Duke University Institutional Biosafety Committee (IBC)
Policies and Procedures
(Revised April 2021)

Mission and Oversight

The mission of the Duke University IBC is to:

Ensure that all recombinant or synthetic nucleic acid molecules research conducted at the institution or sponsored by the institution is conducted in compliance with the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).

a. The purpose of the NIH Guidelines is to specify the practices for constructing and handling:
    i. recombinant nucleic acid molecules,
    ii. synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and
    iii. cells, organisms, and viruses containing such molecules.
b. For the purpose of this policy, “nucleic acid research” encompasses all of the above materials

The Duke University IBC has responsibility for such research throughout the Duke Health System, Medical Center, and University. IBC members are appointed through the Offices of the Chancellor and Provost. The Duke Occupational and Environmental Safety Office (OESO) Biological Safety Division staff support the IBC in carrying out its mission. The IBC is authorized to assess the safety and make the risk determination for nucleic acid research, inspect research facilities, approve research practices and procedures, and to take appropriate actions as warranted, including the enforcement of cessation of research activities, in the event of a significantly unsafe workplace situation.

Structure and Function of the IBC

1. Membership:
    a. The IBC consists of at least five members appointed by Duke leadership/authorities (see above), including:
        i. One or two Chair(s)
        ii. The Biological Safety Officer (BSO)
        iii. At least two members external to the institution (Non-affiliated local members).
        iv. At least three members with expertise relevant to the protocols under review, including as appropriate: expertise in research involving plants, animals, or human subjects.
        v. Other *ad hoc* members may be called upon for specific expertise needs and depending on the research involved.
    b. Membership and qualifications are in compliance with Sections IV-B-2-a-(1) and IV-B-2-a-(2) of the NIH Guidelines.

2. Staff, Meeting Schedules, and Voting
    a. The Biological Safety Division is responsible for keeping records, recording minutes, and scheduling meetings for the IBC. This support also includes a pre-review of submitted registrations (according to the Deadline for Protocol Submission) for completeness of required information and working with the Principal Investigator (PI) or PI's designee to ensure readiness for IBC review.
    b. The Executive Committee (consisting of the IBC Chairs, the BSO, and Biological Safety Division staff) will oversee and support the monthly preparation for the IBC Meeting.
        i. The Executive Committee shall ensure that all completed registrations and amendments are posted to the secure IBC file sharing/information site.
    c. The Full IBC will typically meet monthly and as needed to expedite the registration approval process for specific registrations. The Full IBC will conduct business using the following procedures:
        i. A quorum of IBC members, including at least one Chair, three members, and one public member must be present to conduct official business, including approval of submitted registrations or amendments.
        ii. The Full IBC approves registrations by a majority vote of the membership quorum at the meeting. Although information regarding registrations may be provided via the IBC file sharing/information site, voting must occur at the designated meeting.
        iii. No member of the IBC will vote on a registration with which he or she has any direct connection or in which he or she has a personal or professional interest other than as a member of the IBC. Members shall self-identify potential conflicts and will

recuse themselves from the discussion and vote on that registration.

iv. The final result of the IBC decision for each registration will be noted, along with any comments and recommendations, and will be communicated to the PI of the registration. Any recommendations for other committee review (i.e., Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC)) will be communicated by the IBC Chair(s) or designee.

d. No project requiring IBC approval will commence prior to IBC approval of the registration.
e. PIs will be notified annually and asked to complete an annual review form for continuing projects to document that information regarding gene constructs, work procedures, animal use, or other significant changes are current with the IBC records.
f. Any problems associated with the work, including violations of NIH Guidelines, releases of recombinant material from primary containment, accidents or illnesses associated with the protocol must be reported to the IBC, and, after review, may require a significant change or amendment to the registration, re-review of the registration by the IBC, and/or reporting to the NIH Office of Science Policy (OSP).

Specific Responsibilities

1. Institutional:
    a. Establishes policies and procedures that the IBC shall follow in its initial and continuing review and approval of registrations and activities described in the registrations and supporting documents.

2. IBC:
    a. Reviews registrations for compliance with the NIH Guidelines including the following elements of the required Standard Operating Procedures (SOP) for Biosafety Level 2 (BSL-2) and above research or an Investigational Product Handling Plan (IPHP) for human clinical trials.
        i. Assessment of the containment levels required by NIH, OSHA, and CDC Guidelines for the proposed activity.
        ii. Assessment of the laboratory facility, product handling practices and procedures, and training as applicable presented for the registration.
        iii. Assessment of the emergency plan covering spills, personnel exposures and reporting to Employee Occupational Heath as resulting from such activities.
    b. Periodically reviews guidelines for activities involving nucleic acid research to ensure compliance with all federal agencies.

c. Reports to NIH on an annual basis the requirements stated in the NIH's IBC Registration Management System (RMS)
d. Reports to NIH Office of Science Policy (OSP) any significant research related exposures, releases of recombinant material outside of primary containment, accidents, or illnesses and any substantial problems or violation of the NIH Guidelines.

3. OESO - Biological Safety Division
    a. Maintains and manages records of Duke IBC registered and approved registrations.
    b. Receives registration applications and conducts pre-review prior to IBC review and approval.
    c. Ensures that all laboratories submitting IBC registrations for approval are evaluated for safety procedures for nucleic acid research by the Laboratory Safety Division and are in good standing with the evaluation program.
    d. Maintains records of IBC registrations, any correspondence with PIs and the IBC members, and minutes of Full IBC meetings.
    e. Annually records the renewals of continuing projects, or discontinues completed ones.
    f. Schedules meetings with the IBC.
    g. Communicates decisions of the IBC with the PIs
    h. Maintains the IBC section of the OESO website.

4. Principal Investigator:
    a. Makes an initial determination of the required levels of physical and biological containment, and practices and procedures in accordance with the NIH Guidelines; determines if the protocol is exempt or requires IBC approval.
    b. Submits the appropriate paperwork for the proposed work (see procedure above) per submission deadlines posted on the Duke IBC webpage.
    c. Is responsible for adherence to all requirements of the NIH Guidelines, including required safety practices, personnel training, incident/injury reporting, and compliance with the standards of laboratory evaluations.
    d. Submits an annual update of the continuing registrations to the IBC.
    e. Ensures that all laboratory workers are compliant with required training and trains all laboratory workers regarding the potential hazards of the work and precautions to be taken; maintains documentation of such training, conducts on-going training as needed.
    f. Investigates and reports any significant problems, releases, exposures or illnesses pertaining to the operation and implementation of containment to the Biological Safety Division for review by the IBC.

g. Complies with any shipping requirements for nucleic acid research.
h. Ensures that laboratory workers who work with animals involved in the work participate in the Duke Health Surveillance for Animal Handlers. PI is responsible for compliance with all IACUC requirements.