Institutional Biosafety Committee

Authorization

Hobart & William Smith Colleges shall have an Institutional Biological Safety Committee established under the authority of the Office of the President and reporting to the Office of Academic and Faculty Affairs.

General Charge

The Institutional Biosafety Committee (IBC) is a committee of the faculty that is responsible for reviewing all research and teaching activities conducted by faculty, staff, students, and/or visiting scientists at Hobart and William Smith Colleges that involves 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 College 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 (PIs) 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 College'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, the Occupational Health & Safety Administration (OSHA) Regulations, and those other requirements that overlap with or are reviewed by other established committees of the Colleges. The IBC is expected to advise the Colleges and establish policies to guide principal investigators and the Officer of Environmental Health & Safety (EH&S) in carrying out the Colleges' 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.

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. Regulated 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.

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 may be granted for no more than two years after review at a convened meeting of a quorum of the IBC (i.e., four or more 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 Hobart and William Smith Colleges 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.

Sanctions

The IBC shall assess suspected or alleged violations of protocols, external regulations, or Colleges 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 Provost, the Office of Sponsored Programs, and others as required by Colleges 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.

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.

Appeal Method

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

Membership

The IBC will be comprised of a minimum of 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, viral pathogens and vectors, microbial pathogens, biotoxins, and biotechnology. In addition, one representative from the Office of Academic and Faculty Affairs, two members from the local community not otherwise affiliated with the Colleges, and any others who may be invited to serve when their expertise is required.

The term of membership on the IBC is a 3-year 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 every six months. A meeting agenda will be sent at a minimum of one week in advance of a scheduled IBC by the Chair of the committee. Meeting minutes will be taken each meeting, sent to current committee members, and kept on file in the Provost office.

Annual Report

The Chair of the committee will submit an annual report of IBC activities and deliberations to the Provost and Dean of Faculty, Sponsored Research Office (SRO) and the President by July 1st of the following year.