DARTMOUTH
ENVIRONMENTAL HEALTH & SAFETY
Biological Safety Program

Institutional Biosafety Committee Charter

Version: 5

The Dartmouth Institutional Biosafety Committee (IBC) is a formal committee of subject matter experts and community representatives whose purpose is to ensure safe work practices of biological research conducted at or sponsored by Dartmouth College, Geisel School of Medicine at Dartmouth, Thayer School of Engineering, Dartmouth Hitchcock Medical Center, and the Department of Veterans Affairs Research Service, on the Hanover and Lebanon, NH and White River Junction, VT campuses. Other commercial or nonprofit tenants in these laboratory areas which are bound by a Research Safety and Compliance Service Agreement with the Trustees of Dartmouth College are likewise subject to IBC oversight. Collectively, these locations and entities will be referred to as "Dartmouth" herein.

I. PURPOSE

Institutions that receive support from the National Institutes of Health (NIH) for recombinant or synthetic nucleic acid research are required to establish and register an IBC with the NIH Office of Biotechnology Activities (OBA) in compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*, 2016). The establishment and operation of the Dartmouth IBC fulfill this requirement. The NIH requires all institutions receiving research funds to have all of its recombinant or synthetic nucleic acid research reviewed by an IBC (regardless of whether that research is directly supported by the NIH), as stipulated by the *NIH Guidelines*. If such research is conducted without approval, the NIH has the authority to withdraw research support from that lab or institution. The Dartmouth IBC additionally reviews all research involving biohazardous materials as defined in Section II.

II. DEFINITIONS

A. Biological Agents

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

B. Recombinant or Synthetic Nucleic Acid Molecules

In the context of the *NIH Guidelines*, recombinant and synthetic nucleic acids 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; recombinant or synthetic DNA; and biotoxins.

III. FUNCTION

Experiments involving the use of recombinant or synthetic nucleic acids and/or biohazardous agents can pose potential risk to researchers, the community, and the environment. 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 recombinant or synthetic technology to identify and reduce potential risks to lab personnel, the community, and the environment. The IBC develops, administers, and maintains Dartmouth'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 principal investigators 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, research integrity and ethics, and compliance with applicable biosafety standards outlined by federal, state, and local regulations.

IV. REVIEW OF CHARTER

This charter shall be reviewed and reassessed by the IBC at least every three years and any proposed changes shall be submitted to the IBC for approval.

V. SUBCOMMITTEES

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

VI. BY-LAWS

A. Membership Organization

The Dartmouth IBC may contain no fewer than five members. Based on the types of research activities at Dartmouth, the IBC will normally have the following minimum representation:

- Three to six scientists from Dartmouth who conduct research with potentially hazardous

biological materials, including recombinant or synthetic nucleic acids
- The Institutional Biosafety Officer
- An expert in animal containment principles (required by NIH for animal research)
- An expert in plant, plant pathogen, or plant pest containment principles (required by NIH where recombinant plant or plant pest research occurs)
- An expert in human research protocols
- Two community members who work or live in the Upper Valley area and who represent the interest of the surrounding community with respect to health and protection of the environment. These members will not directly be affiliated with Dartmouth (required by NIH)

The IBC may use consulting experts or establish working groups of members or non-members to execute its responsibilities or acquire needed expertise for select tasks. Consultants or working group members may include, for example, persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, the environment, or any scientific area where the IBC members do not have expertise. Consultants or working group members are not IBC voting members unless nominated and appointed as described below.

B. Procedure for Appointing Members

The Dartmouth College Environmental Health & Safety (EHS) Director 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 a majority of meetings throughout the calendar year, the IBC Chair may motion that a replacement be nominated.

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 principal investigator on a project, the Biosafety Officer and another IBC faculty member present at the meeting will sign the approval letter or any resulting correspondence.

E. Quorum

Meetings will proceed with a majority of current membership and must contain at least two Dartmouth researchers (faculty, animal facility rep, etc.). All IBC members are voting members. Decisions such as approval of research projects or policies are approved when a majority of IBC members present vote for approval.

