

Cornell University (Ithaca Campus)
Charge to the Institutional BioSafety Committee (IBC)

Authorization Cornell University shall have an Institutional Biological Safety Committee established under the authority of The Office of the President.

General Charge Cornell University's (Ithaca –Geneva campuses) Institutional Biosafety Committee (IBC) is a Standing Committee of the Faculty Senate and is responsible for reviewing all University research and teaching activities that are conducted by faculty, staff, students, and/or visiting scientists at, or under the auspices of Cornell University, and that involve the use of recombinant or synthetically derived nucleic acid molecules (r/sNA) or other biohazardous materials (regulated human, animal and plant pathogens and biological toxins). The purpose of these reviews is to ensure that all activities involving r/sNA or other biohazardous materials and the facilities used to conduct such work are in compliance with all applicable external regulations and University policies. Foremost, the IBC's objective shall be to ensure that such activities meet standards of good biological safety practice emphasizing protection of personnel, the general public, and the environment. To this end, the IBC shall assist principal investigators and other researchers in meeting their responsibilities; impose requirements and review and approve policies, procedures, programs, and facilities pursuant to the safe use of (r/sNA) or other biological materials.

The IBC shall work with the Cornell Ithaca research community to ensure that work conducted at, or under the auspices of, the institution involving recombinant or synthetic nucleic acid molecules, including transgenic animal work and human gene transfer research, is carried out in accordance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic acid Molecules ("NIH Guidelines").

In addition to the review of research involving recombinant or synthetic nucleic acid molecules, the IBC is also charged with the review of research involving, but not limited to, agents classified as Risk Group 2, 3, and 4 in the NIH Guidelines, Appendix B and research involving select agents and toxins as regulated by the CDC/USDA.

The IBC shall also meet any oversight obligations that arise from research that is reviewed by other established University Committees – Human Participants, Animal Care and Use, Radiation Safety, etc..

The IBC shall advise the University and establish policies to guide principal investigators and the Department of Environmental Health & Safety (EH&S) in carrying out the University's Biosafety Program in the acquisition, use, training, transfer, storage, disposal, and emergency response procedures for all biosafety activities.

Upon request, the IBC shall review and comment on proposed external regulations

dealing with biosafety.

When appropriate, the IBC shall formulate draft policies and procedures for approval by the appropriate University bodies and promulgation by the Vice Provost for Research.

Definitions

Biohazardous Agents

- A. Infectious/pathogenic agents classified in the following categories: Risk Group 2, 3, and 4 bacterial, fungal, parasitic, viral, rickettsial or chlamydial agents as defined by the National Institutes of Health (NIH) **or**,
- B. Other agents that have the potential for causing disease in healthy individuals, animals, or plants.
- C. Biological toxins include metabolites of living organisms and materials rendered toxic by the metabolic activities of microorganisms (living or dead).

Recombinant and Synthetic Nucleic Acid Molecules

- A. Molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
- B. 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
- C. molecules that result from the replication of those described in (A) or (B) above

Gene Therapy

Delivery of exogenous genetic material (DNA or RNA) to somatic cells for the purpose of modifying those cells.

Scope Of IBC Review

The r/sNA or biohazardous agents subject to IBC review, and the approval requirements specific to the agent/s being used, are:

Biohazardous Agents

- Activities involving Risk Group 2, 3, and 4 biohazardous agents must be reviewed and approved by the IBC **prior to** the initiation of use of agent.
- Activities involving Risk Group 1 agents that **do not** involve recombinant or synthetic nucleic acids, are not reviewed by the IBC.

Toxins

- Activities that involve the isolation and production of toxins from live organisms, and those experiments that involve the acquisition and use of toxins that are listed in the
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CDC Select Agent Program, must be approved by the IBC **prior to** initiation of activities.

Select Agents and Toxins

- Activities involving Select Agents and Toxins under 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121.. Possession, Use, and Transfer of Select Agents and Toxins, must be approved **prior to** initiation of activities
- NOTE: Select Agents and Toxins appearing on these lists must be registered with EH&S and require a significant lead time. Researchers are strongly encouraged to contact the Biological Safety Officer at EH&S if they are considering use of these materials.

Recombinant or Synthetic Nucleic acids

- Experiments with Recombinant or Synthetic Nucleic acid molecules involving human, animal, plant or microbial pathogens, or whole plants or animals require IBC approval prior to initiation.
- If the studies mentioned above use less than 2/3 of a eukaryotic viral genome, OR if whole plant experiments involve microorganisms that have no recognized potential for dissemination or environmental impact, IBC approval can be obtained **concurrently with** project initiation.
- Experiments involving Recombinant or Synthetic Nucleic acid molecules exempt from the NIH Guidelines must still be registered with the IBC for approval. (Click [here](http://oba.od.nih.gov/oba/index.html) for a guide to the NIH Exemptions available on the OBA website (<http://oba.od.nih.gov/oba/index.html>))

Gene Transfer Therapy

- Human participants and animal subjects protocols involving gene transfer or gene therapy must be reviewed and approved by the IBC prior to initiation of protocol. Approval may be granted for no more than one year. Final approval for human participant studies is contingent upon protocol approval by the Recombinant DNA Advisory Committee (RAC)

Operational Guidelines

Activities Exempt from NIH guidelines:

IBC approval for research activities that are considered Exempt from NIH guidelines and do not involve the use of other biohazardous materials requiring IBC review, is valid for the duration of the research. However the IBC may, on its discretion, require subsequent reviews on a periodic basis.

