University of Michigan
Institutional Biosafety Committee
Charge

In accordance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, the University of Michigan (U-M) has established an Institutional Biosafety Committee (IBC). The IBC oversees research with potentially hazardous biological agents at the University's Ann Arbor, Dearborn, and Flint campuses.

The Vice President for Research is the executive officer who has authority over this compliance area, including appointment authority. The IBC is administered through the U-M Office of Research (UMOR).

Mission of the Committee

The primary mission of the IBC is to ensure the safety of faculty, staff, students, and patients involved in biological research at U-M, and also to protect the general public and the environment from adverse consequences related to that research. The work of the IBC supports the institution in meeting all required standards set by federal, state, and local governments, and as necessary, developing specific U-M policies to make any research conducted with hazardous, or potentially hazardous, biological agents (either naturally occurring or synthetically created) as safe as possible.

Composition of the Committee

The IBC is a faculty-led, faculty-majority committee comprised of "no fewer than five members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment" (Section IV-B-2-a-(1), NIH Guidelines). Members of the committee are selected based upon their knowledge of subject areas that the IBC is charged to review, they fulfill the areas of expertise specified by Section IV-B-2-a of the NIH Guidelines, and they are appointed by the Vice President for Research for renewable three-year terms.

Scope of the Committee's Responsibility

The IBC is responsible for reviewing research with potentially hazardous biological agents in order to assess whether the biosafety containment level proposed is adequate to protect workers, the public, and the environment from the risks posed by the work.

The IBC will determine approval or disapproval of the proposed experiments through review of the application submitted by the principal investigator, along with supporting materials as needed. This review and oversight involve independent assessment of the biosafety containment level proposed for the work, and through coordination with the Biological Safety Officer, assessment of facilities, procedures, practices, and training and expertise of personnel involved in the research.

Specifically, the IBC is charged with the review and oversight of research with the following potentially hazardous biological agents and experiments:

- Recombinant DNA and synthetic nucleic acid molecules*
- Infectious agents
- Biological toxins
- Human-derived tissues, fluids, cells
- Certain animal-derived tissues, fluids, cells

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- Federally-regulated Select Agents, experiments with Dual Use Research of Concern potential, and research requiring BSL3 containment*

*Special provisions regarding IBC oversight for the following types of work:

Recombinant DNA and Synthetic Nucleic Acid Molecules

The Regental Policy on Recombinant DNA Research states:

> *The University of Michigan shall adhere to all applicable federal and state laws regarding the approval, conduct, and safety monitoring of recombinant DNA research. The vice president for research shall report to the Regents upon request or when it is deemed appropriate by the vice president. The vice president will report to the Regents on any initiation of research requiring containment above Biosafety Level 3 (BL3) (July 1992).*

With regard to work with recombinant DNA and synthetic nucleic acid molecules, the IBC is responsible for functions as described in NIH Guidelines Section IV-B-2-b. The U-M requires all use of recombinant DNA be registered with the IBC, even if that use is exempt from the NIH Guidelines. For human gene transfer experiments, the IBC performs reviews, grants approval, and provides oversight in accordance with NIH Guidelines Section IV-B-2-b-(1), Section I-E, Section III-C and Appendix M.

Select Agents, Dual Use Research of Concern, and Research Requiring BSL3 Containment

The Vice President for Research has established a BSL3 Subcommittee of the U-M IBC, which has a separate charge to review proposals for research that would require the use of BSL3 containment facilities at U-M, including research with federally-regulated Select Agents. The BSL3 Subcommittee is further designated as the standing Institutional Review Entity required for identification and review of Dual Use Research of Concern, as specified in the US Government Policy on Institutional Oversight of Life Sciences Dual Use Research of Concern. Deans and department chairs in units hosting the research will be included in the review process. After review of the proposed experiment, the BSL3 Subcommittee recommends approval or disapproval to the IBC. In addition to approval by IBC, explicit approval by the Vice President for Research will be required for principal investigators new to performing research with a Select Agent, the commissioning of new BSL3 facilities, the use of a Select Agent not previously existing on campus, or research assessed to have Dual Use Research of Concern potential.

The Responsible Official, who may also serve as the University's Biological Safety Officer, serves on the BSL3 Subcommittee and has institutional responsibilities to authorize and register, as appropriate, with the Centers for Disease Control (CDC) any regulated Select Agents or other specifically designated agents, and to handle the transfer of such agents into and out of the University. At the time of any request to transfer a regulated Select Agent or to commence work with such an agent on campus, including agents that are designated as "select" after the work has commenced, the Responsible Official will ensure application, registration, and approval by the IBC (after review by the BSL3 Subcommittee) and from other designated institutional entities for such research.