F. Meetings

The IBC will convene monthly except when there are no research reviews or other business to address. Additional ad-hoc 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 Biosafety Officer (BSO) or his/her designee. Meeting minutes will be taken by the BSO 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 EHS for at least five years. Principal Investigators 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 meetings will be made publicly accessible upon request.

G. Agenda, Minutes, Approval Letters, and Reports

The Biosafety Officer (BSO), in collaboration with the IBC Chair, shall be responsible for establishing the agendas for meetings. 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 BSO and approved by committee members at the following meeting. Approval letters will be drafted by the BSO and co-signed by the Chair. Reports to the Vice Provost for Research and federal agencies will be drafted by the BSO in collaboration with the Chair.

Dartmouth 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, Dartmouth shall forward both the public comments and the Institutional Biosafety Committee's response to the Office of Biotechnology Activities, 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 Institutional Biosafety Committee (IBC) supports transparency between the IBC, IRBs (Committee for the Protection of Human Subjects at Dartmouth College and D-HH IRB at Dartmouth Health) and Institutional Animal Care and Use Committee (IACUC) for overall research compliance oversight. Overlap of membership between these committees will be prioritized in order maintain this collaborative oversight.

I. Confidentiality

IBC members are required to maintain confidential and/or proprietary information that they may have access to in connection with their role on the IBC strictly confidential, and to use it only for the purposes of carrying out their duties as IBC members. IBC members who are Dartmouth College employees or appointees are bound by Dartmouth policies related to the Confidentiality of Business Information. IBC members who are not Dartmouth College employees or appointees will be asked to sign an acknowledgement of their confidentiality obligations in connection with their service on the IBC.

VII. ROLES & RESPONSIBILITIES

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

Dartmouth is ultimately responsible for the effectiveness of the Institutional Biosafety Committee (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 Vice Provost for Research. Specifically, Dartmouth'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, including a Biosafety Officer, an individual with expertise in plant, plant pathogen, or plant pest containment principles, an individual with expertise in animal containment principles, an expert in human gene transfer studies, experts in the handling of recombinant or synthetic nucleic acids, and community members;

iii. ensuring appropriate training for the IBC Chair and members, Biosafety Officer and other containment experts (when applicable), Principal Investigators, 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)

IBC duties include:

i. review of all biological research conducted at Dartmouth on a three year basis, including review of recombinant or synthetic nucleic acid molecule research for 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. establish, implement, and review policies every three years that provide for the safe conduct of hazardous biological and rDNA research;

iii. assessment of the facilities, procedures, practices, and training and expertise of personnel involved in biological research to determine appropriate biocontainment levels required by the *NIH Guidelines* for the proposed research;

iv. lowering biocontainment levels for certain experiments as specified in *NIH Guidelines* Section III-D;

v. notifying the Principal Investigator of the results of the Institutional Biosafety Committee's review and approval;

vi. developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving rDNA and infectious agent research;

vii. ensuring that the research community is in compliance with the policies of the IBC and Biosafety Program.

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/OBA within 30 days, unless the IBC determines that a report has already been filed by the Principal Investigator. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, 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. Biosafety Officer (BSO) (in accordance with NIH Guidelines Section IV-B-3)

The Biosafety Officer's duties include, but are not limited to:

i. submit an annual report of the Biosafety Program at Dartmouth to the Office of Campus Services. This review shall include but is not limited to, number of IBC reviews conducted with approval/denials, number of laboratory inspections conducted with overview of common infractions, areas of concern for future research oversight and safety, research training compliance summaries, and any changes in the *NIH Guidelines* affecting IBC research oversight at Dartmouth.

ii. submit an annual report to NIH/OBA that includes a roster of IBC members, indicating the Chair, contact person, Biosafety Officer, plant expert, animal expert, human gene therapy expert or ad hoc consultant (if applicable), other member roles, and biographical sketches of each member;

iii. report to the IBC any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents or illnesses of which the BSO becomes aware;

iv. conduct or oversee biological safety laboratory audits as part of IBC review process of new or three year renewals;

v. develop emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecule research;

vi. develop rDNA and biosafety training materials for students, faculty, and IBC members;

vii. provide administrative support for IBC activities, including preparation of meeting agendas, minutes, and materials;

viii. provide technical advice to Principal Investigators and the IBC on research safety procedures;

ix. 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 (in accordance with NIH Guidelines Section IV-B-7)

On behalf of Dartmouth, the Principal Investigator is responsible for full compliance with the *NIH Guidelines* in the conduct of recombinant or synthetic nucleic acid molecule research.