Activities that are non-exempt or use other biohazardous materials

- Activities involving the use of biohazardous materials must be reviewed and approved by the IBC either prior to or concurrently with the start of the activities depending on the classification of the agent or the containment level required as indicated in “Scope of IBC review” above.
- The IBC may approve research applications with or without modifications, or

	<p>withhold approval of all or any portion of a protocol. Approval may be granted for no more than three years.</p> <ul style="list-style-type: none"> - Non –exempt research activities involving r/sNA will be approved only after review at a convened meeting of a quorum of the IBC (i.e., a majority of the voting members) with the affirmative vote of a majority of those present. The IBC may determine the appropriate method of review and approval of all other applications subject to its review (e.g., biohazards only). Procedures for review and approval of applications outside of the convened committee must be discussed and approved at a convened meeting of a quorum of the IBC. - Any changes in agents, practices or project personnel must be communicated to and reviewed by the IBC prior to implementation unless specified otherwise in “Scope of IBC Review” above. - All applications shall be available for review by any member of the IBC. - The IBC shall maintain records of research application reviews, minutes of meetings, including records of attendance and IBC deliberations. All deliberations of the IBC shall meet Cornell confidentiality guidelines. - No member of an IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which she/he has been or expects to be engaged or has a direct financial interest.
Coordination with Other University Committees	<p>All human participant protocols involving gene transfer or gene therapy, as defined in the NIH Research Guidelines on Recombinant or Synthetic Nucleic Acid Molecules, shall be reviewed by the IBC in coordination with the Institutional Review Board (IRB).</p> <p>All protocols that involve gene transfer or gene therapy in vertebrate animals shall be reviewed by the IBC in coordination with the Institutional Animal Care and Use Committee (IACUC). The IBC may consult with the Radiation Safety Committee on applications using radiation.</p>
Non-compliance with Committee requirements	<p>The IBC shall investigate and report any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses involving recombinant or synthetically derived nucleic acid molecules to the appropriate institutional official, the Department Chair or College Dean, and the NIH Office of Biotechnology Activities ("OBA") within 30 days and others as required by University policies and external regulations.. Significance of the problem is concluded on a case by case basis by the IBC Chair in consultation with the Biosafety Officer and Director of ORIA. Activities in which serious or continuing violations occur may be suspended by the IBC.</p>
Appeal Method	<p>In cases of dispute with respect to procedures or decisions of the IBC, appeals may be made to the Vice Provost for Research for cases requiring intervention for problem resolution.</p>
Membership	<p>The IBC Chairperson is appointed by the President upon the recommendation of Dean of Faculty, the Senior Vice Provost for Research. IBC members are appointed by the President upon the recommendation of Dean of Faculty, the Senior Vice Provost for Research and the Chairperson of the IBC.</p>

The IBC shall have at least five members with expertise in general issues of laboratory biosafety, use of infectious materials, and Recombinant or Synthetic Nucleic Acid Molecule technology.

Individuals on the IBC ordinarily include at least one faculty member with expertise in each of the following areas: transgenic plants, transgenic animals or gene therapy in animals, viral pathogens and vectors, microbial pathogens, biotoxins, and biotechnology and a laboratory staff member. In addition, members include two members from the local community not otherwise affiliated with the University, the Institutional Biosafety Officer, and any others who may be invited to serve when their expertise is required.

Voting ex officio members shall include representatives of the: Department of Environmental Health & Safety (Institutional Biosafety Officer), and a veterinarian from Cornell's College of Veterinary Medicine. Nonvoting ex-officio members shall include the Director of the Department of Environmental Health & Safety, Institutional Official, the IBC Administrator, the Director of ORIA and others as required by the IBC.

Members other than ex-officio members are appointed to the IBC for renewable terms of 36 months.

IBC Meetings	The IBC shall ordinarily meet once a month, or as necessary to conduct its business. A meeting agenda shall be sent in advance of a scheduled IBC meeting. Meeting minutes shall be taken each meeting and kept on file by the IBC Administrator.
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Summary Annual Report	The Chair shall submit an annual report of IBC activities and deliberations to the Institutional Official (Senior Vice Provost for Research), and the Dean of the Faculty. This report will cover activities during the previous fiscal year, and submitted by September 1 of the following year.
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Administrative and Regulatory Support	The Office of Research Integrity and Assurance (ORIA) shall provide the regulatory expertise and the administrative support for the IBC. ORIA and the Institutional Biosafety Officer shall provide the technical expertise related to the use of biohazardous materials.
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