

# The University of Texas Health Science Center at Houston Principal Investigator Responsibilities for the Use of Recombinant DNA

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*NIH Guidelines for Research Involving Recombinant DNA Molecules*  
(NIH Guidelines)  
Revised April 2002

<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

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**Purpose:** The purpose of the *NIH Guidelines* is to specify practices for constructing and handling recombinant deoxyribonucleic acid (rDNA) molecules and organisms containing rDNA molecules.

**Definition:** In the context of the *NIH Guidelines*, rDNA molecules are defined as 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 molecules that result from the replication of those previously described.

**Applicability:** As a condition for NIH funding of rDNA research, institutions shall ensure that such research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with the *NIH Guidelines*.

**Principal Investigator Responsibilities:** For responsibilities of the PI please see Section IV-B-7 of the *NIH Guidelines* ([http://www4.od.nih.gov/oba/rac/guidelines\\_02/NIH\\_Guidelines\\_Apr\\_02.htm#\\_Toc7261589](http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261589))

**Experiments Covered by the *NIH Guidelines*:**

**Section III-A** Deliberate transfer of drug resistance to microorganisms that results in compromise of drug use to control disease agents in humans, veterinary medicine, or agriculture.

Requires: Institutional Biosafety Committee (IBC) Approval, Recombinant DNA Advisory Committee (RAC) Review, NIH Director Approval Before Initiation

**Section III-B** Deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD<sub>50</sub> of less than 100 ng/kg body weight.

Requires: IBC & NIH/Office of Biotechnology Activities (NIH/OBA) Approval Before Initiation

**Section III-C** Deliberate transfer of rDNA, or DNA or RNA derived from rDNA, into human research participants (human gene transfer).

Requires: IBC and Institutional Review Board (IRB) Approval, RAC Review Before Research Participant Enrollment

**Section III-D** Use of Risk Group 2, 3, or 4 agents as host-vector systems; DNA from Risk Group 2, 3, or 4 agent inserted into nonpathogenic prokaryotic or eukaryotic host-vector system; Use of infectious or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems; Experiments involving whole animals and plants; Experiments involving more than 10L of culture.

Requires: IBC Approval Before Initiation

**Section III-E** Formation of rDNA with no more than two-thirds of the genome of any eukaryotic virus; Experiments involving transgenic rodents

Requires: IBC Notice Simultaneous with Initiation

**Section III-F** Exempt experiments. Examples include the use of *Escherichia coli K-12* host-vector systems, *Saccharomyces* host-vector systems, purchase or transfer of transgenic rodents, etc.

Please contact Environmental Health & Safety (713-500-8100) for assistance in classifying your rDNA work.

**Institutional Biosafety Committee:** The Institutional Biosafety Committee meets on the first Thursday of every month. Meetings are open to the public, but location and times may vary. The committee is comprised of UTHSC-H faculty, staff, and students, as well as several community interest members. Please contact Environmental Health & Safety (713-500-8100) for further scheduling information or to obtain committee meeting minutes.

**Reporting Laboratory Incidents Involving rDNA or Noncompliance with the NIH Guidelines:** Any significant problems, significant research-related accidents or illnesses involving rDNA, or noncompliance with the *NIH Guidelines* may be brought forward by any person, and should be promptly reported to EHS for investigation and reporting of the incident to the NIH/OBA and the Institutional Biosafety Committee if required.

UTHSC-H must report any significant problems or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the appropriate institutional official and the NIH/OBA within 30 days. Examples include needlesticks containing recombinant DNA, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant materials occurring outside of a biosafety cabinet. Spills and accidents which result in overt exposures to risk group 2 (RG2) organisms or overt or potential exposures to risk group 3 (RG3) organisms containing recombinant DNA molecules must be immediately reported to EHS for investigation and reporting of the incident to the NIH/OBA and the Institutional Biosafety Committee if required. Medical evaluation, surveillance, and treatment will be provided as appropriate and written records will be maintained.

- Environmental Health & Safety (Main line, 713-500-8100)  
Biological Safety Program (After hours, 713-500-5832)  
(713-500-4193)
- National Institutes of Health  
Office of Biotechnology Activities  
<http://www4.od.nih.gov/oba/>
- Institutional Biosafety Committee Chair
- Animal Facility Director