

IBC Policies and Procedures Butler University

Butler University is actively committed to preserving the health and safety of its students, staff, and faculty, and to protecting the environment and the community. It is recognized that use of potentially pathogenic microorganisms, other biological materials, and organisms containing recombinant or synthetic nucleic acid molecules is necessary in many University research and teaching laboratories. Recombinant and synthetic nucleic acid molecules are defined as molecules that: 1) (a) are constructed by joining nucleic acid molecules and (b) that can replicate in a living cell, i.e., recombinant nucleic acids; 2) are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids; or 3) result from the replication of those described above.

To ensure the safe handling of these organisms, the University requires compliance with [NIH guidelines](#) (Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules) and with recommendations from the Centers for Disease Control and Prevention (Biosafety in Microbiological and Biomedical Laboratories). Compliance with other applicable federal, state, and local regulations is also required.

The IBC is the institutional body responsible for oversight of activities involving biohazardous materials. Biohazards mean agents infectious to humans or vertebrate animals, and biological toxins or venom. Regardless of whether an activity has external financial support, all research and teaching activities with recombinant DNA or any biohazards must be reviewed by the committee. The use of materials covered by the federal Occupational Safety and Health Administration's Bloodborne Pathogens Standard and animal tissues suspected to be contaminated with infectious agents also require IBC notification and approval. Teaching or research activities involving recombinant DNA, including NIH-exempt recombinant DNA research, or biohazards, will require an IBC protocol. For those instances where BSL-2 or BSL-3 conditions and precautions are indicated for research projects, IBC approval will also be required. Butler University lacks the facilities requiring BSL-3 plant biological or BSL-4 plant containment, or BSL-4 biological containment. Therefore, research requiring such containment cannot be performed at the Butler campus.

Biosafety policies apply to all Butler personnel engaged in teaching activities and/or research involving recombinant DNA (rDNA), including transgenic plants and animals, and biohazardous agents, materials, and toxins that are sponsored by the University; conducted by University research personnel; conducted using the University's property and facilities; received, stored, used, transferred, or disposed of at any of the University facilities; and conducted on behalf of the University at other institutions.

IBC members are appointed by the Provost/Vice President for Academic Affairs, or designee, in consultation with the IBC chair. The committee comprises no fewer than five members and collectively includes experience and expertise in recombinant or synthetic nucleic acid molecule

technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecules research and to identify any potential risk to public health or the environment. The committee also includes at least one individual with expertise in plant, plant pathogen, or plant pest containment principles, and at least one scientist with expertise in animal containment principles. At least two members are not affiliated with the institution. The Committee members serve for a three year term and can serve no more than two consecutive terms

The IBC Committee meets at least twice a year, with other meetings as needed.

Qualifications and Responsibilities of Researchers

PIs conducting research or teaching activities that fall under IBC jurisdiction must be members of the Butler University faculty.

PIs have the following responsibilities:

- Obtain initial IBC approval before conducting research or teaching activities that fall under IBC jurisdiction. The initial approval is for five years, after which time a new application must be made;
- Submit a protocol update every year;
- Direct and incur primary responsibility for the safe operation of the laboratory;
- Assess the risks of their experiments;
- Ensure the safe operation of their laboratory;
- Refer to University safety policies in the event of an injury or illness that occurs in the laboratory;
- Train laboratory personnel in safe lab-specific work practices;
- Provide necessary personal protective equipment;
- Comply with all applicable state and federal regulations and guidelines; and
- Register the following experiments with the IBC: experiments involving recombinant or synthetic nucleic acid molecules, including transgenic plants and animals; infectious agents; human blood or other potentially infectious materials, such as unfixed human tissues, human cell lines, and certain body fluids, as well as animal and plant pathogens; and biological materials at BSL-2 or higher that are intended to be used as part of teaching laboratories.

Application and Protocol Guidelines

The IBC application form must be submitted to the Butler Office of Sponsored Programs (OSP) office via email, IBC@butler.edu, or in person to JH-109. The approval is valid for five years. The forms are available on [IBC Forms and Submission](#).

