NCCentral UNIVERSITY
Environmental Health and Safety

Institutional Biosafety Committee (IBC) Charter

Version #3.0

Contents

Damon Williams, 1/26/2024

Director of EHS
Signature and Date

01/22/24

IBC Chair
Signature and Date

I. Applicable Regulations and Guidance

The following standards have specific requirements for the IBC and work involving recombinant and synthetic nucleic acid molecules:

- Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules, NIH
- FAQs About IBC Meetings and Minutes
- Biosafety in Microbiological and Biomedical Laboratories, 6th Edition

II. Purpose

The Institutional Biosafety Committee (IBC) at the North Carolina Central University (NCCU) is charged with review and oversight of recombinant and synthetic nucleic acid molecule research conducted at or sponsored by NCCU for compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ("NIH Guidelines")* and approval of those research projects in accordance with the publication *Biosafety in Microbiological and Biomedical Laboratories* 6th edition and their compliance with the *NIH Guidelines*. Institutions that receive support from the National Institutes of Health (NIH) for recombinant or synthetic nucleic research are required to establish and register an Institutional Biosafety Committee (IBC) with the NIH Office of Science Policy (OSP) in compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

This document describes the current policies of the IBC for the University (see Section III of this Charter) and its role in ensuring that research involving biohazardous agents is conducted in a manner that is safe for staff, students, the general public, and the environment. This document is intended to define the role of the IBC and help administrators, Principal Investigators, and IBC members comply with applicable Federal, State of North Carolina, City of Durham, and University guidelines and regulations, including other public regulatory authorities that may have jurisdiction over off-campus sites.

III. Responsibilities

The administrative functions of the IBC will be handled by the Biosafety staff of the NCCU Office of Environmental Health and Safety (EHS) including:

- Maintain reviews, minutes, and reports in an orderly and retrievable fashion.
- Train IBC Committee members in research guidelines and regulations.

The Principal Investigator (PI) designation is given to a NCCU faculty member who has primary responsibility and accountability to direct the proper conduct of a scientific research project or program. If the research is conducted by a team of researchers at a research site, the Principal Investigator is the leader responsible for that team whose name appears as Principal Investigator on the Grant Application or Award. With regard to the Institutional Biosafety Committee, the PI has overall responsibility of laboratory personnel working under the requirements of the NIH/CDC Guidelines and regulations set forth by the FDA, USDA, EPA, and OSHA, and must have an approved NCCU Laboratory-Specific Safety Plan.

Principal Investigators are required to register proposed research meeting any of the following criteria using the IBC Registration form, which once approved will be appended to the Laboratory-Specific Safety Plan:

- All research involving the use of recombinant or synthetic nucleic acid molecules, including their application in animals, arthropods, and plants.
- Any work that involves the use of microorganisms that are pathogenic to humans, plants, or animals. This includes, but is not limited to, parasites, viruses, bacteria, fungi, prions, and rickettsia. It also extends to biological materials that may contain these microorganisms.
- Any work that involves substances derived from humans and other primates/non-primates. This includes blood, blood products, cell lines, primary cells, or tissues.
- Work that involves agents that are biologically active and may cause disease in other living organisms or have a significant impact if released into the environment. Examples of these agents include vaccines, antibodies, hormones, cytokines, neurotransmitters, etc.
- Any work that involves Select Agents or Toxins, regardless of whether their origin is human, animal, or plant.

Principal Investigators who register experiments with the IBC are provided with a copy of the guidance document Investigator Responsibilities under the NIH Guidelines.

NCCU IBC responsibilities are derived from the NIH Guidelines:

1) Review research with recombinant or synthetic nucleic acid molecules conducted at or sponsored by NCCU, for compliance with the *NIH Guidelines,* approving those research projects that are found to conform to the NIH Guidelines.
2) Notify the PI of the results of the IBC's review and approval or disapproval.
3) Lower containment levels for certain experiments as specified in Section III-D-2-a of the NIH Guidelines.

4) Set containment levels for experiments specified in Section III-D-4-b or for other experiments that are not set by the NIH Guidelines.
5) Annually review recombinant or synthetic nucleic acid molecule research as part of the annual laboratory and Lab-Specific Safety Plan inspection for compliance with the NIH Guidelines.
6) Adopt emergency plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid molecule research.
7) Report any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the Chancellor and NIH Office of Science Policy (OSP) in accordance with the NIH Guidelines, unless the IBC determines that an adequate report has already been filed by the PI.
8) File a report with OSP which includes an up-to-date roster of all IBC members whenever a change in membership occurs or when the previous registration has expired (one year from submission).
9) The IBC may not authorize initiation of research or experiments that are not explicitly covered by the NIH Guidelines until NIH establishes the containment requirement.

