

Yale University
Biological Safety Committee Charter

I. Committee Charge

- a. The Yale Biological Safety Committee (BSC, Committee) is a standing committee established by the Provost to:
 - i. ensure that all activities involving biohazardous materials¹ are conducted in compliance with federal, state, and local regulations and applicable University policies;
 - ii. assist and advise the Yale community on incorporating good biological safety practices into all activities involving biohazardous materials;
 - iii. reduce the risk of potential biohazardous threats to the Yale community, the public, and the environment.
- b. The BSC is vested with the authority to:
 - i. review and approve practices and procedures regarding research and other activities involving biohazardous materials;
 - ii. direct inspection by the Biological Safety Officer (BSO) and the Biosafety Office within Environmental Health and Safety (EHS) of facilities where biohazardous materials are used and/or stored; and
 - iii. take appropriate action, including suspending research, in situations that present a risk of harm to life or health and in cases of serious, repeated or continued non-compliance with regulations or BSC safety guidelines.

II. Committee Responsibilities

- a. The BSC, the BSO, and the Biosafety Office develop and implement policies, procedures, and guidelines related to the use of biohazardous materials in the conduct of University activities.
- b. The BSC reviews and monitors all research, teaching, and other activities conducted at Yale that involve the use of infectious agents, biological toxins, recombinant or synthetic nucleic acid molecules, and other biohazardous materials.
- c. The BSC serves as the Institutional Biosafety Committee (IBC) as defined in the National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* ([NIH Guidelines](#)) and carries out all functions required by the Guidelines, including reviewing applications for research at Yale involving recombinant or synthetic nucleic acid molecules (rDNA) to ensure that the research conforms to the *NIH Guidelines*.
- d. The BSC, with the support of the BSO and the Biosafety Office, assists Principal Investigators and others in the Yale community in meeting their

¹ For the purposes of this charter, "biohazardous materials" are biological agents or materials that are hazardous or potentially hazardous to the health of humans, animals, or the environment. Biohazardous materials may include, but are not limited to: recombinant or synthetic nucleic acid molecules; microorganisms; human materials; animals, arthropods, insects, or plants; and biological toxins.

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responsibilities for assessing risks, establishing policies and procedures, training personnel, and maintaining facilities and equipment.

- e. The BSC provides guidance and support to the BSO and the Biosafety Office in carrying out the requirements of the University's Biosafety program.
- f. The BSC advises the Provost and other members of the Yale administration on all matters related to the use of biohazardous materials in the conduct of University activities.

III. Committee Composition

- a. The BSC shall be composed of:
 - i. Regular members, who collectively have the experience and expertise in the activities subject to the Committee's review and the ability to identify and assess the potential risks to laboratory personnel, public health, or the environment;
 - ii. Community members, who are not affiliated with Yale in a current capacity except for their membership on the BSC, and who represent the interest of the surrounding community with respect to health and protection of the environment;
 - iii. Ex officio members, including the Director of Environmental Health & Safety, Biological Safety Officer, and Provost designee; and
 - iv. Consultants, who provide guidance on matters related to the Committee's activities. Consultants are not voting members.
- b. The membership of the BSC shall be consistent with the requirements set forth in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.
- c. Alternates for any of the regular, community, and ex officio members may be appointed to ensure that the BSC is properly constituted at all times. Alternates are voting members when they are standing in for the primary member who cannot attend the meeting. If the primary member and alternate are both present, only the primary member may vote.

IV. Appointment and Terms of Membership

- a. BSC Members are appointed by the Provost, in consultation with the BSC Chair and the BSO.
- b. Members are appointed for a term of one (1) year and serve at the discretion of the Provost.
- c. If any member attends fewer than nine (9) meetings during a calendar year, the BSC Chair may, in consultation with the BSO, request that a replacement be nominated for appointment by the Provost.

V. Committee Meetings

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- a. Meetings of the BSC shall be convened as necessary, generally every month, to conduct its business.
- b. Sub-committees of the BSC may be formed to address specific issues before the Committee. The sub-committee shall report its findings and recommendations to the fully convened BSC for decisionmaking.
- c. Ad hoc consultants may be engaged as needed to aid the BSC in the review of specific protocols that require expertise beyond the scope of the BSC membership. Ad hoc consultants do not have appointed terms and do not vote.
- d. Public access: When acting as the IBC, meetings of the BSC shall be open to the public except when proprietary or sensitive (such as Select Agent location and quantities) information is discussed. Meetings are announced at an open web site.

VI. Quorum & Voting

- a. A quorum of the BSC voting membership is required to be present for the BSC to take action at any convened meeting. Members may participate in BSC meetings in person, or by other means such as telephone or videoconference that permit real-time communication with other committee members, and be counted as "present" for the purpose of establishing a quorum. Participation through means that do not allow real-time communication with other committee members, such as email and absentee ballots, are not allowed.
- b. A quorum is defined as:
 - i. More than fifty percent of the BSC voting membership;
 - ii. At least one community member is *preferred* at all meetings;
 - iii. At least one community member is *required* at any meeting where experiments involving Risk Group 3 or Select Agents (e.g., highly pathogenic avian flu virus) require BSC approval.
- c. A simple majority of the voting members present is sufficient to pass any matter before the Committee.

VII. Conflict of Interest

- a. No member of the BSC will vote on any matter before the Committee in which they have a relevant interest. Relevant interests include:
 - i. Service as principal investigator or co-investigator on a research protocol;
 - ii. A fiduciary relationship, such as service on the board of directors or in an executive capacity, with the sponsor of research; or
 - iii. A financial interest related to the sponsor of the research.

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- b. Members with any of the relevant interests above shall notify the BSC chair about the potential conflict of interest prior to Committee discussion of the matter. At the discretion of the chair, the member may provide information to the BSC, but may not be present during Committee deliberations or voting.

VIII. Meeting Minutes

- a. Minutes will be recorded by the BSO, or their designee, for each meeting of the BSC and maintained by EHS.
- b. Redaction: Sensitive identifiers, such as specific building or room information, will be redacted from the publicly-available minutes of BSC meetings.
- c. Public access: Minutes of the IBC portion of BSC meetings will be made available to the public upon request through the Biosafety Office within Environmental Health and Safety.
- d. Public comments: Comments made by the public on Committee actions along with the Committee's response will be forwarded to the NIH Office of Science Policy.

IX. Reporting

- a. The BSC shall ensure compliance with all external reporting required by federal, state, and local regulations and guidelines.

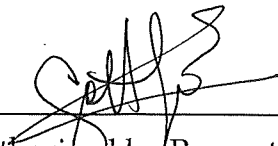
X. Review of Protocols from Other Entities

- a. The Yale BSC may serve as the IBC for other entities although the other entity will remain responsible for compliance with NIH guidelines. Before the Yale BSC begins serving in this role, a memorandum of understanding between Yale and the other entity should be signed that details the respective roles and responsibilities of Yale and the entity.
- b. The Yale BSC will develop separate IBC documents, such as an agenda, minutes and protocol summaries, and will convene a dedicated meeting for the review of proposals from the other entity.

XI. Life Sciences Dual Use Research of Concern (DURC)

- a. The members of the Yale BSC will serve as the members of the Yale Institutional Review Entity (IRE) as required by the 2014 United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.
- b. The Yale BSC, serving as the university IRE, will hold a dedicated meeting for the review of DURC protocols.
- c. The Yale BSC, serving as the university IRE, will conform with the September 14, 2015 university "Policy for Life Sciences Dual Use Research of Concern," and any policy amendments.

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Authorized by Provost Scott Strobel August 30, 2024