# Resolution to Change
# rDNA Committee to Institutional Biosafety Committee

Whereas the National Institutes of Health and the Center for Disease Control in the U.S. Department of Health and Human Services have established requirements for institutions to form an institutional biosafety committee whose purpose is to advise the University and to establish policies to guide principal investigators in carrying out the University's Biosafety Program in the acquisition, use, training, transfer, storage, disposal, and emergency response procedures for all biosafety activities.

Whereas current university legislation proscribes the University Committee on rDNA to review protocols for the use of recombinant DNA only.

Therefore, it is proposed that the committee name be changed from the University Committee on rDNA to the Institutional Biosafety Committee and that the following change be made to the legislation regarding the charge of the committee:

# Cornell University
# Charge to the Institutional Biosafety Committee

## AUTHORIZATION

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

## GENERAL CHARGE

The Institutional Biosafety Committee (IBC) is a Standing Committee of the Faculty Senate and is responsible for reviewing all University research and teaching activities conducted by faculty, staff, students, and/or visiting scientists on Cornell Property that involve the use of biohazardous materials (regulated animal and plant pathogens, biological toxins, and recombinant DNA molecules). The purpose of these reviews is to ensure that all activities involving biohazardous materials and the facilities used to conduct such work are in compliance with all external regulations and applicable 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 protocol directors in meeting their responsibilities; impose requirements and review and approve policies, procedures, programs, and facilities pursuant to the safe use of biological agents, other biological materials, and toxins.

The IBC shall function so as to discharge the University's obligations and responsibilities placed upon the IBC by current governmental requirements, including those described in the National Institutes of Health Guidelines (NIH), the Centers for Disease Control and Prevention (CDC) Guidelines, Occupational Health & Safety Administration (OSHA) Regulations, and those other requirements that overlap with or are reviewed by other established University Committees – Human Subjects, Animal Care and Use, Radiation Safety, etc. The IBC is expected to 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 will formulate draft policies and procedures for approval by the appropriate University bodies and promulgation by the Vice Provost for Research and/or The University Health and Safety Board. In addition, the IBC may be asked by the University administration to review research protocols on behalf of the Cornell Medical School or other institutions with which Cornell has formal affiliation agreements

## DEFINITIONS

*Biohazardous Agents*

A. Infectious/pathogenic agents classified in the following categories: Class 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 DNA Molecules*

A. Molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell **or,**
B. DNA molecules that result from the replication of those described in "A" above.

*Gene Therapy*

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

## OPERATIONAL GUIDELINES

All 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 (see below). The IBC may approve research protocols with or without modifications, or withhold approval of all or any portion of a protocol. Approval of may be granted for no more than three years 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. Any changes in agents, protocols or project personnel must be communicated to and reviewed by the IBC on an annual basis. All biosafety protocols shall be available for review by any member of the IBC. The IBC shall maintain records of research protocol reviews, minutes of meetings, including records of attendance and IBC deliberations. All deliberations of the IBC shall meet Cornell confidentiality guidelines. In accordance with the NIH 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

All human subjects protocols involving gene transfer or gene therapy, as defined in the NIH Recombinant DNA Research Guidelines, shall be reviewed by the IBC in coordination with the Human Subjects Committee. All protocols that involve gene transfer or gene therapy in non-human mammal subjects, shall be reviewed by the IBC in coordination with the Institutional Animal Care and Use Committee. All protocols that involve the use of radioisotopes or radiation producing equipment shall be reviewed by the IBC in coordination with the Radiation Safety Committee.

### Sanctions

The IBC shall assess suspected or alleged violations of protocols, external regulations, or University policies that involve biohazardous materials. Activities in which serious or continuing violations occur may be suspended by the IBC. In such cases, the IBC will immediately notify the affected investigator(s), the relevant school dean, the Office of Sponsored Programs, appropriate University officers, The University Health and Safety Board, and others as required by University policies and external regulations.

The following operational guidelines define the biohazardous agents regulated by the IBC and the timing of the review and approval process.

*Biohazardous Agents*

Activities involving Class 2, Class 3, and Class 4 biohazardous agents must be reviewed and approved by the IBC prior to the initiation of use of agent.

Protocols involving Class 1 agents that ***do not*** involve recombinant DNA, are not reviewed by the IBC.

*Toxins*

The routine use of most toxins will not require IBC review and approval. However, the IBC shall review any experiments 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 CDC Standard, *Additional Requirements for Facilities Transferring or Receiving Select Agents.Toxins appearing on this list must be registered with EH&S.*

*Recombinant DNA*

Recombinant DNA experiments involving human, animal, plant or microbial pathogens, or whole plants or animals require IBC approval before initiation. IBC approval concurrent with project initiation is required if rDNA studies mentioned above use less than 2/3 of a eukaryotic viral genome, if whole plant experiments involve microorganisms that have no recognized potential for dissemination or environmental impact. Experiments involving rDNA molecules exempt from the NIH Guidelines must still be reported to the IBC for approval.

*Gene Transfer Therapy*

Human subjects and other 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 after review at a convened meeting. Final approval for human subjects studies is contingent upon protocol approval to the Office of Recombinant DNA Activities (ORDA/RAC).

## APPEAL METHOD

In cases of dispute with respect to procedures or decisions of the IBC, appeals may be made to the Vice Provost for Research, and to the Health and Safety Board for cases requiring intervention for problem resolution.

## MEMBERSHIP

The IBC Chairperson is appointed by the Dean of Faculty. Half of the IBC members are appointed by the Dean of Faculty and the other half of the IBC members are appointed by the IBC Chairperson after consultation with the University Biosafety Officer and Vice Provost for Research. The IBC shall have at least five members with expertise in general issues of laboratory biosafety, use of infectious materials, and recombinant DNA technology. Individuals on the IBC

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. In addition, at least one laboratory staff member, two members from the local community not otherwise affiliated with the University, the university Biosafety Officer, an executive secretary, 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 (University 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, Director of Office of Sponsored Programs, and a representative from Legal Counsel (consultation basis).

The term of membership on the IBC is a 36-month appointment renewable period beginning June 1 through May 30.

## IBC MEETINGS

The IBC shall meet as necessary to conduct its business but **no less** than once every two months. A meeting agenda will be sent at a minimum of one week in advance of a scheduled IBC. Meeting minutes will be taken each meeting and kept on file by the University Biosafety Officer.

## SUMMARY ANNUAL REPORT

The Chair shall submit an annual report of IBC activities and deliberations to the Vice Provost for Research, the Chair(s) of the University Health and Safety Board, and the President by June 1$^{st}$ of the following year. The report shall be available to the Faculty Senate.

## STAFF SUPPORT

The Department of Environmental Health and Safety (EH&S) and the Office of Sponsored Programs (OSP) shall provide the necessary staffing and administrative assistance for the IBC. EH&S shall provide technical expertise and advise as necessary for the IBC to fulfill its duties