Research Research Integrity and Assurance

Princeton University
Institutional Biosafety Committee
Charter

Title: Institutional Biosafety Committee Charter	
Approval Date: May 15, 2015	**Effective Date:** May 15, 2015

A. Purpose

The Institutional Biosafety Committee (IBC) reviews recombinant or synthetic nucleic acid molecules research (r/s DNA) conducted at or sponsored by the University for compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* and approves those research projects that comply with the *Guidelines*. Additionally, the IBC reviews and approves research involving:

- microorganisms and viruses pathogenic to humans, plants or animals
- select agents*
- biological material from human and non-human primates
- biological toxins
- animal tissues that present zoonotic disease concerns

The IBC reports to the University's Institutional Official (IO).

B. Membership

The Dean for Research, with assistance from the Biosafety Officer (BSO) and the IBC Chair, recruits and nominates IBC members. IBC members are formally appointed by the Dean for Research in writing to three-year terms. The following are voting members:

1. A minimum of three faculty members with expertise in r/s DNA technology, general issues of laboratory biosafety or the use of infectious materials will serve on the IBC.

2. At least two members shall not be affiliated with the University and will represent the interest of the Community with respect to health and protection of the environment.

3. At least one individual with expertise in animal containment practices.

4. The BSO, a University Health Services physician and the Attending Veterinarian are ex-officio voting members of the IBC.

5. A non-voting representative from the Office of Research Integrity and Assurance (RIA) serves as the IBC secretary and administrator. Others who may sit with the IBC include the Director, Environmental Health and Safety (EHS), the Associate Director of EHS for Laboratory Safety and the Director, Department Public Safety.

C. Responsibilities

1. Ensures that Principal Investigators (PI) are aware of the responsibility to register research involving r/s DNA and biohazards with the IBC.

2. Reviews r/s DNA research conducted at or sponsored by the University for compliance with the *Guidelines* and approves those research projects that are found to conform to the *Guidelines*.

3. Notifies the PI of the results of the IBC's review.

4. In accordance with the *Guidelines* and after a thorough risk assessment, lowers containment levels for research that falls under Section III-D-2-a, *Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems.*

5. Sets containment levels as specified in the *Guidelines* (Sections III-D-4-b, Experiments Involving Whole Animals, and III-D-5, Experiments Involving Whole Plants).

6. IBC will not authorize initiation of experiments which are not explicitly covered by the *Guidelines* until NIH (with the advice of the Recombinant Advisory Committee (RAC) when required) establishes the containment requirement.

7. The IBC periodically reviews r/s DNA research conducted at the institution to ensure compliance with the *Guidelines.*

8. Adopts emergency plans covering accidental spills and personnel contamination resulting from rDNA research activities.

9. Makes recommendations for medical surveillance that may be required for staff, students and faculty to the Medical Director, University Health Services.

10. Investigates potential violations of the *Guidelines.*

11. Reports any significant problems with, or violations of the *Guidelines* and any significant research-related exposures, accidents or illnesses to the IO and the NIH Office of Biotechnology Activities (OBA) within 30 days. Incidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure will be reported to NIH OBA, the IBC Chair and the IO by the Biosafety Officer within 48 hours.

12. Reviews and issues approvals, when appropriate, research involving microorganisms and viruses that

are pathogenic to humans, animals or plants.

13. Reviews and approves, when appropriate, research involving biological materials from human and non-human primates.

14. Conducts the local review and approval of all University research activities involving the possession and use of Select Agents and Select Agent Toxins, to assure that these activities and the related facilities comply with applicable federal, state and local laws and regulations and University policies, regardless of the source of funding for the project.

15. Informs the IO of any individual whom the IBC determines has violated the terms of an approved protocol, has conducted projects subject to its authority without gaining appropriate IBC approval, or has otherwise violated any provision of applicable federal, state, and local regulations and guidelines, or institutional policies regarding subjects under its purview.

16. Performs a biennial review of the IBC's compliance with the *Guidelines* and submits the findings to the IO. The review shall be performed using assessment tools available from the NIH OBA.

17. Periodically consults with external experts regarding the IBC's compliance with the *Guidelines* and submits findings to the IO.

D. Conflict of Interest

1. No member of the IBC may participate (except to provide information requested by the IBC) in the review or approval of a project in which he/she has been or expects to be engaged, or has a direct financial interest.

2. If the IBC Chair's research is under review, the IBC Administrator will assign an IBC faculty member to facilitate review and approval of the project.

E. Procedures

1. A quorum shall consist of greater than one-half of the voting members and is required at the IBC meetings to conduct business. Votes will be decided by a simple majority of those present. A quorum must be present (in person or through telephone or video conferencing) to take action on research that is not exempt from the *Guidelines* or involves biosafety level 3 pathogens, select agents and toxins.

2. IBC meetings are held at least quarterly or at the call of the Chairperson. Meeting days and times shall be posted on the RIA website, which is accessible to the general public.

3. RIA staff maintain all approved IBC meeting minutes. The RIA Director and a representative from the University's Office of Legal Counsel will respond to requests for copies of meeting minutes received from persons not associated with the University. RIA Director will redact content of meeting minutes if advised by University Legal Counsel prior to responding to requests.

4. Comments received from the public regarding the IBC's actions are referred by the RIA Director to the IO, the IBC Chair and the BSO. The IO is responsible for review and approval of the IBC's response to public comments. The IBC administrator forwards all public comments and the University's response to NIH OBA.

5. Review and approval of r/s DNA research.
    a. Principal Investigators must register all r/s DNA research with the IBC.
    b. The IBC chair and the BSO will review, request modifications and approve of Registrations describing research that is exempt from the *Guidelines*.
    c. All r/s DNA research that is not exempt from the *Guidelines* will be reviewed and approved, if appropriate, by the IBC at a fully convened meeting prior to initiation of the research.
        i. The IBC will notify the Principal Investigator if the research described on the IBC Registration form requires review and approval by NIH Office of Biotechnology Activities (OBA) and/or the Recombinant Advisory Committee (RAC).

6. Research Involving Infectious Microorganisms and Viruses:

    a. Biosafety Level 2 - The IBC Chair and the BSO will review the Registration. Research involving biosafety level 2 non-recombinant pathogens must be approved by both the IBC Chair and the BSO. Either may request that the Registration be reviewed by the full Committee via email or at a convened meeting.

    b. Biosafety Level 3 - Proposals for all research involving biosafety level 3 pathogens must be approved by the URB. The IBC will review research involving biosafety level 3 human pathogens at a convened meeting. The IBC must also approve of all Standard Operating Procedures for work with Biosafety Level 3 agents.

7. Select Agents and Toxins:

    Proposal for research with Human Health Services (HHS) and United Stated Department of Agriculture (USDA) select agents and toxins must be approved by the URB. The IBC will review and approve of all Registrations describing research with select agents and toxins at a convened meeting.

8. Human and Non-Human Primate Materials:

    The BSO will review and assign containment levels for research involving human and non-human primate materials.

F. References

*APHIS and CDC implemented the provisions of Public Law 107-188, the "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (The Act) through a series of regulations. These regulations culminated with the publication of the final Select Agents Regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121) in the Federal Register on March 18, 2005. The Final Rules were published in the *Federal Register* on March 18, 2005 and became effective on April 18, 2005.

NIH Guidelines for Research Involving Recombinant DNA Molecules. November 2013. Dept. of Health and Human Services, NIH

G. Version History

	Version Number	Revision Date	Revisions
Add	1.0	Oct 26, 2012	Initiated
Add	2.0	March 31, 2015	Minor modifications including editing, abbreviations, and formatting