SOUTHERN CONNECTICUT STATE UNIVERSITY (SCSU)

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) CHARTER

I. PURPOSE

The Southern Connecticut State University (SCSU) Institutional Biosafety Committee (IBC) is a formal committee who collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology, the capability to assess the safety of research with recombinant or synthetic nucleic acid molecules (r/sNA), and the ability to identify any potential risk to public health or the environment. At least two IBC members) must not be affiliated with the institution except for their membership on the IBC. All principle investigators (PIs) must secure IBC approval for their activities with r/sNA or biohazardous materials.

Institutions that receive support from the National Institutes of Health (NIH) for r/sNA research are required to establish and register an IBC with the NIH Office of Science Policy (OSP) in compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines, 2019). The establishment of the SCSU IBC complies with this federal regulation. The NIH requires all institutions receiving research funds to have all of its r/sNA research reviewed by an IBC (regardless of whether that research is directly supported by the NIH), as stipulated by the NIH Guidelines. The SCSU IBC additionally reviews all work involving biohazardous materials as defined in Section II of the charter.

II. MISSION STATEMENT

The mission of the IBC of SCSU is to ensure that all research and teaching laboratory protocols at the University that use or produce including but not limited to; biohazardous organisms, recombinant DNA (rDNA), synthetic nucleotides, infectious agents (human pathogens), biological toxins, human and non-human primate tissues, body fluids, blood, blood byproducts, and cell lines, animal tissues and insects that may harbor zoonotic pathogens or select agents, is classified at the appropriate biosafety level (BSL) and done in accordance with all appropriate guidelines, regulations and good safety practices in full compliance with the current editions of NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Guidelines) issued by the NIH and will ensure that federal, state, and local regulations related to the use of biological materials are followed.

III. DEFINITIONS

A. Biological Agents

Biological agents are defined as any biologically derived material that originated from a living organism. Living organisms include plants, animals, humans, bacteria, viruses, fungi, parasites, and algae. Biological agents also include all materials derived from these organisms, such as tissues, fluids, cells, biological toxins (including select agents), and environmental samples that may include biological materials, such as soil and water.

B. Recombinant or Synthetic Nucleic Acid Molecules (r/sNA)

In the context of the NIH Guidelines, r/sNA are defined as:

i) Molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
ii) Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e. synthetic nucleic acids) or
iii) Molecules that result from the replication of those described in (i) or (ii) above.

C. Biohazardous Materials

Biohazardous materials are defined as any biological agents that are known or suspected to be hazardous to humans, animals, plants, or other forms of life. These include, but are not limited to, known or suspected human, animal, or plant pathogens; human and non-human primate tissues, bodily fluids, blood products, and cell lines; wild -caught or laboratory animals and their tissues and bodily fluids; insects that may harbor zoonotic pathogens; r/sNA; and biological toxins.

IV. FUNCTION

The function of the IBC is to ensure that all biological aspects of research are conducted in a safe manner according to established biosafety standards, principles, practices, and authorizations. To serve in this function, the IBC uses a review and approval process of all biological research involving biohazards and r/sNA technology to identify and reduce potential risks to laboratory personnel, the community, and the environment. The IBC develops, administers, and maintains SCSU's Biosafety Program policies and general standard operating procedures (SOPs) on the proper use of biohazards and recombinant materials. These SOPs serve as guidance documents and do not replace laboratory specific SOPs. The IBC assists and advises PIs and other researchers in meeting their responsibilities to ensure that the handling of biohazardous materials is conducted in a safe manner.

Guidance from the IBC shall take into consideration worker safety, public health, agricultural and environmental protection, and compliance with applicable biosafety standards outlined by federal, state, and local regulations.

V. REVIEW OF CHARTER

This charter shall be reviewed and reassessed by the IBC annually, and any proposed changes shall be submitted to the IBC and voted on for approval.

