While conducting research subject to the *NIH Guidelines*, the PI must:

- Determine the need for IBC review before modifying recombinant or synthetic nucleic acid research already approved by the IBC.
- Submit any subsequent changes (e.g., changes in the source of DNA or host-vector system) to the IBC for review and approval or disapproval.
- Remain in communication with the IBC throughout the duration of the project.
- Report any significant problems pertaining to the operation and implementation of containment practices and procedures, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the IBC, NIH OBA, and, as applicable, the Biological Safety Officer, Greenhouse or Animal Facility Director, and other appropriate authorities.

PIs conducting human gene transfer research subject to Section III-C of the *NIH Guidelines* must:

- Ensure that all aspects of Appendix M have been appropriately addressed prior to submission of a human gene transfer experiment to NIH OBA for review by the NIH Recombinant DNA Advisory Committee (RAC).
- Provide a letter signed by the PI(s) on institutional letterhead acknowledging that the documentation being submitted to NIH OBA complies with the requirements set forth in Appendix M.
- Not enroll research participants in a human gene transfer clinical trial until the RAC review process has been completed; IBC approval (from the clinical trial site) has been obtained; Institutional Review Board approval has been obtained; and all applicable regulatory authorization(s) have been obtained.
- Comply with reporting requirements for human gene transfer experiments (see Appendix M-I-C of the *NIH Guidelines*).

For more information

To receive updates on current initiatives, policies, and news from OBA, subscribe to our listserv, "OBA News," by sending a message to: listserv@list.nih.gov with the message: subscribe OBA_NEWS

Visit the following websites for additional information:

NIH Office of Biotechnology Activities
http://oba.od.nih.gov

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

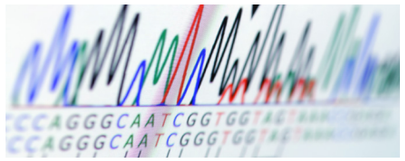
National Institutes of Health
Office of Biotechnology Activities

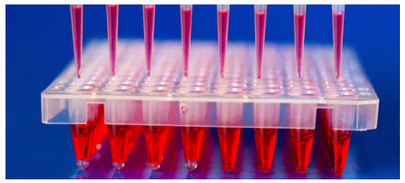
NATIONAL INSTITUTES OF HEALTH
OFFICE OF BIOTECHNOLOGY ACTIVITIES

INVESTIGATOR RESPONSIBILITIES

under the

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules





What are the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*?

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* detail procedures and practices for the containment and safe conduct of various forms of research involving recombinant and synthetic nucleic acid molecules, including research involving genetically modified plants and animals, and human gene transfer research.

Who must comply with the *NIH Guidelines*?

All institutions that receive NIH funding for research involving recombinant or synthetic nucleic acid molecules must comply with the *NIH Guidelines*. Researchers at institutions that are subject to the *NIH Guidelines* must comply with the requirements even if their own projects are not funded by NIH.

What is an Institutional Biosafety Committee?

Institutional Biosafety Committees (IBCs) provide local review and oversight of nearly all forms of research utilizing recombinant or synthetic nucleic acid molecules. They ensure that recombinant and synthetic nucleic acid research conducted at or sponsored by the institution is in compliance with the *NIH Guidelines*.

Safety and science go hand in hand.

What is the NIH Office of Biotechnology Activities?

The NIH Office of Biotechnology Activities (OBA) promotes science, safety, and ethics in biotechnology through the advancement of knowledge, enhancement of public understanding, and development of sound public policies. A core responsibility of OBA is to foster awareness of, and adherence to, the standards and practices set forth in the *NIH Guidelines*.

Principal Investigator Responsibilities

Principal Investigators (PIs) are responsible for full compliance with the *NIH Guidelines* during the conduct of research involving recombinant or synthetic nucleic acid molecules. As part of this general responsibility, the PI should:

- Be adequately trained in good microbiological techniques.
- Provide laboratory research staff with protocols describing potential biohazards and necessary precautions.
- Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents.
- Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).
- Supervise laboratory staff to ensure that the required safety practices and techniques are employed.
- Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid materials.
- Ensure the integrity of physical containment (e.g., biological safety cabinets) and biological containment (e.g., host-vector systems that preclude survival of the agent outside the laboratory).
- Comply with permit and shipping requirements for recombinant or synthetic nucleic acid molecules.
- Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination.

Before initiating research subject to the *NIH Guidelines*, the PI must:

- Determine whether the research is subject to Section III-A, III-B, III-C, III-D, or III-E of the *NIH Guidelines*.
- Propose physical and biological containment levels in accordance with the *NIH Guidelines* when registering research with the IBC.
- Propose appropriate microbiological practices and laboratory techniques to be used for the research.
- Submit a research protocol to the IBC for review and approval.
- Seek NIH OBA's determination regarding containment for experiments that require case-by-case review.
- Petition NIH OBA, with notice to the IBC, for proposed exemptions from the *NIH Guidelines*.
- Obtain IBC approval before initiating research subject to the *NIH Guidelines*.
- Seek NIH approval, in addition to IBC approval, to conduct experiments specified in Sections III-A and III-B of the *NIH Guidelines*.