IV. Oversight

A. Recombinant or Synthetic Nucleic Acid Research

- Experiments that require NIH and IBC approval **prior** to initiation (Sections III-A and III-B).
  - BSO will determine if registration form requires IBC approval prior to initiation. If so, a registration packet will be submitted to the NIH OSP and the IBC. The IBC will review and approve or disapprove all registrations in this category at a convened meeting.
- Experiments that require IBC and IRB approval **prior** to research participant enrollment (Section III-C).
  - BSO and IRB will review the registration and determine if it requires IBC approval prior to initiation. The IBC will approve or disapprove the registration at a convened meeting.
- Experiments that require IBC approval **before** initiation (Section III-D).
  - BSO will review the registration and determine if it requires IBC approval before initiation. The IBC will review and approve or disapprove all registrations in this category at a convened meeting.
- Experiments that require IBC notice simultaneous with initiation (Section III-E).
  - The BSO will review the registration and determine if it requires notification of the IBC, and will inform the PI that the registration has been reviewed and the containment level that is required. The BSO will submit the registration at the next IBC meeting for review and comment. The IBC may change the conditions of the approval at any time it deems necessary to ensure NCCU compliance.

- Experiments that are exempt from the NIH Guidelines (Section III-F).
    - The BSO will review the registration and determine if it is exempt, and will inform the PI that the registration has been reviewed and the containment level that should be used. The IBC will not review or vote on exempt experiments.

B. Research involving the use of microorganisms pathogenic to humans, plants, or animals

The BSO will review and notify the PI of the containment level and engineering, administrative, and PPE required.

C. Research involving human materials, such as tissue, blood, or cell cultures

The BSO will review and notify the PI of the containment level and engineering, administrative, and PPE required.

D. Research involving biologically active agents, such as toxins, allergens, or venoms

The BSO will review and assess compliance with permit-related requirements for work with biological materials and notify the PI of the containment level and engineering, administrative, and PPE required.

V. Committee Structure and Membership

A broad array of available research and regulatory expertise is important for the IBC given the range of recombinant DNA research that the committee reviews. The NIH requires that the IBC have at least five members selected who collectively have the experience, expertise, and capability needed to assess the breadth and safety of recombinant and synthetic nucleic acid molecules as needed to identify any potential risks to workers, public health, or the environment.

A. Composition of Committee

Based on the types of research activities at NCCU, the IBC will have the following representation:

- Two to five technical representatives from NCCU programs that conduct research with recombinant or synthetic nucleic acid molecules who have the ability to identify anypotential risk to public health or the environment
- NCCU Biological Safety Officer (BSO) (permanent)
- A minimum of four NCCU faculty members
- An expert in animal containment principles

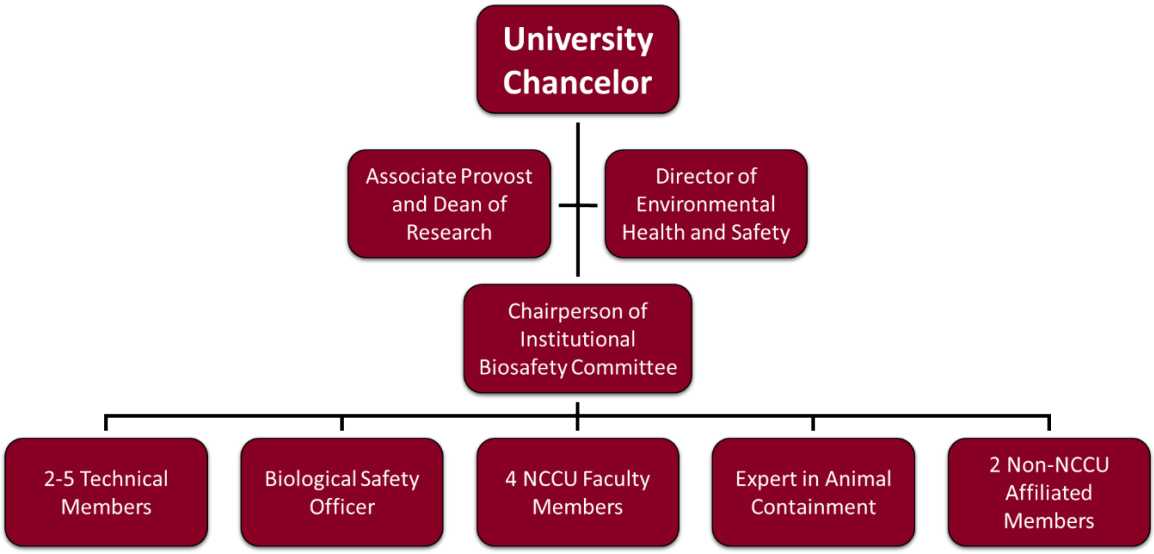
- An expert in plant containment principles (*ad hoc* consultant as needed)
- Two community members who represent the interest of the surrounding community with respect to health and protection of the environment. These members may not be directly affiliated with the North Carolina Central University.

