Institutional Biosafety Committee Charter

A. Introduction to the Purdue IBC

The Purdue University Institutional Biosafety Committee (IBC) is the campus-based committee charged with review of all research including, but not limited to: work with known or suspected pathogens, work with unfixed samples derived from human tissue or cell lines with potential bloodborne pathogens, and work with recombinant or synthetic nucleic acids. Purdue utilizes its IBC to ensure that research is conducted compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (hereinafter referenced as "*NIH Guidelines*") and biosafety guidelines for classification, containment, and safety.

B. Purpose of the Purdue IBC

The purpose of the IBC is to oversee and review biosafety of research carried out by Purdue University faculty and employees. The Purdue IBC reviews and approves protocols to ensure the safe conduct of experiments involving recombinant or synthetic nucleic acids per the *NIH Guidelines*. The IBC strives to mitigate risk to researchers and the surrounding community by:

- Establishing and implementing standard operating procedures and guidance for use by Purdue University researchers.
- Ensuring that proper precautions and procedures are used for research involving biological agents.
- Reviewing proposed activities involving recombinant or synthetic nucleic acid molecules that could affect biosafety of Purdue personnel and the surrounding community.
- Assisting and advising Purdue University research personnel for compliance with international, federal, state, and local biosafety regulations or guidelines.

Protection of health and environment are a shared responsibility, the IBC is responsible for establishment and implementation of policies to safely conduct research with recombinant or synthetic nucleic acid molecules. The IBC works to outline the expectations and standardize the materials that must be addressed prior to conducting research. The primary responsibility in most cases lies with the Principal Investigator and research staff to effectively contain pathogens and recombinant nucleic acids.

All research activities involving recombinant or synthetic nucleic acids or pathogenic microorganisms of animals, humans, or plants must be registered and approved by

the IBC. The IBC will review projects, set appropriate containment levels, and make other safety recommendations. The IBC may delegate these activities to the BSO and/or IBC Chair as appropriate with relevant biosafety regulations.

C. IBC and Institutional Organization

The IBC has the support of the Purdue University administration. The Biosafety organizational structure is part of the Purdue University Department of Radiological and Environmental Management (REM). However, as a function of the research arm of Purdue, the Associate Vice President for Research acts as the Institutional Official (IO) representing the committee to federal and other regulatory bodies. In most cases, the IO is the responsible party to direct incoming and outgoing communications on biosafety and serves as the point of distribution for these messages. In this capacity, the IO also appoints members to the IBC on an annual basis. Members are notified in writing upon their appointment and notified of the duration of their term. The IO maintains the IBC roster and subsequent updates.

Purdue maintains a full-time Biological Safety Officer (BSO) appointed to evaluate the biosafety requirements of research activities with viable organisms with or without recombinant or synthetic nucleic acids. The BSO is an integral part of Purdue's compliance with *NIH Guidelines*. The Purdue BSO serves as the primary intake point for IBC protocols and questions related to containment and safety practices. The IBC relies on the expertise of the Biosafety Officer (BSO) and his/her staff with regard to up-to-date federal, state, and local biosafety regulatory compliance.

D. IBC Membership

The IBC will have no less than five members with varying backgrounds to promote complete and adequate review of activities involving potentially biohazardous materials and recombinant or synthetic nucleic acids conducted at Purdue. The Institutional Official oversees the committee activities as an *ex-officio* member.

The Chair of the committee will be appointed by the Purdue University IO and will possess a thorough understanding of biosafety topics and operations of the university. The IBC will be sufficiently qualified through the experience, expertise, and diversity of the members. Members of the committee are expected to promote respect and widespread knowledge of institutional policies, applicable laws and environmental considerations. IBC members are appointed for their capability to assess the safety of research activities utilizing biohazards or recombinant and synthetic nucleic acids, and provide knowledge to mitigate any potential risk to workers, public health, or the environment.

The BSO is a voting member of the IBC. As necessary, at least one member with primary expertise is in plants, plant pathogens, and plant pest containment principles and at least one member with expertise in animals and animal containment principles will be appointed to the IBC.

