

Utah State University Institutional Biosafety Committee (IBC) Charter

Policy and Purpose

The existence of an Institutional Biosafety Committee (IBC) is required by the National Institutes of Health (NIH) for research involving recombinant and synthetic nucleic acids. The Utah State University (USU) IBC reviews, approves and oversees projects in accordance with the responsibilities defined in Section IV-B-2 of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids*. The scope of the IBC also includes oversight, administration and review of University policies and research involving biological material which may pose a threat to humans, animals, plants or the environment. This committee also identifies dual use research of concern (DURC) and tracks risk mitigation measures implementation as required under the 2015 *US Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC)*.

The IBC is charged with providing institutional assurance to the Vice President for Research and Dean of Graduate Studies that research is conducted according to current local, state and federal directives, guidelines and regulations relating to activities involving BSL-2/3 infectious agents, recombinant DNA, DURC and 'Select Agents'. The IBC assists and advises researchers in meeting their responsibilities to ensure that all biological aspects of research are conducted in a safe manner using established biosafety standards, principles and practices.

The IBC is sanctioned to withhold authorization of any study not explicitly approved by the *Centers for Disease Control and Prevention (CDC)/NIH Guidelines* until containment requirements are established.

Functions and Responsibilities of the IBC

- Review and monitor all USU research projects that fall under the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*; BSL-2/3 infectious agents, Dual Use Research of Concern (DURC) and 'Select Agents'.
- Review IBC procedures annually.
- Review and approve IBC policies in accordance with federal regulations and guidelines and make recommendations to the Vice President on relevant biosafety matters.
- Assess containment levels, facilities, procedures, practices, training and expertise of personnel involved in proposed research in accordance with current biosafety standards.
- Review and approve SOPs.
- Review incidents as reported by the BSO. When appropriate assists with an incident investigation in support of BSO reporting to Department Head, BSO and Vice President.
- Reviews and approves reported significant problems or violations to the NIH Office of Biotechnology Activities (OBA) as per Section IV-B-2-b-(7) of the NIH Guidelines as per OBA FAQ guidance document on incident reporting.

- Reviews minutes and reports and maintains all records in an orderly and retrievable fashion.
- Review and maintain approved annual reports to NIH OBA as per Section IV-B-2-b-(7).
- Report results of investigations to the University Safety Committee.
- Notify the Principal Investigator (PI) of the results of the IBC review and approval process.

Specific Functions and Responsibilities

- The IBC Chair is responsible for ensuring that IBC Committee members are appropriately trained.
- The PI is responsible for ensuring that laboratory staff are appropriately trained.
- The Biosafety Officer (BSO) is responsible for carrying out the functions described in the NIH Guidelines Section IV-B-3.

IBC Membership

The IBC voting members are selected from the USU community with the collective experience and expertise to assess the safety of research. Potential IBC members are recommended by the Chair, BSO, other IBC members, or by the directors of EH&S and Research Integrity and Compliance.

Composition

The IBC is composed of no fewer than five voting members from the USU community with the collective experience and expertise to assess the safety of research involving biohazardous material. The specific areas of expertise can be found in the *NIH Guidelines Section IV-B-2-a*.

At least two additional members, known as "community members", shall be appointed from the local community by the Vice President and cannot be affiliated with the University apart from their membership on the IBC. Community members are not expected to act as primary reviewers for research proposals.

The IBC may use consulting experts to execute its responsibilities or acquire needed expertise for select tasks. Consultants are not IBC voting members unless nominated and appointed as previously described. Consultants are held to the same standards for conflict of interest and confidentiality as voting members of the IBC.

Meetings

The meetings will be held on a monthly basis as needed in a format that facilitates the taking of minutes and accommodate public attendance.

Confidentiality

All business of the IBC shall be subject to disclosure according to USU policy, the *NIH Guidelines* and the *Freedom of Information Act*. Research reviews and other business of the IBC shall be

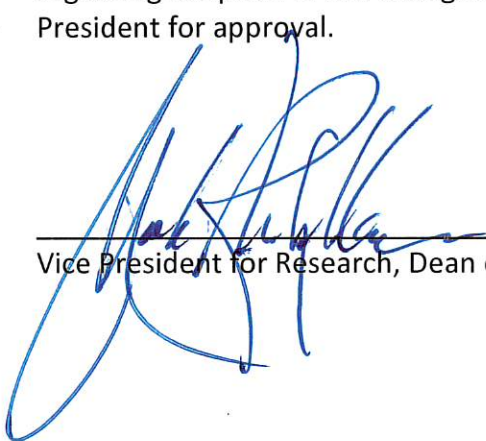
conducted in compliance with these policies, guidelines and laws in such a matter as to preserve the academic freedom and confidentiality of the processes, participants and stakeholders to the extent possible.

Conflicts of Interest

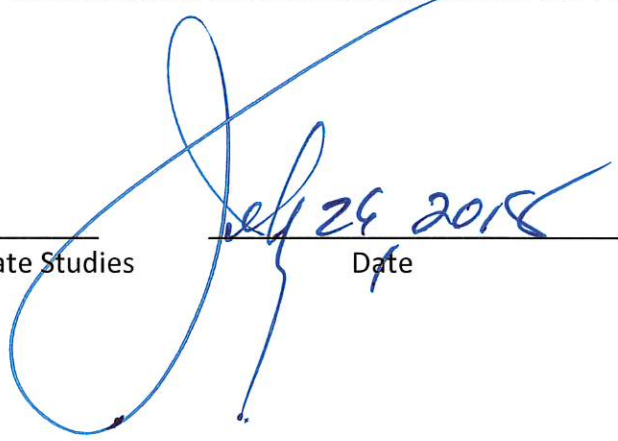
- 1) No member of the IBC may review or vote on a project with the following conflicts:
 - a. Institutional conflict of interest
 - b. Conflicts of commitment
 - c. Individual conflicts
 - i. Financial
 - ii. Competing

Charter Approval

IBC members will review proposed changes to this Charter and make recommendations regarding adoption of the changes. The BSO will submit the IBC recommendations to the Vice President for approval.



Vice President for Research, Dean of Graduate Studies



Date

References

- 7 CFR, Part 331 Plant
- 9 CFR, Part 121, Animal
- 42 CFR, Part 73 Public Health
- CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (5th edition)
- Dual Use Research of Concern
 - <https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/>
 - <http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>
- HHS and USDA Select Agents and Toxins List
 - <https://www.selectagents.gov/regulations.html>
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
 - https://osp.od.nih.gov/wp-content/uploads/2013/06/NIH_Guidelines.pdf