containment barriers (i.e., biosafety cabinets, equipment with safety features to prevent release) as a standard practice. Even so, it should be noted that infectious contamination is generally transmitted by touching contaminated items and then touching one's eyes, nose or mouth, or through cuts or puncture of the skin with contaminated devices. Individuals with certain medical conditions are at greater health risk if an exposure occurs. Factors that can increase health risks from an exposure include (but are not limited to):

- Pregnancy
- HIV infection
- Diabetes mellitus
- Immune deficiency
- Cancer
- Medications that weaken your immune system (e.g. steroids, chemotherapy)

If you believe you have a condition that may impact the proper function of your immune system or otherwise put you at increased risk, you are encouraged to discuss this with a medical or occupational health professional before entering facilities where infectious agents are in use.

***I have reviewed and understand the information regarding my personal health status. At this time, I will complete the BSL-2+ lab visitor training outlined below for entry into this restricted area.***

Lab Visitor Name (printed): _____

Signature/Date: _____

**A BSL-2+ lab member will brief you on the following topics and will escort you during your time in the lab.**

| Briefing Topic | Visitor Initials | BSL-2+ Escort Initials |
|---|---|---|
| Review of agent in use and exposure risk considerations | | |
| Brief explanation of containment procedures used | | |
| Personal protective equipment (PPE) to be worn in the lab; escort will assist in donning and doffing, as needed | | |
| Lab conduct (no pictures, no visitor handling of lab materials, etc.) | | |
| Lab layout and actions to be taken in the event of an emergency (fire alarm, power outage, spill, etc.) | | |
| Opportunity to ask any remaining questions about lab procedures | | |

***I have completed a biosafety briefing with the research visitor referenced in this form. I have verified that all safety requirements have been met for their BSL-2+ entry and agree to escort them during their time in the lab.***

BSL-2+ Escort Name (please print):_____

Signature & Date:_____

**Once this form is completed and signed, give or send a copy to the Biosafety Officer. Give a copy to the lab visitor for their records. Keep the original form on file with the BSL-2+ designated oversight person of the lab to be entered.**

*One completed training form may be used for all entries needed within one work week (Monday-Friday). If subsequent entries are needed beyond the work week of original entry, contact the Biosafety Officer (biosafety@vumc.org) to determine next steps.*

## Vanderbilt BSL-2 with Enhanced Practices (BSL-2+) Entry Training
## For Equipment, Maintenance, and Operational Support Personnel/Contractors (Lab Support Visitors)

| | |
|---|---|
| Name (print): | Date(s) of Entry: |
| Company/Entity: | Lab to be Entered: |
| Purpose for Lab Entry: | |

**Why is training required?**

"All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements" according to the Centers for Disease Control and Prevention/the National Institutes of Health's "*Biosafety in Microbiological and Biomedical Laboratories*".

**What practices are in place to reduce my exposure risk?**

The following practices have been adopted to minimize your exposure risk to potentially infectious materials while doing your work within the lab:

- The lab staff will ensure that no potentially infectious materials are worked with or handled in the immediate lab area while lab support visitors are present;
- All who enter the BSL-2+ area must wear attire that completely covers legs and feet;
- Any personal protective equipment (PPE) required for working in the lab will be provided to you and your escort will assist you with putting it on and taking it off;
- Consider all work surfaces as potentially contaminated- be mindful of where you place your tools, etc; if your tools may be contaminated during work plan ahead for effective cleaning;
- If you are sick do not enter the lab. If you know or suspect your immune system is not functioning properly, you should consult with a medical professional before entering the lab;
- When you are entering the lab, an escort will be present to go over pertinent information and answer any questions that arise. If the escort will not be staying with you, they will provide a phone number where they can be reached at any time if you need assistance;
- No food or drinks are permitted in the lab; these items should be left outside of the lab and not consumed at any point while in the lab working;
- ALWAYS wash your hands prior to leaving the lab.

<u>Risk of Materials Present and Personal Health Status</u>

Labs designated as BSL-2+ perform all work with biological materials inside containment barriers (i.e., biosafety cabinets, equipment with safety features to prevent release) as a standard practice. Contaminants on environmental surfaces should be minimal (and in many cases surfaces have been disinfected to further minimize risk). Even so, it should be noted that infectious contamination is generally transmitted by touching contaminated items and then touching one's eyes, nose or mouth, or through cuts or puncture of the skin with contaminated devices. Individuals with certain medical conditions are at greater health risk if an exposure occurs. Factors that can increase health risks from an exposure include (but are not limited to):

- Pregnancy
- HIV infection
- Diabetes mellitus
- Immune deficiency

- Cancer
- Medications that weaken your immune system (e.g. steroids, chemotherapy)

If you believe you have a condition that may impact the proper function of your immune system or otherwise put you at increased risk, you are encouraged to discuss this with a medical or occupational health professional before entering facilities where infectious agents are in use.

***I have reviewed and understand the information regarding my personal health status. At this time, I will complete the lab support visitor training outlined below for entry into this restricted area.***

Lab Support Visitor Name (printed): _____

Signature/Date: _____

**An authorized lab member will brief you on the following topics and will assist you with lab entry procedures. Please initial the columns as each topic is discussed.**

| **Briefing Topic** | **Visitor Initials** | **Authorized Escort Initials** |
|---|---|---|
| Review of agent in use and exposure risk considerations | | |
| Brief explanation of containment procedures used | | |
| Personal protective equipment (PPE) to be worn in the lab; escort will assist in donning and doffing, as needed | | |
| Lab conduct (no pictures, limit touching lab surfaces, where to place tools, etc.) | | |
| Lab layout and actions to be taken in the event of an emergency (fire alarm, power outage, spill, etc.) | | |
| Opportunity to ask any remaining questions about lab procedures | | |

Escort/Accessible Lab Member Name (print): _____

Date/Time Frame of Scheduled Work: _____

Phone number where escort may be reached if not directly escorting personnel (must be available for the duration of the lab support visitor's stay in the lab): (_____)_____-_____

One completed training form may be used for all entries needed within one work week (Monday-Friday). If subsequent entries are needed beyond the work week of original entry, a new form must be completed.

**Once this form is completed and signed, give or send a copy to OCRS Biosafety (bioafety@vumc.org). Give a copy to the lab visitor for their records. Keep the original form on file with the lab manager of the lab to be entered.**