The IBC will include at least two members from the surrounding community. Community members will be unaffiliated with Purdue, and both shall represent the interest of the surrounding community with respect to health and the protection of the environment.

E. IBC Procedures

All information related to biosafety procedures is collected on the IBC Form 1A and amended on the IBC Form 2A. These forms standardize the information necessary for proper analysis of a protocol. Protocols forms will be maintained and updated by the IBC and BSO and made publically available online. As the primary point for protocol intake, the BSO will conduct the initial review and classification of biosafety level and categorization of the appropriate recombinant or synthetic nucleic acids to be utilized by the researcher.

Should the BSO identify studies that are categorized in the *NIH Guidelines* as III-A through III-E, s/he will prepare the information for presentation to the committee. In parallel with arranging an IBC meeting, the BSO and/or associated staff will conduct a laboratory inspection, verify training, and validate disposal methods. These methods will be documented as a summary within the applicable protocol alongside any other comments or recommendations.

The completed information along with any accessory materials (e.g. agenda, minutes for review) will be supplied to the IBC in either electronic means or hard copy prior to the meeting in order to allow proper review and clarification of any questions prior to the scheduled meeting. Prospectively scheduled meetings will be posted to a publically available website or available by contacting the BSO or Committee Chair via phone or e-mail.

The IBC must have a quorum present to conduct business that requires a vote. The Purdue IBC will conduct business with no fewer than five of its voting members present. If a particular area of expertise is necessary, the presence of a particular IBC member may be crucial to the conduct of business. Per OBA recommendations, all efforts will be made to include at least one unaffiliated member at each IBC meeting.

Investigators conducting research categorized as III-E or III-F under *NIH Guidelines* are allowed to initiate their work at the time of registration with the IBC and

satisfactory inspection and training as determined by the BSO. However, protocols with a III-E classification will be reviewed and subject to vote by the IBC committee at a fully convened meeting. The IBC may request revisions or clarifications. All other protocols must be approved prior to initiation of the study and could be subject to further approvals from US Government agencies (i.e. CDC, NIH) or local committees, such as the Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) as required by *NIH Guidelines.*

Minutes of the meeting will be recorded. The minutes will be a reflection of the substantial items, reviews, discussions and actions of the IBC as required by the *NIH Guidelines*. A draft of the minutes from the prior meeting will be available for review and comment at each meeting. The finalized version of the minutes will be subject to a vote by a convened quorum.

F. Avoiding Conflicts of Interest

In the event that any member of the committee has a protocol that requires review by the full committee, s/he will not be a part of the review or voting process. Plans to assemble a quorum must accommodate any potential conflicts of interest to maintain a majority of present committee members. A committee member may not vote on his/her own protocol. Committee members are free to voluntarily recuse or abstain from a vote for any reason of perceived or actual conflict of interest. Members will be encouraged to recuse themselves from any conflicts such as co-investigators on funded proposals, spousal relationships, or supervisory relationships that could alter their ability to objectively review a protocol.

If review and voting is to be conducted on a protocol for the IBC Chair, s/he will not review or vote on the protocol. Another IBC member, such as the Associate Chair, will conduct the business of the meeting in the absence of the Chair.

G. References to Relevant or Related IBC Regulations

The IBC operates based upon the following regulations/guidelines:

- *NIH Guidelines for Research Involving Recombinant DNA or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*), most current edition; April 2016
- Best practices and recommendations from the Office of Biotechnology Activities (OBA);
- Biosafety in Microbiological and Biomedical Laboratories (BMBL), most current edition, developed by the Center for Disease Control (CDC) and the National Institutes of Health (NIH);
- USDA/APHIS 7 CFR Part 340, Introduction of Organisms and Products Altered or Produced through Genetic Engineering and all APHIS Permit Regulations/Guidelines;
- 42 CFR Part 73, Possession, Use, and Transfer of Select Agents and Toxins;

- 7 CFR Part 331 and 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins;
- USDA/ARS Facilities Design Standards, Chapter 9, Biohazard Containment Design.