CASE WESTERN RESERVE UNIVERSITY
Office of Research and Technology Management

Institutional Biosafety Committee
case-ibc@case.edu

Institutional Biosafety Committee (IBC) Researcher Manual

April 2026

1. Overview and Applicability

The Institutional Biosafety Committee (IBC) oversees biological materials that may pose risks to the environment and the safety and health of plants, animals, or humans, specifically recombinant or synthetic nucleic acid molecule (r/sNA) experiments governed by the NIH Guidelines at Case Western Reserve University (CWRU), MetroHealth Medical Center, Louis Stokes Veteran's Administration, and University Hospitals Cleveland Medical Center.

All work that falls under the NIH Guidelines for r/sNA (Sections III-A, III-B, III-D, and III-E) need to be submitted to the CWRU IBC for review and approval. Research that likely requires IBC review includes:

- Viral vectors / Virus-based gene delivery vectors (e.g., Adenovirus, Adeno-Associated Virus, Retrovirus, Lentivirus, Herpes virus, Pox virus)
- Genetically modified or reprogrammed cells (e.g., CAR T cells, iPSCs)
- Generation of transgenic or gene modified organisms
- Gene editing/silencing tools (CRISPR-Cas9, TALEN, sh/siRNA, etc)

Clinical research involving administration of investigational products that contain r/sNA (vaccines, immunotherapy, cellular therapy) to human subjects falls under Section III-C. Depending on the funding of the study, the research may be reviewed by the CWRU IBC or sent to an external IBC for review.

2. PI Responsibilities and Training

Principal Investigators (PIs) must hold a CWRU faculty appointment or be approved by the Institutional Official. If a PI will be absent from campus, another faculty member must temporarily assume PI responsibilities. PIs are responsible for:

- Identify research requiring IBC review and maintain active approvals, including amendments and continuing reviews.

- Ensure research congruence by referencing r/sNA hazards and IBC approvals in related grants, IACUC, and IRB protocols. Institutional review processes will verify these approvals.
- Reporting problems/violations, accidents, and exposures immediately.
- Provide training and ensure compliance with the approved protocol.

All individuals listed on the application must complete the required safety training prior to IBC approval.

- Everyone must complete the **CITI NIH Recombinant DNA Guidelines** course
- **Laboratory research:** Personnel must complete lab safety and biological safety training, with yearly retraining required, conducted through Environmental Health and Safety (EHS).
- **Clinical research:** Personnel must complete the CITI training module on Human Gene Transfer
- PIs are responsible for **lab specific training** on procedures detailed in the IBC protocol.

3. Submission Process and Timelines

The convened IBC meets monthly on the second Thursday of the month. Submissions via the electronic system are due one month prior to the meeting.

- **Initial Submissions**: Must be approved prior to starting work (Exception: Section III-E experiments may begin at the time of submission)
- **Amendments**: Must be approved before implementing protocol changes. Minor administrative changes (e.g., personnel, location, funding) can be approved without a convened meeting.
- **Continuing Review**: Required annually for all human studies and Biosafety Level 3 (BL-3) projects. Required triennially (every 3 years) for BL-1 and BL-2 lab projects.

4. Protocol Preparation and Risk Assessment

A risk assessment identifies an agent's hazards, likelihood of exposure, and severity of the consequences of an exposure. Your protocol must clearly detail agent hazards alongside the facilities, PPE, equipment, and practices needed to protect personnel, the community, and the environment.

Specific information to include:

- **Project Overview:** Summary of the hypothesis and the overall goal of the project(s).
- **Materials:** Detail the agent/vector system/recombinant materials being used, including characteristics of the material that influence risk (tropism, virulence, transmission) and safety features. Genes that will be manipulated or expressed must be listed. Viral vector maps need to be uploaded.
- **Procedures:** Describe your in vitro and in vivo experiments using the agents/vectors/recombinant materials, highlighting risks like aerosol production or sharps usage. Specific locations for the planned experiments must be listed.
- **Risk Mitigation and Biosafety Measures:** Describe required PPE , sharps safety/disposal, safety equipment (e.g., sealed centrifuge rotors, biosafety cabinets), and biohazard waste disposal and spill response.

5. Committee Review and Administrative Actions

Submissions reviewed by the committee will be given an outcome of:

- **Approved:** Containment will be specified for the proposed research
    - **Modifications Required:** Specific items must be addressed for approval
    - **Training Required:** Training required for approval
- **Tabled:** additional information is needed; revised protocol may be reviewed at a future committee meeting.
- **Disapproved:** Research cannot be conducted.

Administrative actions that do not require a convened meeting:

- **Amendment Approval:** minor changes to an approved protocol, including updates to personnel (other than PI), research location, funding.
- **Acknowledgement:** submission of updated documents that do not require review (do not impact risk assessment) such as clinical protocols with no changes to r/sNA.
- **Protocol Closure:** expired IBC protocol (>2 months) with no continuing review submission.
- **Withdrawal:** IBC submission which has been sitting with the PI for > 6 months.

6. Reporting Requirements

Medical attention is the priority; report exposures only after the individual has received care.

- **Immediate Notification**: The IBC must notify NIH of spills or accidents resulting in an overt exposure in a BL-2 lab.
- **Immediate Notification**: The IBC must notify NIH **of s**pills or accidents resulting in an overt ***or potential*** exposure in a BL-3 lab.
- **Prompt Notification:** The IBC must notify the NIH of significant violations of NIH Guidelines or significant research-related accidents/illnesses within 30 days.

7. Protocol Closure

Protocols should be closed when experiments end or there are no plans to continue the research.

- Clinical Studies: May close after the last participant receives their final dose of the investigational product containing r/sNA.
- Material Storage: You may store r/sNA materials after closure, but a new protocol is required to handle or use them.

Resources:

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, April 2024

CWRU Institutional Biosafety Committee website

CWRU ORTM Biosafety Training website

CWRU Environmental Health and Safety (EHS) Biological Safety website

CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th edition

Questions? Contact the Institutional Biosafety Committee:
case-ibc@case.edu