DARTMOUTH
ENVIRONMENTAL HEALTH & SAFETY
Biological Safety Program

Policy 200: Submission of Research to the IBC

I. PURPOSE

This policy outlines how to submit research for review and approval by the Dartmouth Institutional Biosafety Committee (IBC). For research involving human gene transfer studies, please refer to the IBC for Clinical Gene Transfer (IBC-CGT) website for submission policies:
http://www.dartmouth.edu/~ehs/biological/biological_subcom.html

II. REGULATORY BACKGROUND

All institutions that receive NIH funding for any research involving recombinant or synthetic nucleic acids (r/sNA) must comply with the *NIH Guidelines* for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*, 2019). As an NIH-funded institution, Dartmouth College and all Dartmouth Principal Investigators are required to comply with the federal regulatory requirements outlined in the *NIH Guidelines*, regardless of funding source or research. If research is conducted without IBC approval, the NIH has the authority to withdraw research support from that lab or institution.

III. RESPONSIBILITIES

A. Principal Investigator (PI)

All Principal Investigators who conduct research at institutions that are subject to the *NIH Guidelines* must comply with the requirements even if the NIH does not directly fund his/her own research program. Section IV-B-7 of the *NIH Guidelines* states, "on behalf of the institution, the Principal Investigator is responsible for full compliance with the *NIH Guidelines*." According to Section IV-B-7, it is the PI's responsibility to:

i. Not initiate or modify r/sNA research that requires IBC approval (*NIH Guidelines* Sections III-A through III-E) until that research or proposed modification has been IBC approved. Please refer to the Biosafety Program website for guidance on Sections III-A through III-E of the *NIH Guidelines*.

ii. Communicate any significant changes to the IBC throughout the conduct of the project.

iii. Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination and train lab personnel in these procedures.

iv. Immediately report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents or illnesses to the Biological Safety Officer (BSO), IBC, NIH/OBA, and other applicable authorities. Examples of significant problems: skin puncture with needle containing r/sNA, escape of transgenic animal, spill of high-risk materials outside of a biosafety cabinet.

v. Investigate and report any significant problems pertaining to containment practices and procedures to the BSO. Examples of significant problems: release of r/sNA into environment, misuse of biosafety cabinet, unauthorized transport of material.

vi. Make an initial determination of the required biosafety level (BSL) for containment practices and procedures and the applicable NIH Section classification.

vii. Please refer to *NIH Guidelines* for more specific details of Principal Investigator Responsibilities.

B. Institutional Biosafety Committee (IBC)

i. Provides review and oversight of the Dartmouth College Biosafety Program in accordance with all local, state, and federal regulations and guidelines, including the *NIH Guidelines*.

ii. Reviews all biological research at Dartmouth to ensure labs have proper containment for various types of biological agents, including recombinant or synthetic nucleic acids as pertains to the *NIH Guidelines*, and infectious or pathogenic agents, animals, human source materials, biotoxins, etc.

iii. Ensures that all lab personnel are properly trained in biological safety.

iv. Serves as an advisory board to the research community on all aspects of biological safety.

IV. PROCEDURE FOR IBC REGISTRATION

A. Register Research in BioRAFT

i. Online submission to the IBC is achieved using the BioRAFT online registration system.

ii. All information pertaining to biological agent usage (such as r/sNA materials [including viral vectors], infectious or pathogenic agents, animal use, human source material, biotoxins, etc.) and the personnel involved with the research will be queried in this system.

iii. The PI (or designee) must enter all relevant information into the BioRAFT "Bio Summary" (aka "Biological Usage Summary" or "IBC Registration") by completing a series of surveys aimed to identify the biohazards involved in the research program. The BioRAFT Bio Summary is designed to communicate the biohazardous aspects of research to the IBC so that it can properly review and approve the work.

iv. If a lab already has a Bio Summary and needs to update it, the PI may edit any of these surveys to make the necessary modifications.

v. Once new information has been entered, BioRAFT will then prompt the PI to "certify" that the Bio Summary (registration) is complete and correct. **IMPORTANT: The registration will not advance through the review process until it has been certified by the PI.** This step cannot be delegated.

vi. The IBC registration is maintained in BioRAFT and should be updated or revised any time there is a change in the research program.

vii. All lab members must be up-to-date on mandatory Dartmouth College laboratory safety training

available in BioRAFT. Training must be up-to-date prior to IBC review or the committee may refuse to review the registration. Laboratory training compliance summaries are available in a lab's "Compliance Summary" box in BioRAFT.

B. Biological Safety Officer (BSO) Pre-Review

i. The BSO will review your research information and conduct a risk assessment based upon the information submitted.

ii. A biosafety audit of the lab may be conducted as part of the risk assessment.

iii. Any questions/problems/concerns will be directed back to the PI for clarification.

iv. The BSO will generate a Summary Report of submitted research and present it to the IBC on the PI's behalf. **Thus, it is in the PI's best interest that the information provided in BioRAFT is complete and accurate so that the BSO can justly present the research registration to the IBC.**

C. IBC Review

i. The IBC will review the research registration submitted through BioRAFT and discuss the safety and regulatory aspects of the research project.

ii. Insufficient or incorrect information may delay the approval process. Any PI is welcome to present his/her work directly to the IBC if he/she would like.

iii. Discussion topics include: the nature of experimentation, location, r/sNA aspects, training requirements fulfilled by research staff, past laboratory inspection record, dual use aspects, waste handling, etc.

iv. IBC approval must be renewed at least every 3 years; however, any new research (new funding, new collaborations, etc.) is reviewed ad hoc as a modification.

v. Please refer to the IBC Charter on the IBC website for details of the review process: http://www.dartmouth.edu/~ehs/biological/biological_ibc.html.

D. Decision Letter Sent to PI

Once the IBC has made a decision regarding the research project, a decision letter will be sent to the PI from the BSO and the IBC Chair. This decision letter should be retained in the PI's records, and a copy will be on file in the Office of Environmental Health & Safety and uploaded into a lab's BioRAFT profile.

E. Conduct Research

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