Institutional Biosafety Committee – Charter
Oklahoma State University

Revised May 2015

I. Mission

The charge of Oklahoma State University's (OSU) Institutional Biosafety Committee (IBC) is to review all research and instructional activities involving biohazardous material, including recombinant and synthetic nucleic acid molecules, performed by individuals acting as agents (e.g., faculty, researchers, staff, students, and employees) of the university. The IBC provides oversight of biological safety at OSU and compliance with applicable regulations and guidelines, as well as University policies.

II. Definition of Biohazardous Material

Biohazardous material includes all infectious agents, vectors known to carry and transmit infectious agents, infected or potentially infected animals, infectious material, recombinant and synthetic nucleic acid molecules, and biologically-derived toxins that are capable of producing deleterious effects upon humans, animals, plants, or the environment either directly through infection or indirectly through damage to the environment (George Mason University, 2007). Therefore, it includes known human, animal, and plant pathogens and infectious agents that encompass biological toxins, select agents and/or toxins, prions, bacteria, viruses, fungi, mycoplasmas, and parasites; laboratory animals including insects that harbor such infectious agents; and human and primate cell lines or body fluids that are known to contain pathogens. Also included are potentially biohazardous organisms used in procedures such as the creation of recombinant nucleic acids and genetic manipulations. Biohazards will be classified according to risk groups requiring appropriate containment.

III. Definition of Recombinant and Synthetic Nucleic Acid Molecules

The *NIH Guidelines* define recombinant and synthetic nucleic acids [r(s)NA] as:

1) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
2) 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
3) molecules that result from the replication of those described above (National Institutes of Health, 2013).

IV. Responsibilities of the Institutional Biosafety Committee

Specific responsibilities with which the IBC is charged include:

- providing oversight for biological safety at the University;
- providing oversight for compliance with the *NIH Guidelines*;
- providing oversight for compliance with the Select Agent Final Rule;

- establishing campus specific policies and procedures governing all research and instructional activities involving biohazardous material and recombinant or synthetic nucleic acid molecules conducted by individuals acting as agents of the University (e.g., faculty, researchers, staff, students, and employees);
- reviewing all instructional and research activities that involve recombinant or synthetic nucleic acid molecules conducted at or sponsored by the University for compliance with the *NIH Guidelines*, regardless of source of funding;
- approving those instructional and research activities that conform to the *NIH Guidelines*, including work with recombinant or synthetic nucleic acid molecules that qualifies for exemption, as OSU PIs may only self-exempt for activities involving synthetic nucleic acid molecules that cannot replicate or generate nucleic acid molecules that can subsequently replicate in any living cell (e.g., oligonucleotides);
- reviewing all instructional and research activities that involve biohazardous material (as defined in this policy) conducted at or sponsored by the University, regardless of source of funding, for compliance with the guidelines in the latest edition of the Center for Disease Control and Prevention's (CDC) *Biosafety in Microbiological and Biomedical Laboratories*; approving those activities that conform to the *BMBL* guidelines;
- reviewing all instructional and research activities that involve select agents and toxins conducted at or sponsored by the University, regardless of source of funding, for compliance with the Select Agent Final Rule; approving those activities that conform to the pertinent regulations;
- performing risk assessments to determine the containment levels required by all applicable regulations and/or guidelines;
- assessing facilities, procedures, practices, and the training and expertise of personnel involved in the proposed activities;
- performing periodic reviews of all research and instructional activities that fall within the purview of the IBC to ensure compliance with all applicable governmental guidelines and regulations, as well as university policies;
- notifying Principal Investigators in writing of the outcomes of IBC review of initial and renewal applications/protocols;
- receiving and reviewing incident reports regarding: 1) exposures of individuals to biological agents or recombinant or synthetic nucleic acid molecules, 2) loss or theft of biological agents, and 3) any incident that warrants an emergency response;
- reporting any problems with or violations of the *NIH Guidelines* and any instructional or research related incidents or illnesses involving recombinant or synthetic nucleic acid molecules to the Vice President for Research and the NIH Office of Biotechnology Activities within 30 days, unless it is determined that a report was already filed by the Principal Investigator or personnel of the Office of University Research Compliance;

- reporting any noncompliance with IBC requirements and determinations and noncompliance with pertinent regulations, guidelines, and University policies to the Vice President for Research; and
- performing periodic reviews of this policy and recommending changes, as needed, to the Vice President for Research

Additionally, the IBC may withhold approval for all or any portion of a protocol and require modifications in order to secure IBC approval. Any changes in project scope, organisms to be worked with, research methodology, and/or changes in project personnel must be prospectively reviewed and approved by the IBC prior to the changes being instituted. The Office of University Research Compliance maintains records of IBC protocols, meeting minutes, laboratory inspection reports, and other documentation relevant to OSU's biosafety program.

V. Institutional Biosafety Committee

a. IBC Membership

The committee shall consist of no fewer than five members, of whom:

- At least one member must have expertise in plant, plant pathogen, or plant pest containment;
- At least one member must have expertise in animal containment principles;
- One is the biological safety officer;
- At least two members must represent the local community and shall not be affiliated with OSU (apart from their membership on the IBC);
- At least one member must have expertise in recombinant or synthetic nucleic acid technology.
- The Assistant Vice President for Research Compliance will serve as an ex-officio member.