VI. SUBCOMMITTEES

When needed, the IBC can form subcommittees for specific research oversight. These subcommittees will report to the IBC.

VII. BY-LAWS

A. Membership Organization

As per NIH Guidelines, the IBC may contain no fewer than five members, including two community members. These community members are not otherwise affiliated with the university, nor have an immediate family member who is affiliated with the university. Ex-officio non-voting members will include representation from Environmental Health and Safety (EH&S) and Sponsored Programs and Research (SPAR). The IBC may work with consultants in specific areas of expertise as needed. Consultants or working group members are not IBC voting members unless nominated and appointed as described below.

B. Procedure for Appointing Members

The SCSU Provost formally appoints all IBC members. Department Chairs are consulted prior to membership invitation of faculty.

C. Terms of Membership

IBC membership is a minimum three – year period of service. Members may be appointed for subsequent three – year terms if they are willing to continue to serve. If a member does not attend two meetings throughout the calendar year, the IBC Chair may motion that a replacement be nominated. The Committee Chair is voted on by the SCSU faculty membership and will serve for a term of three years. The chair of the IBC at SCSU may serve additional terms.

D. Conflict of Interest Policy

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 in which he/she has a direct financial interest. IBC members are also asked to withdraw from decisions where, owing to their personal relationships, there might be either real or perceived conflicts of interest. Each member is expected to notify the IBC chair in these circumstances and recuse him/herself when such proposals are being discussed and are up for a vote. In addition, if the IBC Chair is the PI on a project, another IBC committee member present at the meeting will sign the approval letter or any resulting correspondence.

E. Quorum

Meetings will proceed with no less than four voting members present and must contain at least two members from the SCSU faculty. Decisions such as approval of research projects or policies are approved when a majority of IBC members' present vote for approval. In the event that the IBC Chair must be absent, he/she will request another committee member to serve as chair during the absence.

F. MEETINGS

The IBC will convene twice during a year. Meetings must occur in person or through video conference as per NIH regulation (Section IV-B-2-a-(6). Additional meetings may be called as needed to review and approve research in a timely manner. A proposed agenda will be developed and distributed before the meeting by the chair or his/her designee. Meeting minutes will be taken by SPAR 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 for at least five years. PIs are always welcome to present their work to the IBC and are encouraged to attend. When possible and consistent with protection of privacy and proprietary interests, IBC meeting will be made publically accessible upon request.

G. Agenda, Minutes, Approval Letters, and Reports

The IBC Chair shall be responsible for establishing the agendas for meetings. All members may submit items to the chair, which to be considered for addition to the agenda. An agenda, together with relevant materials, shall be sent to committee members at least 5 days in advance of the meeting. Minutes for all meetings shall be drafted by the SPAR representative and approved by committee members at the following meeting. Approval letters will be drafted by EH&S and cosigned by the Chair. Reports to the SCSU Provost and federal agencies will be drafted by SPAR after consultation with the Chair. SCSU shall make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies upon request in accordance with requirements of the NIH Guidelines. If public comments are made on IBC actions, SCSU shall forward both the public comments and the IBC's response to the Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

H. Relationships to Other Committees

The IBC at SCSU supports transparency between the IBC, Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) for overall research compliance oversight. Overlap of membership between these committees will be prioritized in order to maintain this collaborative oversight.

VIII. ROLES & RESPONSIBILITIES

A. Institution (in accordance with NIH Guidelines Section IV-B-1)

SCSU is ultimately responsible for the effectiveness of the IBC and may establish procedures that the IBC shall follow in its initial and continuing review and approval of applications, proposals, and activities. Institutional responsibilities will fall under the auspices of the SCSU Provost. Specifically, SCSU’s responsibilities include:

i. Maintaining the IBC so that the committee meets the requirements and carries out the functions detailed in the NIH Guidelines;

ii. Appointing the required expertise to the IBC from the research and/or teaching faculty.

iii. Ensuring appropriate training for the IBC Chair and members, EH&S and other containment experts (when applicable), PIs, and laboratory staff regarding laboratory safety and implementation of the NIH Guidelines.

