Institutional Biosafety Committee (IBC) Charter

1. Purpose

The purpose of the Institutional Biosafety Committee (IBC) is to ensure that research involving recombinant or synthetic nucleic acid molecules is conducted in a manner that protects the health and safety of researchers, the public, and the environment, and complies with applicable federal regulations.

2. Authority and Scope

The CWRU Institutional Biosafety Committee (IBC) is charged with responsibility for the oversight and approval of research activities involving recombinant DNA and synthetic nucleic acid molecules (r/sNA) that take place at CWRU and fall within the scope of the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). The CWRU IBC may also act as the reviewing IBC for research activities conducted by CWRU faculty at MetroHealth Medical Center (Metro), the University Hospitals Cleveland Medical Center (UH), and the Veterans Affairs Northeast Ohio Healthcare System (VANEOHS). IBC review for the VANEOHS will be in accordance with VHA DIRECTIVE 1200.08(1) Section 7.

3. Institutional Official

The CWRU Senior Research Officer will serve as the Institutional Official and will appoint individuals to review and approve research in compliance with the NIH Guidelines to specify biosafety practices and containment principles to protect individuals and the environment. The Institutional Official may request additional guidance from the committee regarding working safety, public health, environmental protection and compliance with other biosafety regulations and best practices as needed.

4. Responsibilities

The IBC is responsible for the following:

- Reviewing and approving non-exempt research involving recombinant or synthetic nucleic acid molecules.
- Assessing containment levels, facilities, training, and biosafety procedures.
- Ensuring compliance with NIH Guidelines and institutional policies.
- Reporting significant problems, violations, or research-related accidents to NIH OSP.

5. Membership

The committee will be registered with the NIH Office of Science Policy (OSP) and the membership will follow the requirements defined in the NIH Guidelines, including:

- CWRU researchers with experience and expertise in recombinant and synthetic nucleic acids (r/sNAs)
- At least two individuals not affiliated with CWRU
- A biosafety officer
- Individuals with knowledge of human gene transfer studies, animal and plant containment, and gene drives if those types of studies are reviewed.

Laboratory and affiliate hospital representation on the committee will be sought whenever possible. VANEOHS representation is required for review of any VA research.

6. Review of Research

IBCs will review research activities involving recombinant or synthetic nucleic acid molecules in accordance with the NIH Guidelines, as required by the terms and conditions of federal research funding. This will include all new research, ongoing review (continuing review) of existing research, and significant changes to the research.

Consultants may be used if specific expertise is needed on the science or biosafety elements of the research under review.

7. Meetings and Quorum

The IBC will meet as needed, typically monthly. A quorum for the IBC shall consist of at least five voting members. Additional members may be required when specific expertise is necessary to review the scope of research under consideration. The committee will make every effort to include at least one unaffiliated at the meetings, but their presence is not strictly required to conduct official business.

Meeting notices will be posted to a public website and considered open to interested members of the public, except for discussions involving private or proprietary information. Meeting minutes, once approved, will also be posted to a public website. Information considered proprietary, confidential commercial information, or a matter of institutional or national security will be redacted prior to posting.

8. Collaboration and Training

The committee will collaborate with the CWRU Environmental Health and Safety Executive Director and CWRU Health and Counseling Services to establish and maintain training and education, emergency plans for spills and personnel exposure, and a health surveillance program.

The IBC will communicate with the Institutional Animal Care and Use Program (IACUC) or an Institutional Review Board (IRB) as needed when the research involving r/sNAs also involves vertebrate animals or human subjects.

9. External IBC Agreements

Case Western Reserve University may enter into an agreement with an external IBC for review of r/sNA, including research involving human gene transfer, conducted at CWRU, Metro, or UH. Representatives from CWRU/affiliate hospitals will be included as voting members on the external IBC, which will be registered with NIH OSP under CWRU.

10. Charter Amendments and Review

This charter will be reviewed periodically and may be amended by the Institutional Official in consultation with the IBC.