Vanderbilt Institutional Biosafety Committee (IBC) Policy:
Temporary Trainee Researchers and Infectious Agent Activities

NOTE: While this policy does not apply to trainee researchers who meet the legal definition of a minor, the IBC does not recommend that minor trainee researchers work with infectious agents requiring BSL-2 or higher containment.

Background

Visiting scientists and other trainees – such as undergraduate students – who are hosted by a lab for short periods of time to complete a specific project are often left out of IBC registration documentation because of the brief duration of their appointment. However, if their planned activities will involve handling an infectious agent, a process needs to be implemented to assure that the work and the individual performing it comply with the biosafety standards approved by the IBC. For purposes of this policy, an infectious agent is any agent assigned a Risk Group 2 or 3 by the World Health Organization (WHO), National Institutes of Health (NIH) or similar health authority and for which Biosafety Level 2 (BSL-2) containment has been assigned for the activities.

Below are relevant passages from the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th edition.

> BSL-1 Standard Microbiological Practices
>
> The laboratory supervisor ensures that laboratory personnel receive appropriate training regarding their duties, potential hazards, manipulations of infectious agents, necessary precautions to minimize exposures, and hazard/exposure evaluation procedures (e.g., physical hazards, splashes, aerosolization) and that appropriate records are maintained. Personnel receive annual updates and additional training when equipment, procedures, or policies change. All persons entering the facility are advised of the potential hazards, are instructed on the appropriate safeguards, and read and follow instructions on practices and procedures. An institutional policy regarding visitor training, occupational health requirements, and safety communication is considered.
>
> BSL-2 General Description
>
> Biosafety Level 2 (BSL-2) builds upon BSL-1. BSL-2 is suitable for work with agents associated with human disease and pose moderate hazards to personnel and the environment. BSL-2 differs from BSL-1 primarily because: 1) laboratory personnel receive specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.
>
> BSL-2 Special Practices
>
> The laboratory supervisor is responsible for ensuring that laboratory personnel demonstrate proficiency in standard microbiological practices and techniques for working with agents requiring BSL-2 containment.

Direct handling of infectious agents should be restricted to only those who are proficient as outlined in the BMBL. In the case of undergraduate students, their experience level and time allotted for project completion may make it difficult for them to become proficient within the time allotted for some projects. If this were the case, lower risk agents (i.e., less pathogenic surrogates) should be used. If an infectious agent must be used, the student's handling of the pathogen should be limited as much as possible, directly supervised, and should not involve (i) sharps, (ii) high concentrations or (iii) equipment with a high capacity for aerosol-generation under routine or failure conditions (i.e., centrifuges, cell sorters, sonicators, lyophilizers) unless proficiency has already been fully demonstrated and

documented. Similarly, arrangements should be made to ensure that any prophylactic medical services, such as vaccinations, are obtained prior to starting work.

Policy

A. Undergraduate Students
If an undergraduate student will handle an infectious agent or materials known to contain an infectious agent, then the following actions are required for Institutional Biosafety Committee approval:
   1. The sponsoring Principal Investigator (PI) is registered with, and approved by, the IBC for work with the infectious agent, and the infectious agent does not require BSL-3 containment.
   2. The sponsoring PI submits an Undergraduate Infectious Agent Project Profile (see Attachment 1) at least 4 weeks before the proposed project start date. This will ensure adequate time to address any risk assessment questions and vaccination/med surveillance considerations before the project starts; this information will be shared with the IBC and Occupational Health.
   3. A lab mentor is assigned by the PI to the student. This person must have completed all required biosafety training and must have documented proficiency for the techniques required to support the project.
   4. The student completes all required biosafety training as outlined on the EHS training website; additionally, the student completes a lab-specific biosafety orientation with their mentor or Lab Manager.
   5. The student demonstrates proficiency performing all required techniques with a non-hazardous simulant before beginning work with the infectious agent. This activity must be documented by the mentor.

B. Other Temporary Trainees (visiting scientists, rotating graduate students, house staff)
If other temporary trainees will handle an infectious agent or materials known to contain an infectious agent, then these personnel need to complete training and proficiency requirements for BSL-2 work as it applies to the hosting lab. These temporary trainees should be restricted from handling any infectious agents that have a vaccination or medical surveillance requirement. If they cannot be restricted, then these individuals must be added to the PI's IBC registration and complete all requirements outlined by Vanderbilt Occupational Health.