B. Institutional Biosafety Committee (IBC) (in accordance with NIH Guidelines, section IV-B-2)

The SCSU IBC will report to the SCSU Provost. IBC duties include:

i. Review of all biological research conducted at SCSU on a three-year basis, including review of r/sNA research or compliance with the NIH Guidelines as specified in Section III: Experiments covered by the NIH Guidelines, and approving those research projects that are found to conform with the NIH Guidelines;

ii. Review and approval of the research or teaching activity performed by individual researchers, whom will be required to submit new protocols or changes to existing protocols for approval.

iii. Establish, implement, and annually review policies that provide for the safe conduct of hazardous biological and rDNA research;

iv. Assessment of the facilities, procedures, practices, work-alone policy and training and expertise of personnel involved in biological research to determine appropriate biocontainment levels required by the NIH Guidelines for the proposed research;

v. Lowering biocontainment levels for certain experiments as specified in NIH Guidelines Section Section IV-B-2-b-(3).

vi. Notifying the PI of the results of the IBC's review and approval;

vii. Ensuring that the research community is in compliance with the policies of the IBC and Biosafety Program. Non-compliance shall be reported by EH&S to the IBC chair, the IBC Chair will notify the Faculty of non-compliance in writing indicating steps required to rectify the situation. If the PI still does not comply with the regulations, the IBC Chair will notify the Department Chair. If compliance is still not met, the IBC has the authority to suspend all activities involving biohazardous agent usage in the offending laboratory. Upon request, the PI will be granted a hearing before the IBC.

viii. Investigating and reporting any significant problems with or violations of the NIH Guidelines and any significant research - related accidents or illnesses to the appropriate institutional official and NIH OSP within 30 days, unless the IBC determines that a report has already been filed by the Faculty. Reports to NIH OSP shall be sent to the Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892 - 7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

C. Environmental Health and Safety (EH&S) (in accordance with NIH Guidelines Section IV – B - 3)

The EH&S Officer's duties include:

i. Report to the IBC any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which EH&S becomes aware;

ii. Conduct or oversee biological safety laboratory audits as part of IBC review process of new protocols or three-year renewals;

iii. Provide administrative support for IBC activities, including preparation of meeting minutes, and materials;

iv. Provide technical advice to PI and the IBC on research safety procedures;

v. Follow - up on contingent approvals to ensure all contingencies are met and report to the IBC when contingencies have been met and final approval given.

D. Principal Investigator (PI) (in accordance with NIH Guidelines Section IV – B - 7)

On behalf of SCSU, the PI is responsible for full compliance with the NIH Guidelines in the conduct of r/sNA research. Definition: The PI designation is given to a SCSU 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 PI is the leader responsible for that team whose name appears as PI on the Grant Application or Award. With regard to the IBC, the PI has overall responsibility of laboratory personnel working under the requirements of the NIH Guidelines.

Responsibilities: To comply with the NIH Guidelines and adhere to the institutional requirements of the SCSU IBC, the PI shall:

i. Not initiate or modify any research involving r/sNA, infectious agents, biological toxins (including select agents), human or non-human primate blood, tissues, or cells prior to review and approval by the SCSU IBC.

ii. Remain in communication with the IBC throughout the conduct of the project;

iii. Immediately report any significant problems, violations of the NIH Guidelines, or any significant research – related accidents and illnesses to EH&S, Animal Facility Director, IBC, NIH OSP, and other applicable authorities;

iv. Adhere to SCSU IBC approved emergency plans for handling accidental spills and personnel contamination;

v. Comply with national and international shipping requirements for infectious agents and r/sNA;

vi. Provide instruction to laboratory staff in: (a) the practices and techniques required to ensure safety, (b) the procedures for dealing with accidents, and (c) the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection);

vii. Ensure that the required safety practices and techniques are employed and notify the IBC chair if they are not;

viii. Ensure the integrity of the physical containment (e.g. biological safety cabinets) and the biological containment

ix. Work with EH&S to develop emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving rDNA and infectious agent research;

E. Sponsored Programs and Research (SPAR)

SPAR will provide administrative support to the IBC and input on compliance with funding agencies.

