

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



# What are the NIH Guidelines?

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- ***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

Amendment Effective: July 26, 1994, Federal Register, August 5, 1994 (59 FR 40170)	
Amendment Effective: April 17, 1995, Federal Register, April 27, 1995 (60 FR 20126)	
Amendment Effective: December 14, 1995, Federal Register, January 19, 1996 (61 FR 1482)	
Amendment Effective: March 1, 1996, Federal Register, March 12, 1996 (61 FR 10004)	
Amendment Effective: January 23, 1997, Federal Register, January 31, 1997 (62 FR 4182)	
Amendment Effective: September 30, 1997, Federal Register, October 14, 1997 (62 FR 5333)	
Amendment Effective: October 20, 1997, Federal Register, October 29, 1997 (62 FR 5619)	
Amendment Effective: October 22, 1997, Federal Register, October 31, 1997 (62 FR 5300)	
Amendment Effective: February 4, 1998, Federal Register, February 17, 1998 (63 FR 3059)	
Amendment Effective: April 30, 1998, Federal Register, May 11, 1998 (63 FR 2018)	
Amendment Effective: April 29, 1999, Federal Register, May 11, 1999 (64 FR 2536)	
Amendment Effective: October 2, 2000, Federal Register, October 10, 2000 (65 FR 6036)	
Amendment Effective: December 28, 2000, Federal Register, January 5, 2001 (66 FR 1149)	
Amendment Effective: December 11, 2001, Federal Register, December 11, 2001 (66 FR 6405)	
Amendment Effective: December 19, 2001, Federal Register, November 19, 2001 (66 FR 5919)	
Amendment Effective: January 10, 2002, Federal Register, December 11, 2001 (66 FR 6405)	
Amendment Effective: January 24, 2002, Federal Register, November 19, 2001 (65 FR 5710)	

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

**April 2002**

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

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

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

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

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

[http://oba.od.nih.gov/rdna/nih\\_guidelines\\_oba.html](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html)

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

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- **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**