



**NIH rDNA Guidelines Training Key Points**

**1. Scope of the Guidelines:**

- a. All institutions that receive NIH funding for rDNA research must comply with Guidelines
- b. All researchers using rDNA at institutions that receive NIH funding for rDNA must comply with the Guidelines even if their individual rDNA projects are not NIH funded.
- c. The NIH can suspend, limit, or terminate funding for an institution that is not in compliance

**2. Principal Investigator Responsibilities include:**

- a. Instruct staff in practices required to ensure safety and procedures for dealing with accidents.
- b. Supervise safety performance of staff to ensure they are working safely.
- c. Correct work errors and conditions that may cause release of rDNA materials.
- d. Report incidents involving rDNA to the Biosafety Officer.

**3. Reporting Requirements**

- a. The following incidents involving rDNA must be reported to the NIH:
  - i. Splash to eyes, nose, mouth, or a needlestick
  - ii. Missing transgenic animals or cultures of recombinant organisms
  - iii. Illness related to recombinant agents in the lab
- b. Immediate reporting:
  - i. Overt exposure to RG2 or RG3 agents
  - ii. Potential exposure to RG3 agents
- c. Reporting within 30 days:
  - i. Significant problems, violations of the Guidelines, or significant research-related accidents and illnesses
- d. No reporting necessary:
  - i. Minor spills of low-risk agents not involving a breach of containment that were properly cleaned and decontaminated

**4. Review Required**

<b>Experiments</b>	<b>Required Review</b>
Transfer of drug resistance that affects disease control	IBC, RAC, and NIH Director
Cloning toxin molecules with LD50 < 100 ng/Kg body weight	IBC and NIH
Transfer of rDNA into human subjects	RAC, IBC, and IRB
a) Testing viable rDNA modified microorganisms in whole animals where BL2 containment or greater is necessary b) Generating transgenic animals where BL2 containment or greater is necessary c) Large scale rDNA production	IBC approval before initiation of experiment
Generating transgenic rodents that require BL1 containment	IBC notice at initiation

**5. NIH Risk Group examples**

RG1	ecotropic avian sarcoma virus
RG2	amphotropic murine leukemia virus, human adenoviruses, human herpesviruses, influenza viruses types A, B, and C
RG3	<i>Mycobacterium tuberculosis</i> , <i>Francisella tularensis</i>
RG4	Herpes B Virus ( <i>Herpesvirus simiae</i> )