



Biological Safety

Federal Guidelines and Regulations Pertaining to Biological Science

I. National Institutes of Health Guidelines

[NIH Guidelines for Research Involving Recombinant DNA Molecules and Human Gene Transfer Research](#)

The *NIH Guidelines* (September 2009 or latest revision) apply to all research projects that involve recombinant DNA and are conducted at or sponsored by an organization that receives NIH support for recombinant DNA research.

As defined by the NIH Guidelines, recombinant DNA molecules are either

- (1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell or
- (2) molecules that result from the replication of those described in (1).

The NIH Guidelines apply to both basic and clinical research studies. Recombinant DNA research involving select agents also is subject to pertinent CDC and USDA regulations.

Specific guidance for the conduct of human gene transfer clinical trials appears in Appendix M of the NIH Guidelines.

Failure to comply with these requirements may result in suspension or termination of an award for recombinant DNA research at the organization, or a requirement for NIH prior approval of any or all recombinant DNA projects at the organization.

Two specific requirements of the NIH Guidelines are discussed below, but the grantee should carefully review the NIH Guidelines in their entirety to ensure compliance with all of the requirements for projects involving recombinant DNA techniques.

A. Institutional Biosafety Committee

Each organization that conducts research involving recombinant DNA...must have policies and procedures to ensure compliance with the NIH Guidelines and must establish a standing IBC.

The IBC is required to review each proposed project for recombinant DNA experiments and certify that the procedures, project, personnel, and facilities are adequate and in compliance with the NIH Guidelines.

B. Safety and Annual Reporting for Human Gene Transfer Clinical Trials

Appendix M-I-C-4 of the NIH Guidelines requires Serious Adverse Events (SAE) that are unexpected and are possibly associated with human gene transfer intervention to be reported to OBA and the IBC within 15 calendar days of investigator notification of the sponsor, or within 7 days if life-threatening or fatal.

Annually, investigators must submit to OBA certain information about protocols.



Further information about the content of these reports can be found in Appendix M-I-C-3 of the NIH Guidelines.

II. Public Health Security and Bioterrorism Preparedness and Response Act

P.L. 107-188 is designed to provide protection against misuse of [Select Agents and Toxins](#) whether inadvertent or the result of terrorist acts...implemented, in part, through regulations published by CDC at [42 CFR 73](#) Select Agents and Toxins.

Also, animal and plant pathogen Select Agents are covered under the regulations published by USDA-APHIS [at 9 CFR 121 and 7 CFR 331](#) (Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins).

Research involving Select Agents and recombinant DNA molecules also is subject to the NIH Guidelines for Research Involving DNA Molecules (NIH Guidelines) (see "[NIH Guidelines for Research Involving DNA Molecules and Human Gene Transfer Research](#)")

III. USA PATRIOT Act

P.L. 107-56 provides criminal penalties for possession of any biological agent, toxin, or delivery system of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose... [and] establishes restrictions on access to specified materials.

IV. Bloodborne Pathogens and Other Health and Safety Regulations and Guidelines

Grantees are responsible for meeting Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to NIH grants.

In addition to applicable Federal, State, and local laws and regulations, the following regulations must be followed when developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- **29 CFR 1910.1030, Bloodborne pathogens;**
- 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and
- Other applicable occupational health and safety standards issued by the Occupational Health and Safety Administration (OSHA) and included in 29 CFR Part 1910.

The following guidelines are recommended for use in developing and implementing health and safety operating procedures and practices for both personnel and facilities:

CDC and NIH, HHS [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#)..

Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street, NW, Lockbox 285, Washington, DC 20055 (ISBN 0-309-05229-7).