

Charter
NIEHS INSTITUTIONAL BIOSAFETY COMMITTEE

The National Institute of Environmental Health Sciences (NIEHS) Institutional Biosafety Committee (IBC) is chartered to approve permits for the use of recombinant DNA, human materials, and potentially hazardous biological materials. The IBC will promote training in the use of these materials and provide Institutional oversight in their use. Additionally, the IBC will review safety policy matters pertaining to the control of hazards associated with research and serve as an advisory body to the Health and Safety Branch. It also represents the interests of the surrounding community with respect to public health and protection of the environment.

Members serve 3-year terms. The Committee Chair shall be elected by the membership for a 2-year term. The Chair and members may be reappointed for additional terms. For the purpose of a quorum for voting on permit approvals, etc., 51% of the voting members shall be present at a meeting and must include at least one community representative.

The Institutional Biosafety Committee is composed of members who are appointed by the Associate Director for Management in consultation with the NIEHS Scientific Director.

1. One individual shall be from the Division of Intramural Research
2. One individual shall be from the National Toxicology Program
3. One individual shall be from the Comparative Medicine Branch
4. One individual shall be a non-doctoral employee from a research laboratory
5. The NIEHS Biosafety Specialist
6. There shall be at least 2 voting members selected from the local area who are not affiliated with NIEHS, apart from their membership on the Committee.
7. At least 4 members shall be doctoral-level scientists representing diversity relevant to biomedical research, infectious diseases, and recombinant DNA technology.
8. The Chief, Health and Safety Branch, shall serve as a permanent ex officio member.

The duties of the Committee are as follows:

1. Review and approve Recombinant DNA permits received from NIEHS researchers.
 - i. Permits expire after six years but must be reviewed and certified by the PI annually. They may be renewed by request at any time during the annual review process.
2. Recommend policies regarding biosafety to the Chief, Health and Safety Branch.
3. Provide technical advice and assistance to the NIEHS BSS in matters regarding biosafety.
4. Identify substantive biomedical research areas where biohazards may exist.
5. Reviews accidents resulting in personnel exposures to potentially hazardous microorganisms and research area contamination.
6. Reports significant incidents, violations and research related accidents and illnesses to OSP (Office of Scientific Policy) within thirty days or immediately depending on the nature of the incident.
7. Establishes work groups and appoints *ad hoc* members to the Committee, as the Committee deems necessary to effectively carry out the Committee's duties.
8. Annually reviews the *NIEHS Exposure Control Plan for Laboratory Personnel*.
9. Initiates reviews of biosafety issues of particular interest or concern to the Institute and the surrounding community.
10. Perform the function of an Institutional Biosafety Committee as specified in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. And enforce the conditions therein.

IBC members are hereby given authority to serve as reviewers for NIEHS bio permits. However, IBC members **may not** vote to approve NIEHS permits in which the IBC member is:

1. Listed on a permit as the Primary Investigator (PI) or an associated researcher in which the IBC member is a member of the PI's laboratory and has an active role in the study design and performance. The IBC member may not serve as a designated reviewer and must not be present during permit review, discussion and voting.
2. A person in the lab of the Supervisor on the permit, who is not explicitly listed on the permit, must recuse themselves

from voting.

3. Listed on a permit as an associate researcher but in a supportive role (e.g., NIEHS Core Facilities). The IBC member may serve as a designated reviewer and is not required to leave the room but will abstain from voting. Core facility members who are not explicitly listed on the permit but are still providing core services to the PI must recuse themselves from voting.

Electronic IBC business parameters:

1. The NIEHS Biosafety Specialist (BSS), in consultation with the IBC Chair, may elect to cancel a scheduled meeting of the committee and conduct business electronically, by means that preserve the record, and include ALL IBC members.
2. The BSS will assign a designated reviewer(s) for each permit application/amendment submitted for review.
3. Submissions and designated reviewer comments will be sent to committee members via electronic means by the BSS. All voting members will be given at least 7 business days to respond, with a reminder sent by the Chairperson after 5 business days. All voting members should respond indicating: 1) approval, 2) approval with minor revision, or 3) request for review at a convened meeting.
 - i. Approval of the submission requires a simple majority of the voting committee members, unless any one voting member requests review at a convened meeting. The BSS will assure that any requested, minor revisions are completed before final approval.
 - ii. Voting members may contact the BSS for clarification or further information. The BSS will be responsible for informing the requestor of the committee's decision.
 - iii. The following month, the BSS will provide the committee with a summary report of all electronic business.

Delegations to the NIEHS Biosafety Specialist (BSS):

Consistent with the assigned duties and responsibilities of the position, the NIEHS BSS is hereby- delegated authority to:

1. Act on behalf of the NIEHS IBC to review and approve the following documents:
 - i. Permits for work with Human Blood and Bodily fluids
 - ii. Supplemental documents required by NIH policy approved for BSL-1 and BSL-2 laboratories associated with permits.
 - iii. Permits renewed for storage of samples only.
 - iv. Minor changes to permits:
 - a. Amendments to procedures included within Standard Operating Procedures (SOPs) that do not require changes in personal protective equipment or affect the containment level.
 - b. Amendments to permits which involve changes in the reporter gene or promoter sequences only.
 - c. Review ASPs to determine agreement with the bio permit and advise the ACUC if discrepancies exist.
 - d. If the BSS feels there is any question as to the impact on biosafety or biocontainment of any proposed modifications and updates to these documents, the BSS shall consult with the chair of the IBC as to whether the proposed changes should instead be reviewed by the IBC (given a designated expert reviewer).
 - e. This delegation does not in any way limit the authority of the NIEHS IBC as described in the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, or the Charter for the NIEHS.
2. Serve as the Executive Secretary.
 - i. Upon request, IBC meeting minutes must be made available to the public, but all personally identifiable information will be redacted from the minutes prior to being released.