

Title: Policy on Research Involving Recombinant or Synthetic Nucleic Acid Molecules	Policy Category: Research
Issuing Authority: Vice President for Research	Responsibility: Office of Research Compliance
Publication Date: 07/10/2024	Next Review Date: 07/10/2027

Printed copies are for reference only. Please refer to the [electronic copy](#) for the latest version.

Policy Statement/Background:

National Institutes of Health policy (found [here](#)) allows research involving recombinant or synthetic nucleic acid molecules, *regardless of the source of funding*.

Policy:

Stony Brook University allows research involving recombinant or synthetic nucleic acid molecules in accordance with this policy. Research covered under this policy includes the following:

- **Recombinant nucleic acid molecules which** are constructed by joining nucleic acid molecules **and** can replicate in a living cell.
- **Synthetic nucleic acid molecules which** 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. Molecules that result from the replication of those described in bullet points (1) or (2) above.
- Human gene transfer research or the deliberate transfer into human research participants of either:
 - Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or

- Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:
 - Contain more than 100 nucleotides; or
 - Possess biological properties that enable integration into the genome (e.g., *cis* elements involved in integration); or
 - Have the potential to replicate in a cell; or
 - Can be translated or transcribed.

Research that meets the criteria for review in the regulations referred to above must be submitted to and approved by the Institutional Biosafety Committee (IBC) prior to initiation of the study.

Institutional Biosafety Committee (IBC)

The Institutional Biosafety Committee (IBC) is a campus committee administered by the Office of Research Compliance, within the Office of the Vice President for Research, in compliance with the requirements of the NIH Guidelines. The Institutional Official responsible for oversight of the IBC is the Vice President for Research (VPR), who delegates this responsibility to the Assistant Vice President for Research Compliance.

The responsibilities of the Institutional Biosafety Committee include the review of recombinant or synthetic nucleic acid molecule (rsNAM) research. This review includes an assessment of:

- Containment levels required by the *NIH Guidelines* for the proposed research;
- Facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acid molecule research;
- Recombinant or synthetic nucleic acid molecule research involving human research participants, assessment is focused on biosafety issues (e.g., administration, shedding).

The Institutional Biosafety Committee has adopted operating procedures to implement this policy (available [here](#)). These procedures serve as the governing procedures for the conduct and review of radioactive drug research carried out under the auspices of the University in conjunction with all other federal and state guidelines and institutional policies, as applicable.

Definitions:

None

Contact:

Additional information about this policy is available here:

Office of Research Compliance

W5530, Frank Melville Jr. Memorial Library

Stony Brook, NY 11794-3368

Phone: (631) 632-9036

Fax: (631) 632-9839

<https://www.stonybrook.edu/commcms/research-compliance/index.php>

Relevant Standards, Codes, Rules, Regulations, Statutes and Policies:

- [National Institutes of Health Office of Science Policy – Biosafety Guidance](#)
- [Center for Disease Control and Prevention – Biosafety Resources and Tools](#)
- [Stony Brook Institutional Biosafety Committee – Standard Operating Procedures](#)