

Policy 330: Transgenic Risk Group 1 Invertebrates and Microorganisms

I. PURPOSE

To prevent the accidental release of genetically altered organisms or microorganisms into natural ecosystems in order to prevent the transmission of recombinant or synthetic molecules to non-laboratory organisms.

II. REGULATORY BACKGROUND

- i. 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*).
- ii. Experiments involving transgenic organisms at Dartmouth are subject to the *NIH Guidelines* regardless of funding source. All transgenic organisms/microorganisms must be rendered biologically inactive by appropriate methods before disposal outside the facility, consistent with the institutional policy on the disposal of any biohazardous agents ([Biohazardous Waste Disposal Guide](#)) and proper disposal procedures as outlined in the *NIH Guidelines* and Biosafety in Microbiological and Biomedical Laboratories.
- iii. It is the policy of the Dartmouth College Institutional Biosafety Committee (IBC) that all procurement, storage, and research involving genetically altered organisms must receive approval from the IBC prior to commencement.

III. DEFINITIONS

Risk Group 1 (RG-1) Organism: According to *NIH Guidelines* Appendix B-I: “RG-1 agents are those that are not associated with disease in healthy adult humans.” These organisms pose a low individual risk and a low community risk to human health. These organisms are handled at Biosafety Level 1 (BSL-1).

Transgenic Organism: The generation of an organism in which the organism’s genome has been altered by either introduction of recombinant or synthetic nucleic acid molecules into, or by deletion of sequence from, the germ-line. Examples of RG-1 organisms include (but are not limited to) the following. Please note that vertebrate animals and plants are covered separately under IBC Policies #310 and 320, respectively.

- *Drosophila melanogaster*
- *E. coli* K12, DH5α
- *Bacillus subtilis*
- Yeast (*Saccharomyces*)
- *C. elegans*
- *Chlamydomonas*
- *Ashbya gossypii*
- *Pseudomonas fluorescens*
- *Aspergillus niger*
- *Neurospora crassa*



IV. RESPONSIBILITIES

- i. All personnel working with transgenic/genetically altered organisms in Dartmouth research and teaching labs are responsible for adherence to this policy.
- ii. All Dartmouth College/Geisel School of Medicine Principal Investigators (PIs) must comply with the *NIH Guidelines* regardless of funding source. Failure to follow *NIH Guidelines* can result in the suspension, limitation, or termination of NIH funds for all recombinant or synthetic DNA research at the College.
- iii. The PI is responsible for reporting the inadvertent release of transgenic organisms, improper disposal of transgenic organisms or other incidents in the laboratory to the Biosafety Officer, who shall report them to the IBC, EHS Director, and to the NIH, if deemed necessary. Please see below for reporting procedures.
- iv. The PI is responsible for training students, teaching assistants, and lab staff about the policies and procedures for transgenic animal handling and appropriate carcass disposal.

V. PROCEDURES

A. Approvals

- i. Research (internal and extramural funding) activities that are conducted with the goal of producing transgenic organisms by use of recombinant DNA technologies, as described in the *NIH Guidelines*, must be reviewed and approved by the Institutional Biosafety Committee (IBC).
- ii. Projects involving the use of transgenic organisms that have already been created do not need to be registered with IBC, but these organisms still need to be disposed of by the procedures outlined below.
- iii. Although some projects will qualify as exempt from the *NIH Guidelines*, all projects that involve the creation of transgenic organisms must be registered with the IBC. In very rare cases, the project may need to be referred to the NIH Office of Biotechnology Activity for federal review.

B. Transportation of Transgenic Organisms on Campus

If transgenic/genetically altered organisms need to be transported outside of the laboratory to another research space, they must be securely contained within a secondary container to prevent accidental release. The container should be affixed with a biohazard label that includes the researcher's name, date, and agent name. For transport or shipping of the material outside of the facility, additional training requirements apply. Contact the Biological Safety Officer (BSO) at biosafety@dartmouth.edu for more information.

C. Disposal of Solid Wastes (solid cultures, plates, euthanized *Drosophila*)

- i. Dispose of solid waste in orange biohazard autoclave bags and securely fasten with autoclave tape.
- ii. Put in a secondary autoclave-proof container for transport and for autoclaving.



- iii. If autoclaving right away is not possible, put the bag at -20°C until autoclaving can be performed.
- iv. Autoclave at 121°C for 60 minutes.
- v. Remove autoclaved waste from the autoclave and put into the large, clear bag waste containers for custodial pickup.
- vi. Non-transgenic organisms used as controls in experiments should be disposed of as if they were transgenic.

D. Disposal option for *Drosophila* and associated materials

- i. Euthanize flies, if applicable.
- ii. Collect vials and bottles in doubled clear plastic bags in a covered bin.
- iii. When the bag is full, tie the inner bag, then tie the outer bag to seal the contents.
- iv. Use a permanent marker to write the **date and time** on the outer bag (not on the tape).
- v. Freeze the bag for AT LEAST 24 hours in a freezer used solely for this purpose.
- vi. After the bag has been in the freezer for at least 24 hours, place the bag in a large trash can for pickup.
- vii. Non-transgenic organisms used as controls in experiments should be disposed of as if they were transgenic.

E. Disposal of other RG-1 transgenic organisms (liquid cultures)

- i. Decontaminate liquid cultures for 20-30 min with a fresh dilution of 1:10 bleach or 0.5% Wescodyne (final concentrations).
- ii. Drain dispose with copious water.

VI. REPORTING AND EXPOSURE OR RELEASE

Notify the Biological Safety Officer within 24 hours via email (biosafety@dartmouth.edu) or phone (603-646-9790). The BSO will investigate the incident and consult with the IBC Chair. If it is determined that the incident involves r/sNA molecules, the BSO will submit an incident report to the NIH Office of Biotechnology Activities within 30 days.

VII. RESOURCES

- *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/>