

Responsibilities Under the *NIH Guidelines for Research Involving Recombinant DNA Molecules*



What are the NIH Guidelines?

- **The *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* detail procedures and practices for the containment and safe conduct of various forms of recombinant DNA research, including research involving genetically modified plants and animals, and human gene transfer.**

NIH Guidelines for Research Involving Recombinant DNA Molecules

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NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (NIH GUIDELINES)

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Visit the OBA Web site at:
<http://www4.od.nih.gov/oba>

For current information on Guidelines, Protocols, Principal Investigators, Meetings, and information about upcoming Gene Therapy Policy Conferences.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institutes of Health
Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

These NIH Guidelines supersede all earlier versions and shall be effective immediately.

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A current version of the *NIH Guidelines* is available at:

http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

What type of research is covered by the *NIH Guidelines*?

- The *NIH Guidelines* are applicable to all recombinant DNA research that is conducted at or sponsored by an institution that receives any support for recombinant DNA research from NIH
- In the context of the *NIH Guidelines*, recombinant DNA molecules are defined as either:
 - (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or
 - (ii) molecules that result from the replication of those described in (i) above.

Who must comply with the *NIH Guidelines*?

- **All institutions that receive National Institutes of Health (NIH) funding for recombinant DNA research must comply with the *NIH Guidelines*.**
- **Researchers at institutions that are subject to the *NIH Guidelines* must comply with the requirements even if their individual projects are not funded by NIH.**

Who must comply with the *NIH Guidelines*?

- Even though they are called “guidelines,” the *NIH Guidelines* are a term and condition of NIH funding for recombinant DNA research.
- If your institution is subject to the *NIH Guidelines* you must follow the requirements and adhere to the practices outlined in the document.

Non compliance with the *NIH Guidelines*

Non compliance with the *Guidelines* may result in suspension or termination of NIH funds for recombinant DNA research, or the requirement to have all recombinant DNA projects at the institution receive prior NIH approval