Alternate Members: Individuals may be appointed to the committee as alternates for specific IBC members. Alternate members may vote in the absence of the member he/she is assigned to as an alternate. If both the member and his/her designated alternate member are present at a convened meeting of the IBC, the alternate member may not vote.

Members will be appointed by the Vice President for Research for three year terms, unless they are appointed to complete the term of a member who will no longer serve. Members may be re-appointed at the end of each three year term.

A member who cannot serve a complete term (e.g., sabbatical or separation) may be replaced by a new member who will be expected to serve the remainder of the initial member's term, unless the initial member plans to return and complete his/her term.

b. IBC Member Training

All newly appointed members are required to complete training on the regulatory responsibilities and functions of an IBC. This training must be completed before a new member participates in committee activities (e.g., convened meetings, protocol review and approval, and voting). Annual refresher training is required of all IBC members. This training will cover topics that will enhance members' understanding of biosafety-related issues and review policies. The Biological Safety Officer and/or the IBC Chair will facilitate this training.

c. IBC Member Responsibilities

The IBC Chair shall:

1. Serve as a member of the IBC and understand all functions, policies, and procedures of the IBC and the University's biosafety program.
2. Attend scheduled meetings of the IBC.
3. Direct the proceedings of convened meetings of the IBC.
4. Review research protocols, including protocols slated for review via an expedited review process and at convened meetings of the IBC.
5. Assist in setting meeting agendas.
6. Assist the IBC Coordinator in drafting letters from the IBC regarding IBC decisions and actions.
7. Sign IBC letters, as needed.
8. Make decisions about researcher responses to IBC conditions for protocol approval, in collaboration with the Biological Safety Officer.
9. In concert with the Biological Safety Officer and other members of the IBC, conduct post-approval monitoring of protocols.
10. Assist in the development and implementation of new standard operating procedures (SOPs).
11. Assist with periodic reviews of IBC policies and procedures.
12. Ensure member training (this task may be delegated to the Biological Safety Officer).
13. Participate in periodic review of the IBC Charter and update as necessary.
14. Complete required biosafety training.

The IBC Vice-Chair shall:

1. Serve as a member of the IBC and understand all functions, policies, and procedures of the IBC and the University's biosafety program.
2. Attend scheduled meetings of the IBC.
3. Perform duties of the Chair in the Chair's absence or in instances where the Chair has a conflict of interest.
4. Participate in periodic review of the IBC Charter and update as necessary.
5. Assist with periodic reviews of IBC policies and procedures.
6. Complete required biosafety training.

IBC members shall:

1. Understand all functions, policies, and procedures of the IBC and the University's biosafety program.
2. Attend scheduled meetings of the IBC.
3. Notify the IBC Coordinator when unable to attend IBC meetings.
4. Complete required biosafety training.
5. Review protocols as requested and provide feedback to the IBC Coordinator, the IBC Chair, and/or the Biological Safety Officer.
6. Assist with periodic reviews of IBC policies and procedures.

d. IBC Schedule and Meetings

Convened meetings of the IBC are held during the fourth week of odd-numbered months unless otherwise indicated. Additionally, the IBC will hold meetings via teleconference during the fourth week of even months. Teleconference meetings are only for the review of r(s)NA protocols that are exempt from the *NIH Guidelines*. Meetings are open to the public and are announced on an open Website (http://compliance.okstate.edu/ibc/ibc-meeting-dates). Should any comments be received from the public, these comments and the IBC's response to the comments will be provided to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA).

The IBC, in its discretion, may close any meeting, or part of a meeting, consistent with protection of privacy; proprietary interests; health and safety of University employees, the environment, and the community; or as required by law or regulation.

e. Quorum

A quorum is defined as 50 percent of the committee's membership plus one additional member. Non-members may not be counted in determining a quorum.

f. Conflict of Interest

No IBC member shall be allowed to participate in the review and approval of any project in which he/she has a conflicting interest, including financial conflicts of interest, except to provide information requested by the IBC.

References

George Mason University Biological Safety Manual (February 2007). Fairfax, VA: Office of Laboratory Safety (Producer).

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (November 2013). National Institutes of Health, Office of Biotechnology Activities. Washington, DC: U.S. Government Printing Office. http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276218

Wilson, D.E., & Chosewood, L.C. (Eds.). (2007). *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). U.S. Department of Health & Human Services. http://www.cdc.gov/biosafety/publications/bmbl5/index.htm

Title 42 Code of Federal Regulations Part 72 & 73 (42 CFR 72, 73) *Possession, Use, and Transfer of Select Agents and Toxins; Final Rule* (December 2012). United States Department of Health and Human Services. http://www.selectagents.gov/regulations.html

Title 7 Code of Federal Regulations Part 331 (7 CFR 331) and Title 9 Code of Federal Regulations Part 121 (9 CFR 121) *Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins; Final Rule* (October 2012). U.S. Department of Agriculture. http://www.selectagents.gov/regulations.html