

Institutional Biosafety Committee Policy: Acquisition & Use of Non-viable High Risk Biological Agents

Applies to:

- Vanderbilt University (VU)
- Vanderbilt University Medical Center (MC)

Recent events involving shipments of viable high risk infectious agents (presumed to be biologically-inactivated) from a government lab to numerous labs have brought public attention to the widespread use of non-viable materials, both for research and lab proficiency purposes. Biological agents that typically require biosafety level 3 or 4 containment may be safely handled in lower containment settings (i.e., BSL-2), but they must be effectively rendered non-viable using a validated process first. (A [guidance document](#) addressing this issue has recently been developed by the Centers for Disease Control (CDC).) While the possession and use of most non-viable agents is not an activity that the Institutional Biosafety Committee (IBC) typically monitors, the events mentioned previously have prompted the need to develop a policy as it relates to non-viable high risk biological agents. This policy is intended to strengthen:

1. institutional communication and knowledge regarding what non-viable high risk agents are on campus, who has them, and for what purpose; and
2. Vanderbilt's ability to respond quickly to circumstances when a notification is received that a biological inactivation process for a high risk agent may have failed on the part of the lab of origin.

In doing so, the IBC in conjunction with the Vanderbilt Environmental Health & Safety (VEHS) Biosafety Team can support the necessary actions to manage research compliance, personnel safety and press issues that could arise. For the purposes of this policy, high risk biological agents are defined as those that are:

1. Currently listed as [CDC/USDA select agents](#), or
2. [Risk Group 3 agents](#) for which the recommended containment level is typically BSL-3 or higher based on the latest recommendations from the CDC, or
3. [Risk Group 4 agents](#).

In addition to purified agent, the policy includes body fluids, tissues, cultures, or any other materials that could harbor the agent. This policy is not intended to replace existing protocols pertaining to viable agents/materials received into or propagated in a BSL-3 lab at Vanderbilt.

If a Principal Investigator (PI) plans to acquire a non-viable high risk biological agent, they must contact Vanderbilt's Biosafety Officer (BSO) and provide the following information:

1. a succinct but thorough written explanation of:
 - a. the materials to be received
 - b. intended research purpose for use including desired start date and duration of use
 - c. list of all lab personnel who will be actively engaged in using the materials
2. contact information for the party who will be providing the materials
3. contact information for the Biosafety Officer of the originating entity
4. validated method that the originating lab will use to determine that the material in question will be rendered non-viable; references to substantiate the efficacy of the method should be provided if at all possible. This information must include:
 - a. a detailed standard operating procedure (SOP) describing the inactivation process,
 - b. a detailed SOP describing the validation process to confirm the agent has been inactivated
 - c. the results of the validation process for the sample being sent to Vanderbilt.

Once this information is received, the BSO (or designated VEHS Biosafety Team Member) will:

1. take action to contact the Biosafety Officer of the originating entity and verify the processes and methodologies in place for rendering materials non-viable;

2. add information provided to the PI's electronic folder and update the master spreadsheet for non-viable agents;
3. prepare a summary for the IBC regarding the proposed use for consideration at the next IBC meeting.

Once IBC approval is granted, the following actions and responsibilities apply:

1. Materials may be shipped to the receiving PI only after documentation verifying that the agents are non-viable has been provided by the originating entity to the PI and the Vanderbilt Biosafety Officer.
2. It is the receiving PI's responsibility to assure that no materials are shipped before the previously mentioned documentation is received.
3. In the event that the PI is informed by the originating entity after receipt of materials that the materials may be viable, they must take action to:
 - a. secure the materials in a manner that no lab personnel can gain access to them;
 - b. notify the BSO immediately and be prepared to provide a summary of recent activities involving the use of the materials.
4. The PI must notify the BSO if activities with non-viable high risk biological agents are to be terminated so that appropriate action can be taken for disposal of the materials.
5. Non-viable high risk biological agents may not be transferred to another PI without notification of Vanderbilt's BSO and approval by the IBC.

Questions regarding this policy should be directed to VEHS Biosafety at 322-0927 or 322-2057.

Policy adopted by the MC IBC on 7/26/16

Policy adopted by the VU IBC on 7/26/16