

Institutional Biosafety Committee Policy: Expedited Institutional Biosafety Approval for Testing/Analyses Requested by Public Health Authorities

Public health authorities such as the Centers for Disease Control (CDC), United States Department of Agriculture (USDA) and Tennessee Department of Health rely on partnerships with research institutions like Vanderbilt when new and emerging infectious disease concerns arise. Because of its unique testing/analytical capabilities and biocontainment facilities, Vanderbilt research teams may be approached by public health authorities when time-sensitive testing/analyses of potentially infectious materials are needed.

If a research team receives such a request, and the suspected agents and/or activities fall outside the scope of the lab's current Institutional Biosafety Committee (IBC) approval, the team must contact the Biosafety Officer (BSO) before agreeing to receive or analyze these materials. If the requested testing/analyses does not involve the use of recombinant DNA molecules, and the testing is deemed urgently important for public health reasons, the IBC can grant expedited provisional approval when the following conditions are met:

1. The Principal Investigator (PI) must provide the following to the BSO:
 - a. a succinct but thorough written explanation of:
 - i. the materials to be manipulated
 - ii. scope of the testing/analyses that will be performed
 - iii. why the testing/analyses is time-sensitive and therefore requires expedited review/approval
 - iv. who will be performing the testing/analyses
 - v. time frame for testing/analyses (not to exceed 30 days)
 - b. a written communication from the public health authority requesting the testing/analyses, including the health authority's biocontainment recommendations for manipulation of the materials in question
 - c. documentation to demonstrate that the proposed testing/analyses is within the scope of a currently approved IRB/IACUC protocol, or an explanation of why the testing is not subject to IRB approval
2. The PI's lab must have appropriate and established biocontainment capabilities for the requested testing/analyses. The BSO must verify based on a review of IBC registration files and the lab's written procedures:
 - a. The PI is currently approved (and in good standing) for the biosafety level required for manipulation of the materials in question.
 - b. The lab has an established process in place (with written procedures and trained personnel) to support the requested testing/analyses.
3. All applicable permit requirements for receipt of the materials have been satisfied. The BSO will work with the PI and public health authority on this matter.

Once the conditions above are met, the BSO will share all related information with the IBC Chair and Executive Director of Environmental Health & Safety and request permission to proceed according to the testing plan submitted by the PI. At the next IBC meeting (special called or routinely scheduled), the PI or their designee will provide a briefing to the membership regarding the expedited approval request and any developmental information. The IBC will vote on full endorsement of the additional time-sensitive testing/analyses for requested purpose.

Limitations:

- This expedited review process cannot be applied if the agent suspected to be present is a select agent or contains recombinant DNA molecules.
- Materials/processes approved under this process are intended for temporary, time-sensitive testing/analyses in support of public health authority requests only. If materials/processes approved under the expedited process

will be used beyond the originally requested timeframe, these activities and materials must be added to the PI's IBC registration as an amendment for ongoing approval.

Policy Endorsement & Revision

The policy on this subject was approved by the Vanderbilt University Medical Center (MC) Institutional Biosafety Committee (IBC) on June 27, 2017.

The MC IBC 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.

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