Definition: The Principal Investigator (PI) designation is given to a Dartmouth 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 Principal Investigator is the leader responsible for that team whose name appears as Principal Investigator on the Grant Application or Award. With regard to the Institutional Biosafety Committee, 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 Dartmouth IBC, the PI shall:

i. not initiate or modify any research involving recombinant or synthetic nucleic acids, infectious agents, biological toxins (including select agents), human or non-human primate blood, tissues, or cells prior to review and approval by the Dartmouth IBC;

ii. submit the initial research protocol and any subsequent changes to the IBC for review and approval or disapproval and make an initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*;

iii. remain in communication with the IBC throughout the conduct of the project;

iv. immediately report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the Biosafety Officer, Greenhouse/Animal Facility Director, IBC, NIH/OBA, and other applicable authorities;

v. adhere to Dartmouth IBC approved emergency plans for handling accidental spills and personnel contamination;

vi. comply with national and international shipping requirements for infectious agents and recombinant or synthetic nucleic acid molecules;

vii. instruct and train 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);

viii. supervise and correct the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;

ix. ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).

VIII. IBC SUBMISSION AND REVIEW PROCESS

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

A. IBC Submission

Online submission to the IBC is achieved using the BioRAFT online registration system. All information pertaining to biological agent usage (rDNA technology, including viral vectors, animal research, human source material, infectious agents, biotoxins, etc.) and the personnel involved with the research will be queried in this system. This information is maintained in BioRAFT and can be updated or revised any time there is a change in the research program.

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

i. EHS Pre-Review: The Biosafety Officer (BSO) will review the submitted research information and conduct a risk assessment based upon the information provided. A biosafety audit of the lab will be conducted as part of the risk assessment for all new laboratories, as part of the 3-year renewal cycle, or more frequently as needed. Any questions/problems/concerns will be directed back to the principal investigator (PI) for clarification. Once all aspects of the risk assessment have been satisfied by EHS, the research will be presented for review by the IBC by either the BSO or the PI. The BSO will summarize the information provided by the PI onto a review form which is submitted to the IBC with the meeting agenda.

ii. IBC Review: The IBC will review the research information submitted through BioRAFT 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, location, recombinant or synthetic nucleic acid aspects, training requirements, past laboratory inspection record, etc. After review, the IBC will vote for one of the following:

- Approve without conditions: the proposed research is approved as submitted by the PI without any stipulations. New registrations and renewals are approved for a 3-year term and modifications are approved until the PI's next 3-year review date (i.e. modifications do not change the registration expiration date). The IBC reserves the right to impose a shorter approval period for special circumstances on a case-by-case basis.

- Actions Required: approval for the proposed research requires specific additional actions by the PI, such as confirming certain details, changing a practice, or completing overdue training, as deemed necessary by the IBC. Satisfactory fulfillment of conditions is determined by the BSO, unless otherwise specified, and updates of all required actions are provided to the IBC at each meeting. Required actions are given a deadline of two months (usually to the date of two IBC meetings later) unless otherwise specified. Research for which a current approval (at the time of review) is being renewed may continue during the Actions Required period. When required actions are fulfilled, approval from the date of IBC review is granted. If actions are not met after one month (the date of the next IBC meeting), the Chair will send a letter reminding the PI of the conditions and deadline for meeting them, following the steps in Section IX of this Charter as needed. If actions are not met by the deadline then the approval will expire.

- Deny: the proposed research is not approved. This may be due to grossly incomplete information, unsafe practices, inadequate facilities for the proposed work, or other factors as determined by the IBC. In the event of denial, the decision letter will state the reason(s) for denial and any remedial steps necessary for future review, if applicable. In some cases and at its discretion, the IBC may suggest alternatives to the proposed research, for example when the available facilities are inadequate but could accommodate a different or less hazardous model system or procedure.