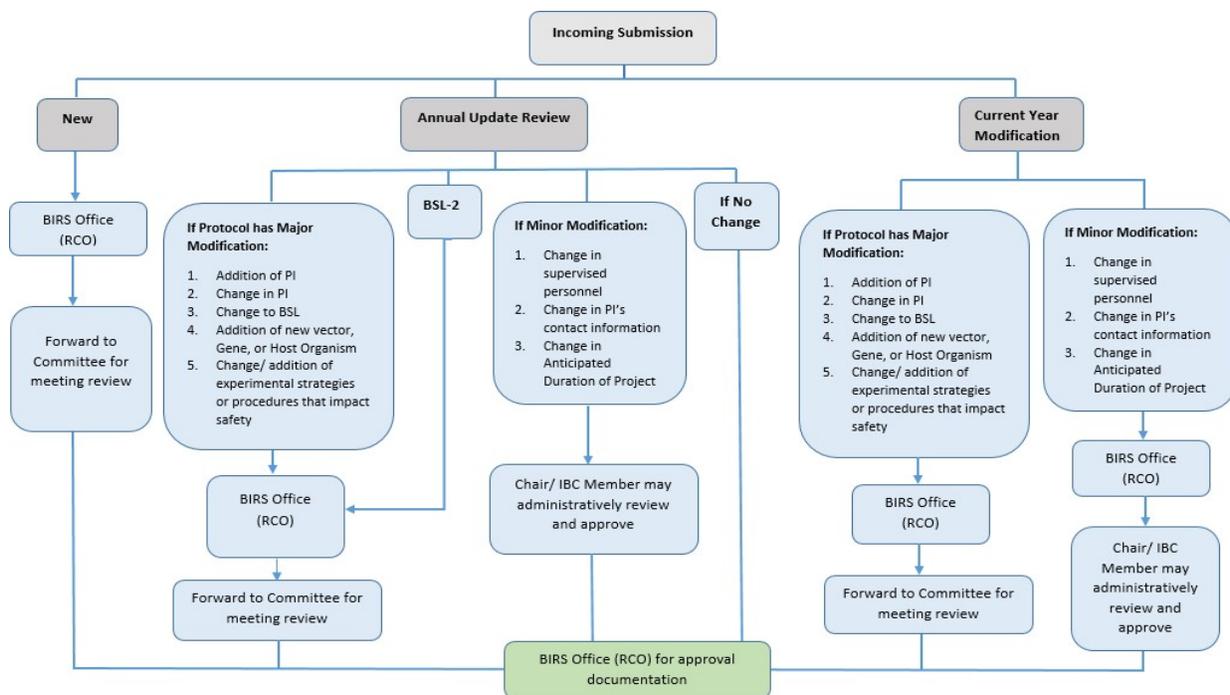
- [Application for approval of research involving recombinant DNA or other biohazardous materials](#) is intended for any research activities involving rDNA or other biohazardous materials

- [Institutional biosafety committee's qualifications form for instructional activities](#) is intended for any work with biohazardous materials as part of formal laboratory courses.

Each year, the PI is required to submit a [protocol annual update form](#) to assess any changes that have been made during the previous year. This review also verifies that all work has been conducted in accordance with the approved protocol.

All incoming submissions will be handled by the Research Compliance Officer. A preliminary review (pre-review) will be performed to ensure that all application elements are complete. Upon satisfactory preliminary review, the application is forwarded to the IBC for the final review.

- Any new applications will be sent to the convened meeting for review.
- During annual update review and current year modification submission,
 - If the protocol has major modifications and/or under BLS-2 level, the submission will be sent to the convened meeting for review.
 - If the protocol has minor modification or no modification, the chair/ designated IBC member may administratively review and approve it.



Definitions

Institutional Biosafety Committee (IBC). Institutional body responsible for oversight of activities involving recombinant DNA or biohazardous materials as required by the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) and the Centers for Disease Control and Prevention (CDC) Biosafety in Microbiological and Biomedical Laboratories (BMBL).

NIH Guidelines. Document that specifies practices and provides guidelines for constructing and handling recombinant or synthetic nucleic acid molecules and organisms containing recombinant or synthetic nucleic acid molecules. Institutions conducting or sponsoring recombinant or synthetic nucleic acid molecules research covered by NIH Guidelines are responsible, through established policies and its IBC, for ensuring that such research is conducted in compliance with the NIH Guidelines and are available under the forms/resources. Each organization involved in the conduct of NSF-supported recombinant DNA research is subject to the NIH Guidelines as well.

Recombinant and synthetic nucleic acid molecules. Molecules that a) are constructed by joining nucleic acid molecules, and b) can replicate in a living cell, i.e., recombinant nucleic acids; nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids; or molecules that result from the replication of those described in either of the above.