

What is the Institutional Biosafety Committee (IBC)?

The Institutional Biological Safety Committee (IBC) provides review and oversight of the University's Biosafety Program in accordance with all local, state, and federal regulations and guidelines. The Southern Connecticut State University IBC reviews all biological research on campus to ensure labs have proper containment for various types of biological agents, including recombinant DNA, infectious agents, toxins, human source materials, etc., and that all Principal Investigators (PI's) and lab personnel are properly trained in biosafety. As such, the IBC serves as an advisory board to the research community on all aspects of biological safety.

What research/teaching activities require Institutional Biosafety Committee (IBC) Approval?

The Institutional Biosafety Committee is charged under the NIH Guidelines and SCSU Policy with oversight of all research and teaching activities involving:

- Recombinant/synthetic nucleic acid molecules (r/sNA), as covered by the NIH.
- Infectious agents that can cause disease in healthy humans and/or significant environmental or agricultural impacts, as covered by the Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- Select agents and toxins, as covered by the CDC Division of select agents (DSAT) regulations
- Human and nonhuman primate materials, as covered by the CONN OSHA Bloodborne Pathogens Standard (*including human and non-human mammalian cell lines*)
- Genetically-modified animals and whole plants, as covered by the NIH Guidelines

At its discretion, the IBC may also review protocols involving animals or animal specimens known to be reservoirs/vectors of zoonotic diseases.

What does the IBC look for when reviewing a research project? Does this include a scientific or ethical review?

The IBC is evaluating whether the proposed activities can be conducted in a manner that will ensure protection of personnel, the general public, and the environment. The IBC is not responsible for the scientific or ethical review of the project, except in cases where the scientific design of the study contributes to public health or environmental risks and/or requires potentially unsafe or risky practices. In those cases, the IBC may require modifications that would reasonably mitigate the risk without impacting the research outcomes.

Specifically, the IBC considers the following items when reviewing a research project:

1. Does the Principal Investigator have sufficient expertise to oversee the safe conduct of the research?
2. Is the proposed Biosafety Level appropriate for the work?
3. Does the proposed location(s) meet the requirements for the assigned Biosafety Level?

4. Will the work be conducted using appropriate biological safety practices and equipment?
5. Is there a potential for environmental release or public exposure? If so, how is this risk mitigated?
6. Are there Standard Operating Procedures (SOPs) in place outlining procedures for waste disposal, decontamination, spill response, exposure response, transport of materials, etc.?
7. Are personnel properly trained, including appropriate Collaborative Institutional Training Initiative (CITI) Program training?
8. Is hazard communication provided to all personnel who are at reasonable risk of exposure to hazardous biological or r/sDNA materials?
9. Have occupational health considerations been addressed, including vaccinations and medical surveillance, when appropriate?

What is the IBC Review Process?

The research review process by the IBC is conducted in the step-wise fashion above, starting with the submission of research information by the PI. The IBC strongly recommends working with EH&S before submitting your registration. EH&S can help conduct a risk assessment of your work and work with the PI to develop a safe and effective research program. EH&S feedback is helpful to the IBC in the review process.

1. Submit your research to the IBC:

Online submission to the IBC is achieved using an electronic system Quali. All information pertaining to biological agent usage (rDNA technology - including viral vectors, animal research, human source material, infectious agents, biotoxins, etc.) and the personnel involved with the research will be queried in this system. This information will be maintained electronically in the future and you will be able to update or revise it any time there is a change in your research program.

2. IBC Review

The IBC will review the research information submitted through an electronic means and discuss the safety and regulatory aspects of the research project. Discussion topics include: the nature of experimentation, location, rDNA aspects, training requirements fulfilled by research staff, past laboratory inspection record, etc. If it is warranted, researchers can be invited to present their research protocols to the IBC committee.

3. Decision Letter Sent to PI

Once the IBC has made a decision regarding the research project reviewed, a decision letter will be sent to the PI from the Chair of the IBC. This decision letter should be retained for your records.

4. Conduct Research

Once an approval letter has been received from the IBC, only then can the proposed research, which includes ordering of biological material, begin.

How do I submit my research for IBC review?

At SCSU, we will use an electronic submission system Quali as the online application mechanism for IBC approval. To submit your research to the IBC, you need to enter all relevant information into system. The registration of your lab using the SCSU IBC Registration Document is conveniently setup to ask you specific questions ("surveys") about your research to make this process easier. As the PI, you will be required to complete a series of surveys in the SCSU IBC Registration Document that are aimed to identify the biohazards involved in your research program (rDNA, cells, animals, toxins, human source materials/cells, pathogenic microbes, viruses, etc). If you have already have a Bio Summary and need to update it, you can edit any of these surveys to make the necessary modifications. This allows you to have a "live" snapshot of current research in your lab.

Once this information has been inputted, you will then prompt you to "certify" that your Bio Summary (registration) is complete and correct. Once certified, you will be asked to initial several compliance statements before submitting the registration.

IBC meets once per semester but can meet more frequently depending on protocol submission in order to facilitate your research being approved in a timely fashion.

Notes:

To obtain IBC approval without contingencies, all lab members must be up-to-date on mandatory SCSU laboratory safety training.

IBC approval is good for 3 years; however, any new research (new funding, new collaborations, etc.) can be reviewed ad hoc as a modification.