B. Appointment of Members

- IBC Chair nominations are recommended by EHS to the NCCU Chancellor who will formally appoint the IBC Chair for a three-year period.
- Potential IBC members are recommended by Committee members to the IBC Chair. The IBC Chair in consultation with the NCCU Biological Safety Officer, then appoints the nominee to serve on the IBC for a three-year period.

C. Membership Terms

IBC membership is typically a three-year period of service. Members may be appointed for subsequent three-year terms if they are willing to continue to serve. The IBC Chair may remove a Committee member when necessary, e.g., due to resignation, excessive absence (4 or more absences in a calendar year), lack of contribution, or unavailability.



VI. Meetings

The NCCU IBC will schedule monthly meetings and conduct that monthly meeting anytime there are items for discussion. Additional meetings may be called as required. A proposed agenda will be developed and distributed before the meeting by the Biological Safety Officer or his/her designee. Meeting minutes will be taken by the Biological Safety Officer or his/her designee to accurately reflect the topics of discussion. Meeting minutes will be reviewed, approved by the members, and maintained on file at EHS.

A. Procedures for Defining a Quorum

In the event that the IBC chair must be absent, they will request another committee member to serve as chair during the absence. Meetings will proceed with no less than six members present and must contain at least two members from the NCCU faculty. A quorum is declared at the beginning of each meeting and consists of the committee members in attendance. All IBC members are voting members. Decisions such as approval of research projects or policies are approved when a majority of IBC members present vote for approval. If a quorum is not met, the meeting will be adjourned and rescheduled when feasible.

The IBC may use consulting experts or establish working groups to execute its responsibilities or acquire needed expertise for select tasks. Consultants or working group members may include, for example, persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, the environment, or any scientific area where the IBC members do not have expertise. Consultants or working group members are not IBC voting members unless nominated and appointed as described previously.

B. Minutes

Minutes will be reviewed by the Chair and then released to all committee members for review. The minutes will be voted on and accepted by the IBC at the next convened meeting before being considered final.

At a minimum, NIH-advised minutes should reflect the date and place of the meeting, whether minutes of the prior meeting were approved, individuals in attendance, whether and why the meeting was open or closed, all major motions, major points of order, and whether motions were approved. In general, the minutes should offer sufficient detail to serve as a record of major points of discussion and the committee's rationale for particular decisions, documenting that the IBC has fulfilled its review and oversight responsibilities as outlined under Section IV-B-2-b of the NIH Guidelines.

VII. Conflict of Interest Policy

It is the policy of this committee that no member of the IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest. Each member is expected to notify the IBC chair in these circumstances and recuse themselves when such proposals are being discussed and are up for a vote. In addition, if the IBC Chair is principal investigator on a project, the Biological Safety Officer or another IBC committee member present at the meeting will lead the review and approval of the project.

VIII. Confidentiality

IBC members shall not discuss or disclose the details of meetings or submitted protocols with individuals not directly affiliated with the IBC. IBC members who receive a public records request directly from an individual should guide the requester to the NCCU Public Records Request portal and forward request to the IBC Chair. The IBC Chair will then consult with the Office of Legal Affairs and the Office of Communications and Marketing as needed.

IX. IBC Charter Approval

This charter will be approved initially and reviewed annually by the IBC. It may be modified or amended by approval of a majority of voting members of the IBC during a regularly scheduled meeting.