

LAB RESEARCH ACTIVITIES INVOLVING BIOLOGICAL MATERIALS: WHEN IS IBC REVIEW & APPROVAL REQUIRED? WHAT BIOCONTAINMENT PRACTICES APPLY?

Biosafety level 2 (BSL-2) is a combination of containment practices, equipment and facilities intended to support safe handling of viable* biological materials that may harbor a moderate risk agent that is infectious to humans primarily through contact transmission. In accordance with Vanderbilt University Institutional Biosafety Committee (IBC) policy, BSL-2 containment is also required for handling any viable biological materials that are potentially infectious to animals or plants. The following viable biological materials require biosafety level 2 (BSL-2) containment at a minimum for most common in vitro activities:

- Microbiological agents that may be infectious to humans, animals or plants
- Microbiological agents that contain recombinant or synthetic nucleic acid molecules and require BSL-2 containment per the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#)
- Human-derived body fluids, tissues and cells
- Nonhuman primate-derived body fluids, tissues and cells
- Toxins or venoms of biological origin
- Materials/media containing any of the above.



Use of materials requiring BSL-2 containment requires registration with, and approval by the Vanderbilt IBC. Labs working at BSL-2 are expected to adhere to all BSL-2 criteria outlined in the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories](#), in addition to any other material-specific standards applicable to the materials in use.

In general, biological materials that are not regarded as potentially infectious to humans, animals or plants may be handled using BSL-1 containment. Examples of such materials include:

- Biological materials/media that are no longer viable
- Body fluids, tissues or cells from animals other than humans or nonhuman primates that are not anticipated to contain an infectious agent
- Plant materials that are not anticipated to contain an infectious agent
- Microbiological agents that are not infectious to humans, animals or plants and do not contain recombinant or synthetic nucleic acid molecules
- Microbiological agents that are not infectious to humans, animals or plants that do contain recombinant or synthetic nucleic acids, but these inserts are non-hazardous in nature**. Examples of such inserts include:
 - fluorescent markers;
 - antibiotic resistance used for colony selection;
 - non-oncogenic, non-toxicogenic inserts.

* For purposes of this document, viable biological materials include those that have not been sterilized, chemically-fixed or biologically inactivated by a means recognized in research literature for destruction of potentially infectious agents.

** Refer to the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#) for specific details regarding containment level for the materials in question, or contact the VU EHS Biosafety Team for assistance. Most recombinant or synthetic nucleic acid activities involving viral vectors will require BSL-2 containment. BSL-1 will apply for most recombinant or synthetic nucleic acid activities involving non-pathogenic *E. coli* or *S. cerevisiae*. **Regardless of the containment level, all recombinant or synthetic nucleic acid molecule use that is not specifically exempted from the NIH Guidelines requires registration with, and approval by the Vanderbilt IBC. The latest biomaterials registration form is available upon request from VU Biosafety (VUBiosafety@vanderbilt.edu).**

A note about graduate student projects...

The mentoring Principal Investigator who is responsible for the lab where the activities will be taking place needs to include the graduate student and their biological materials use activities in their IBC registration documents by the time that the work is scheduled to begin.

Have more questions?

Please contact the VU Biosafety Team at (615) 343-8918 or VUBiosafety@vanderbilt.edu.