UTHealth
The University of Texas
Health Science Center at Houston

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: September 9, 2021

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
(NIH Guidelines)
Revised April 2019

https://osp.od.nih.gov/biotechnology/nih-guidelines/

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); or
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 IV-B-7 of the *NIH Guidelines*

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 and NIH Director Approval Before Initiation

Section III-B: Deliberate formation of rDNA or sNA containing genes for the biosynthesis of toxin

molecules lethal for vertebrates at an LD_{50} of less than 100 ng/kg body weight.
Requires: IBC and NIH/Office of Science Policy (NIH/OSP) Approval Before Initiation

Section III-C: Deliberate transfer of rDNA or sNA, or DNA or RNA derived from rDNA or sNA, into human research participants (human gene transfer).
Requires: IBC and Institutional Review Board (IRB) Approval, 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 non-pathogenic 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; Experiments involving influenza viruses.
Requires: IBC Approval Before Initiation

Section III-E: Formation of rDNA or sNA 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 (IBC) meets on the second Thursday of every month. Meetings are open to the public, but location and times may vary. The committee is comprised of UTHealth faculty, staff, and students, as well as 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 sNA, 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/OSP and the Institutional Biosafety Committee if required.

UTHealth 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/OSP within 30 days. Examples include needlesticks containing recombinant DNA, the escape or improper disposal 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/OSP 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; after hours, 713-500-5832
- Biological Safety Program Main number, 713-500-8170
- National Institutes of Health
  Office of Science Policy
  Biosafety, Biosecurity, and Emerging Biotechnology Policy Division
  https://osp.od.nih.gov/biotechnology/
  6705 Rockledge Drive, Suite 750, MSC 7985
  Bethesda, MD 20892-7985
  Phone: (301)496-9838
  Fax: (301)496-9839

For further information, please contact Environmental Health & Safety at 713-500-8100 or visit our website at https://www.uth.edu/safety/biological-safety/index.htm.

This policy has been reviewed and approved by the Institutional Biosafety Committee.

X

Institutional Biosafety Committee Chair