Policy Endorsement & Revision

The original policy on this subject was approved by the Vanderbilt University (VU) and Vanderbilt University Medical Center (MC) Institutional Biosafety Committees (IBCs) on October 22, 2019.

This policy was rewritten as a Vanderbilt University IBC Policy in October 2023 to reflect current responsible parties, institutional guidance documents and biosafety standards. The policy was endorsed by the VU Institutional Biosafety Committee on 0ctober 24, 2023.

The policy will be reviewed periodically when determined appropriate by the Biosafety Officer for purposes of compliance with regulatory requirements.

UNDERGRADUATE INFECTIOUS AGENT PROJECT PROFILE

This form is intended to capture risk assessment-relevant information about undergraduate temporary trainees (excluding minors) handling infectious agents/materials. In the event of a project requiring multiple agents that are closely related, and for which the planned activities are integral, one form may be prepared provided that details are sufficient to address risk assessment questions.

Please complete this form and submit it to the VU EHS Biosafety Team e-mail at VUbiosafety@vanderbilt.edu. Please add lines to tables or expand text fields as necessary to provide all applicable information for the amendment.

Principal Investigator Name:	VU BMR#:
Form prepared by:	Date of preparation:
Email address:	Phone:
Name of Temporary Trainee:	Temporary Trainee Education Level:
Temporary Trainee email address:	Temporary Trainee Major Department:
Project start date (month/year):	Expected duration of project (in months):

1. **Please describe the infectious material(s) the trainee will be handling as part of this project. Please include complete nomenclature to identify infectious agents.**

2. **Has the agent been/will the agent be genetically modified in a way that foreign DNA or RNA will be introduced and expressed? (YES or NO)**

3. **If you responded YES to #2, please describe the hosts, vectors, and inserts involved in this modification.**

4. **Please provide a rationale explaining the need for the temporary trainee to work directly with infectious material. This should include a justification explaining why working with a simulant combined with observation of a skilled worker handling the infectious material will not achieve the same educational experience or goal.**

Attachment 1: Undergraduate Infectious Agent Project Profile (Page 2 of 3)

5. **What members of your lab staff will be assigned to mentor and train the trainee? Briefly describe their technical and biosafety qualifications/proficiency for this work in particular.**

6. **As outlined in the Temporary Trainee Researchers and Infectious Agents Activities policy, the following expectations apply for initiating this training experience:**

   - Details of the training experience are shared with Occupational Health to determine the need for vaccines or medical surveillance. (NOTE: The completed project profile form will be shared with Occupational Health. The assigned mentor should ensure that the trainee has obtained any prophylactic medical services, such as vaccinations, prior to starting work.)
   - The student completes all required biosafety training as outlined on the VU EHS training page ; additionally, the student completes a lab-specific biosafety orientation with their mentor or Lab Manager.
   - The student demonstrates proficiency performing all required techniques with a non-hazardous simulant before beginning work with the infectious agent. This activity must be documented by the mentor.

   Please outline the specific training and proficiency plan to be used with this trainee for the planned research activities and any progress made to date.

7. **Where will work with the agent take place (room/building)?**

8. **Will your planned activities require any of the following?**

Check if YES	Activity
	Use of sharps (NOTE: The use of slip-tip devices or blades without handles is prohibited unless scientifically justified and safe handling practices explained)
	Use of glass vessels or devices
	Stock culturing of agent
	Centrifugation of agent
	Use of agent in an animal model
	Manipulation of agent OUTSIDE of a biosafety cabinet (NOTE: Please provide a justification for this in #9 and details regarding how others working in the area will be protected from exposure while this work is carried out.)

Attachment 1: Undergraduate Infectious Agent Project Profile (Page 3 of 3)

9. **The categories in #8 indicate equipment or activities with an elevated exposure risk due to the potential for injury or aerosol generation. If you checked any of the activities in #8, please provide details regarding the safety devices and practices that will be employed to reduce injury/exposure risk.**

Please contact anyone on the VU Biosafety Team for assistance with form completion or risk assessment questions.

Please submit your completed form, along with planned technical procedures involving use of the agent, to the VU EHS Biosafety Team at VUbiosafety@vanderbilt.edu in preparation for IBC review.