

Charter
NIEHS INSTITUTIONAL BIOSAFETY COMMITTEE

The National Institute of Environmental Health Sciences (NIEHS) Institutional Biosafety Committee (IBC) is chartered to approve registration documents 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.

The Institutional Biosafety Committee is composed of at least 5 voting members who are appointed by the Associate Director for Management in consultation with the NIEHS Scientific Director. At least five members shall be doctoral-level scientists representing diversity relevant to biomedical research, infectious diseases, and recombinant DNA technology. One of these five members shall be from the Comparative Medicine Branch. One individual is a non-doctoral employee from a research laboratory. The NIEHS Biosafety Specialist is a voting member and serves as the Executive Secretary. The NIEHS Safety Officer is a voting member of the Committee. The Chief, Health and Safety Branch, shall serve as a permanent ex officio member of the Committee. There shall also be two voting members selected from the local area who are not affiliated with NIEHS apart from their membership on the Committee. The Committee Chair shall be elected by the membership for a two year term. The members serve 1-3 year terms. The chair and members may be reappointed for additional terms. For the purpose of a quorum for voting on registration approvals, etc., 51% the voting members shall be present at a meeting and must include at least one community representative.

The duties of the Committee are as follows:

1. Reviews and approves Recombinant DNA registration documents (RDs) received from NIEHS researchers.
 - i. PI dashboard registrations expire after six years, but may be renewed by request during the annual review process. Completing the annual renewal is required for all registrations. Note: Health and Safety Branch (HSB) protocols are rewritten every six (6) years and renewed annually.
2. Recommends policies regarding biosafety to the Chief, Health and Safety Branch.
3. Provides technical advice and assistance to the NIEHS Biosafety Specialist in matters regarding biosafety.
4. Identifies substantive biomedical research areas where biohazards may exist.
5. Performs the function of an Institutional Biosafety Committee as specified in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. Enforces the *NIH Guidelines* to ensure that IBC approved conditions are adhered to, fully investigating potential violations or compliance problems.
6. Reviews accidents resulting in personnel exposures to potentially hazardous microorganisms and research area contamination. 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 its duties.
8. Annually reviews the *NIEHS Exposure Control Plan for Laboratory Personnel*.
9. Can initiate reviews of biosafety issues of particular interest or concern to the Institute and the surrounding community. Upon request, IBC meeting minutes must be made available to the public, but all personally identifiable information will be redacted from minutes prior to being released.

10. Consistent with the assigned duties and responsibilities of the position, the NIEHS Biosafety Specialist (BSS) is hereby- delegated authority to act on behalf of the NIEHS Institutional Biosafety Committee (IBC) to review and approve the following documents:
 - i. Registration Documents for work with Human Blood and Bodily fluids
 - ii. Pathogen Registration Documents (PRDs) approved for BSL-1 and BSL-2 laboratories not associated with RDs
 - iii. Minor changes to RDs:
 - 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 RDs which involve changes in the reporter gene or promoters sequences only. Amendments for new transgenes will also be reviewed by one designated IBC reviewer. Entirely new RDs or RDs linked to PRDs will be reviewed by a primary and secondary reviewer (novel registrations involving previously undescribed recombinant work will be reviewed at the next IBC meeting as necessary).
 - c. Amendments associated with review and concurrence of Animal Study Protocols (ASPs): If the BSS determines that the new ASPs are not in concurrence with those previously approved by the IBC, these will be reviewed by one designated IBC reviewer. The initial ASP attached to any RD or RD linked to a PRD will always be additionally reviewed by one primary and one secondary reviewer.
 - 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.
11. IBC members are hereby given authority to serve as reviewers for NIEHS registrations and protocols. However, IBC members **may not** vote to approve NIEHS registrations in which the IBC member is:
 - i. Listed on a registration 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 leave the room during voting.
 - ii. Listed on a registration 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 registration but are still providing core services to the PI must recuse themselves from voting.
12. Electronic IBC business parameters:
 - i. The BSS, in consultation with the IBC Chair, may elect to cancel a scheduled meeting of the committee and conduct business electronically via emails that include ALL IBC members.
 - ii. The BSS will assign a designated reviewer(s) for each submissions as necessary.
 - iii. Submissions and any designated reviewer comments will be sent to committee members via e-mail by the BSS. All voting members will be given from 7 business days to respond to the e-mail, with an e-mail reminder sent by the Chairperson after 5 business days. All voting members should respond via email indicating: 1) their approval, 2) approval with minor revision, or 3) request for review at a convened meeting.
 - a. 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.
 - b. 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.
 - c. The following month, the BSS will provide the committee with a summary report of all electronic business.