- Table: a final decision has not been made and the IBC will revisit the review at a future time. This may be due to the need for further consideration or discussion, but generally not due to specific deficiencies which would otherwise result in Actions Required.

iii. 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 co-signed by the IBC Chair and BSO. Decision

letters are sent for any approval, actions required, denial of approval, or expiration of approval.

iv. Research Commences: Once an approval letter has been received from the IBC, only then may 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 BioRAFT registration that occur during the 3-year approval timeframe) will be initially reviewed by the Biosafety Officer (BSO). The BSO, in consultation with the IBC Chair or committee expert if needed, will determine whether the full committee must review the research or if it may be reviewed by the BSO and/or IBC Chair without going to full committee.

Whether full committee review is warranted may be determined by, but is not limited to:

i. New projects that have not been previously reviewed by the IBC;

ii. New agents or procedures that would require different practices or containment from what is currently approved for that laboratory;

iii. Whether the changes are covered by the *NIH Guidelines* (Section III-A through III-E) or exempt from the *NIH Guidelines* (Section III-F).

The BSO, in consultation with 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 co-signed by the IBC Chair and the BSO. All administratively approved research will be reported to the IBC at regularly scheduled meetings.

D. Administrative Approval of Biological Research

At the discretion of the Biosafety Officer (BSO) and in consultation with the IBC Chair, administrative review and approval of an IBC submission is permitted for work that does not involve recombinant or synthetic nucleic acids, is exempt from the *NIH Guidelines* (Section III-F), and may be conducted at Biosafety Level (BSL) 1 or 2. The BSO, in consultation with 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 co-signed by the IBC Chair and the BSO. All administratively approved research will be reported to the IBC at regularly scheduled meetings.

IX. NON-COMPLIANCE

A. Initial Actions

Reports or findings of non-compliance with IBC policies will be investigated and addressed with the PI by the BSO, in consultation with the Chair as needed. Most cases of non-compliance are minor and easily resolved at this level.

B. Escalation

i. In the event of non-compliance that the BSO has been unable to resolve with the PI, the IBC Chair will notify the PI of non-compliance in writing, indicating steps required for resolution and a

deadline. The IBC will be notified at the next meeting.

ii. If the PI still does not comply by the deadline imposed by the Chair, or an Actions Required deadline is approaching (Section VIII.B.ii.b), the IBC Chair will notify the PI's Department Chair. The BSO will notify the EHS Director.

iii. If non-compliance continues and/or the PI's approval is within two weeks of expiration, the Vice Provost for Research will be notified.

iv. The above are general guidelines and may be modified by the IBC on a case-by-case basis. Major concerns may be escalated immediately to any level.

v. Upon request, the PI will be granted a hearing before the IBC.

C. Suspension of Research Activities

i. The IBC has the authority to suspend all use of biohazards in a noncompliant laboratory, either through expiration or revocation of an existing approval.

ii. When a PI is notified of suspension, all biohazardous work must cease immediately.

iii. Suspension of research is a last resort with effects beyond the individual laboratory and all reasonable efforts will be made to avoid this action. Compliance is ultimately the PI's responsibility. At minimum, the EHS Director and Vice Provost for Research must be notified as early as practical prior to suspension.

iv. Violations and/or suspensions will be reported to the NIH or other entities where required by the *NIH Guidelines* or any other applicable rules or standards.

v. Upon request, the PI will be granted a hearing before the IBC.

vi. The decision of the IBC is final. Research may resume only when reauthorized by the IBC.

X. RESOURCES

- *Biosafety in Microbiological and Biomedical Laboratories*, 6th ed. Centers for Disease Control and Prevention and National Institutes of Health, 2020 June
  https://www.cdc.gov/labs/BMBL.html

- *Laboratory Safety Monograph: A Supplement to the NIH Guidelines for Recombinant DNA Research*. National Cancer Institute Office of Research Safety, 1978 July
  https://catalog.hathitrust.org/Record/000216223

- *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. National Institutes of Health Office of Science Policy, 84 FR 17858, 2019 April
  https://osp.od.nih.gov/biotechnology/nih-guidelines/