In collaboration with EH&S and the IBC chair, SPAR will submit

i. An annual report to NIH OSP that includes a roster of IBC members, indicating the Chair, contact person, EHS, and biographical sketches of each member.
ii. An annual report of the Biosafety Program at SCSU to the SCSU Provost. This review shall include but is not limited to:
    a. Number of IBC reviews conducted with approval/denials
    b. Number of laboratory inspections conducted with overview of common infractions
    c. Areas of concern for future research oversight and safety, research training compliance summaries
    d. Changes in the NIH Guidelines effecting IBC research oversight at SCSU.

IX. IBC SUBMISSION AND APPROVAL PROCESS

The research review process by the IBC is conducted in a step-wise fashion, starting with the submission of research information by the PI.

A. IBC Submission

Online submission to the IBC is achieved using the online system. All information pertaining to biological agent usage (rDNA technology, including viral vectors, animal research, human material, infectious agents, biological toxins, etc.) and the personnel involved with the research will be queried in this system. This information is maintained in online system and can be updated or revised any time there is a change in the research program. PIs are encouraged to work with EH&S to help generate risk assessment and protocols. Feedback from EH&S will be valuable to the IBC when considering protocols.

B. IBC Approval Process of New Research Projects, 3-year Renewals, or Significant Modifications

i. IBC Review: The IBC will review the research information submitted through online system and discuss the safety and regulatory aspects of the research project. Discussion topics include:

- The nature of experimentation

- Biohazards and use of other hazardous materials

- Containment and elimination of r/sNA

- Training requirements fulfilled by research staff

- Past laboratory inspection record

ii. 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 which is signed by the IBC Chair

iii. Research Commences: Once an approval letter has been received from the IBC, only then can the proposed research begin.

C. Administrative Approval of Modifications to Currently Approved Research

Any modifications to currently IBC approved research (e.g. changes or updates to the registration that occur during the 3 - year approval timeframe) will be submitted to IBC for review.

i. A new project is added that has not been previously reviewed by the IBC;

ii. A new agent or procedure is added to a current project that would require different practices or containment from what is currently approved for that laboratory;

iii. Research involving non-exempt work covered by the NIH Guidelines. the IBC Chair or committee expert, has the authority to administratively review and approve modifications if a risk assessment determines a full committee review is not warranted, and a decision letter will be sent to the PI signed by the IBC Chair. All administratively approved research will be reported to the IBC at regularly scheduled meetings.

D. Review and approval of an IBC submission is permitted for work that does not involve r/sNA

Research that does not involve r/sN is exempt from the NIH Guidelines as per Section III – F, and may be conducted at BSL 1 or 2. The IBC Chair or committee expert, has the authority to review and approve such research after conducting a risk assessment, and a decision letter will be sent to the PI signed by the IBC Chair. All administratively approved research will be reported to the IBC at regularly scheduled meetings.

X. RESOURCES

• Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), Federal Register (April 2019).

• Laboratory Safety Monograph : A Supplement to the NIH Guidelines for Recombinant DNA Research, Office of Research Safety, National Cancer Institute, Special Committee of Safety and Health Experts, July 1978.

• Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, CDC and NIH.

• Bloodborne Pathogens Standard, Occupational Safety and Health Administration (OSHA), 29 CFR 1910,1030.

• Select Agents and Toxins, Health and Human Services (HHS), 42 CFR 121.

• Plant Pathogens and Pests, USDA, 9 CFR Parts 92,94,95,96,122 and 130.

• Importation of Human Pathogens, U.S. Public Health Service (USPHS), 42 CFR 71