



UTHealth Institutional Biosafety Committee (IBC)

Title: Principal Investigator Responsibilities for the Use of Recombinant or Synthetic Nucleic Acid Molecules Section: Biological Safety

IBC Approval Date: February 2016 Revision Date: April 9, 2024

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
(NIH Guidelines)
Revised April 2024

<https://osp.od.nih.gov/policies/biosafetyandbiosecuritypolicy#tab2/>

Purpose: The purpose of the NIH Guidelines is to specify practices for constructing and handling recombinant or synthetic nucleic acid molecules (rDNA or sNA) and organisms containing recombinant or synthetic nucleic acid molecules

Definition: In the context of the NIH Guidelines, recombinant and synthetic nucleic acid molecules are defined as

- 1) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell (i.e., recombinant nucleic acids)
- 2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids
- 3) molecules that result from the replication of those previously described.

Applicability: As a condition for NIH funding of rDNA and sNA 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 B17 of the NIH Guidelines

Experiments Covered by the NIH Guidelines

Section IIIA: Deliberate transfer of drug resistance to microorganisms that results in compromise of drug use to control disease agents in humans, veterinary medicine, or agriculture (A20)(2)(i)-(j), 50 CFR 121.21

Section IIIB: Deliberate formation of rDNA or sNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD₅₀ of less than 100 ng/kg body weight
Requires IBC and NIH/Office of Science Policy (NIH/OSP) Approval Before Initiation

Section III-C:

