

Chapman University Institutional Biosafety Committee (IBC)

Charter & Procedures

Mission Statement

It is the responsibility of the Chapman University Institutional Biosafety Committee (IBC) to establish and maintain policies and procedures for the protection of staff, students, community members and the environment from potentially hazardous biological research materials, and to maintain compliance with all Federal and State regulations.

Responsibilities

The IBC is responsible for the registration, review and approval of all research projects involving potentially hazardous biological materials such as human or non-human primate blood and other potentially infectious materials, recombinant and synthetic nucleic acids, viruses, bacteria, biological toxins (microbial and non-microbial), prions, and others. The IBC help support the interests of the University-recognized Institutional Official (IO) with regard to all National Institutes of Health (NIH) and related research reviews and approvals and other compliance-related matters.

Membership

The Committee is composed of at least two community representatives who are not otherwise affiliated with Chapman University, scientists, non-technical staff, the Biosafety Officer, and representatives from the IACUC.

All members of the IBC are voting members. These members are appointed by the Institutional Official or designee for a renewable term of three years.

An IBC Chair will be selected by the Institutional Official. The chair cannot be a member of the Environmental Health and Safety Office or the Biosafety Officer.

The Biosafety Officer will prepare the meeting agenda and minutes and schedule the IBC meeting. The Chair will oversee the IBC meetings following the policies and procedures established in this document. Modified Roberts Rules of Order will be followed.

Quorum

A quorum is defined as 50 percent plus one of the voting membership and must include at least one community representative. Guests attending the meeting and written proxies are not counted when determining a quorum. In extenuating circumstances, voting members may participate via conference call if they are unable to physically attend the meeting.

Conflict of Interest

Conflict of interest is considered in cases of financial involvement with a commercial sponsor, personal relationship with investigators or related to the project that is being reviewed. Any member with a conflict of interest must disclose the conflict to the IBC. The IBC Chair will decide the proper course of action depending on the situation. Committee members can participate in discussions of their own projects but must not vote in the final decision of the committee. Committee members or guests that have a project that is reviewed at an IBC meeting will be asked to leave the room during the final

discussion and voting on the project.

Meetings Schedule

The IBC will hold a meeting at least once per semester. Additional meetings may be held as needed. Ad-hoc subcommittees can be formed as requested by the IBC Chair.

Minutes from the IBC Meeting

Members should be aware that the Minutes of the IBC meeting are required by NIH OBA, and may be provided to other public agencies as may be requested and required. Minutes will be documented by the BSO and will not link comments to specific IBC members or contain proprietary information.

Minutes will be prepared by the Biosafety Officer and reviewed by the IBC Chair in advance of distributing the minutes to the full committee for review and approval. The Biosafety Officer will complete this process within two weeks of the meeting date. The meeting minutes from the previous meeting will be reviewed and updates provided at the next scheduled IBC meeting.

Initial Project Registration Review and Approval

The Biosafety Officer will perform an initial review on all new or amended project registrations and may request additional information or clarification from the submitter and/or Principal Investigator. Once the initial review is completed, the submission will be reviewed to determine if the research can be administratively approved. If the research falls under Sections III-A through III-D of the NIH Guidelines, it must be reviewed at a convened meeting of the IBC. Additionally, research with biological agents is typically reviewed at a convened meeting.

Administrative Review

Is your submission eligible for expedited administrative review?		
	Initial Application	Amendment
Research involving only the use of human or nonhuman primate materials	X	X
Biological agent research warranting BL1 practices and procedures	X	X
Biological agent research warranting BL2 or higher practices and procedures		X
Research covered by Sections III-A through III-E of the NIH Guidelines		X
Research Covered by Section III-F of the NIH Guidelines	X	X
Research involving the use of biological toxins with the exception of Select Agent toxins, which require committee review for initial applications and amendments	X	X

Renewal of Previously Approved Project Registrations

Once approved, projects must be updated as necessary and resubmitted on a yearly basis, or more frequently if changes are made. The Biosafety Officer will administratively approve each resubmission, unless new biohazardous materials and/or procedures are added that change the risk profile of the project, in which case the Biosafety Officer will forward the project to the full IBC for review at a convened IBC meeting as necessary based on the criteria in the previous section. Every three (3) years the registration will be reviewed and approved by the full IBC at a convened meeting.

Institutional Biosafety Committee Policies Related to Registration of Research Projects

The policies described in this document describe how the IBC oversees research involving recombinant and synthetic nucleic acids, human or non-human primate blood and other infectious materials, biological toxins and infectious agents in compliance with Federal and State regulations.

PI Responsibility

It is the policy of the IBC that the Principal Investigator (PI), Laboratory Director, or Supervisor is responsible for the following:

- Safe handling of recombinant and synthetic nucleic acids and potentially infectious biological materials and toxins in their facilities.
- The registration with the IBC of the research projects that involve the use those agents
- The compliance with the recommendations and stipulations given by the IBC at the time of approval.
- Remaining in communication with the IBC throughout conduct of the project.

Research Project Registration

Investigators need to register their work on the approved form that can be obtained by way of the EH&S website, or by direct request from the BSO.

- The PI will propose a Biosafety level following the NIH guidelines
- The BSO will do an initial review and may ask an IBC member for additional review of the project.
- BL-1 studies can be approved administratively by the IBC Chair and/or the BSO.
- Studies that require a higher level than BL1 or additional stipulations, will be reviewed by one or more members, discussed and voted on for approval at the next IBC meeting.
- If approved by the Committee, an electronic voting system can be initiated for projects that require full Committee approval but due to timing circumstances, a meeting with a Quorum cannot be held before research would like to begin. The Committee can review and approve projects electronically or request an interim meeting for thorough review prior to project initiation.
- The committee members can request some changes related to the safe handling of the biological agent and approve the study "conditional to the compliance of the stipulated change".

- The approval letter will be signed by the BSO for BL1 registrations and by the Chair for Biosafety levels higher than BL1.

Timetable

Applicants should make every effort to submit their application well in advance of any required approval so that it can be reviewed by the Biosafety Officer and can be taken to the full membership of the IBC, as needed.

When submitting the IBC Registration Form, it is important that the data provided contains not less than the minimum data elements on that form. Further descriptive detail can be beneficial in expediting the review and approval process. Researchers are encouraged to attend the meeting in which their proposal is to be reviewed to allow for an immediate response to questions that might be asked of the Committee members.

Policy on Amendments to approved registrations

- Any changes in the registrations without safety consequences should be sent to the BSO. These amendments can often be reviewed and administrative approved by the BSO.
- Any changes that may have safety consequences but not changes in the containment level, like addition of vectors, or agent of the same risk group, will generally be reviewed and approved by the BSO in consultation with the IBC Chair or other IBC member. Full Committee review is necessary if there is an addition of new strains of previously approved agents, closely related cell types, or staff changes