**Research and Teaching Involving UPPS No. 04.05.17**

**Recombinant or Synthetic Nucleic Issue No. 1**

**Acid Molecules and Biohazardous Effective Date: 06/21/2021**

**Materials, Agents, and Toxins Next Review Date: 09/01/2026 (E5Y)**

**Sr. Reviewer: Assistant Vice President for Research and Sponsored Programs**

**POLICY STATEMENT**

*Texas State University is committed to providing students with a safe environment for research and teaching.*

**01. DEFINITIONS**

01.01 Biohazardous Materials, Agents, and Toxins – infectious biological or synthetic agents, biologically derived materials, and toxins that present a risk or potential risk to the health of humans, animals, or plants either directly through exposure or infection or indirectly through damage to the environment.

01.02 Biosafety in Microbiological and Biomedical Laboratories (BMBL) – manual published jointly by the National Institutes of Health (NIH) and the Center for Disease Control and Prevention (CDC) that contains guidelines for microbiological practices, safety equipment, and facilities that constitute the four established biosafety levels (BSL). The BMBL is generally considered the standard for biosafety.

01.03 Institutional Biosafety Committee (IBC) – under NIH guidelines, IBCs were established to provide local review and oversight of all aspects of research that plan to utilize recombinant or synthetic nucleic acid molecules. At the discretion of the institution, this oversight may also expand to research that involves infectious biological material or other potentially hazardous agents (e.g., carcinogens, mutagens, etc.).

01.04 Institutional Official (IO) – an individual who signs, and has the authority to sign, Texas State Univeristy’s assurance, making a commitment on behalf of Texas State that the requirements of the United States Public Health Service (USPHS) and the United States’ Department of Agriculture (USDA) policy are met. The institutional official is the assistant vice president for Research and Sponsored Programs.

01.05 Institutional Biosafety Officer (BSO) – an individual who provides expert technical consultation and is responsible for developing, implementing, coordinating, and maintaining a comprehensive biosafety, biocontainment, and biosecurity management program for all units of Texas State, including regional campuses, to ensure compliance with appropriate regulatory requirements for research and teaching laboratories

01.06 Investigator – the researcher, faculty, or staff member with primary responsibility for the education, research, research training, experimentation, or other activities involving recombinant DNA (rDNA) and biohazardous materials, agents, and toxins.

01.07 NIH Guidelines – detail safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules.

01.08 Principal Investigator (PI) – the head researcher responsible for the management, preparation, and conduct of a research grant and maintaining the integrity of collaborative works. Additionally, the PI is responsible for assuring that research is conducted in accordance with the institutions policies and procedures and federal regulations.

01.09 Recombinant or Synthetic Nucleic Acid Molecules – In the context of the NIH guidelines, recombinant and synthetic nucleic acid molecules are defined as:

a. molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell (i.e., recombinant nucleic acids);

b. 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

c. molecules that result from the replication of those described in a. or b.

 above. Synthetic nucleic acid molecule segments that are likely to yield apotentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered equivalent to their natural DNA counterpart.

01.10 Biosafety Manual – a manual that provides Texas State with university-wide safety guidelines for employees working with rDNA and biological materials, agents, and toxins.

01.11 Section III-F of the [NIH guidelines](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf#page=27) outlines recombinant or synthetic nucleic acid molecules that are exempt from the NIH guidelines and for which registration with the IBC is not required; however, other federal and state standards of biosafety may still apply to such research.

**02.** **RESEARCH AND EDUCATION INVOLVING THE USE OF RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES AND BIOHAZARD MATERIALS, AGENTS, AND TOXINS**

02.01 Under the authority of The Office of the Provost and Vice President for Academic Affairs, Texas State has established an IBC charged with oversight responsibilities for all research-related activities involving use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins.

02.02 Oversight of the IBC is the responsibility of the IO, with administrative support provided by Research Integrity and Compliance (RIC).

02.03 Additional support of the IBC is provided by the Environmental Health, Safety, and Risk Management (EHSRM) office, which consults with researchers, assesses risks, inspects labs, and arranges for ongoing remediation of environmental and occupational safety hazards related to research under review by the committee.

02.04 Texas State is committed to maintaining the highest possible standards for research and education involving the safe use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins and endorses as its own the following federal guidelines:

a. the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf);

b. the [CDC BMBL](https://www.cdc.gov/labs/BMBL.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fbiosafety%2Fpublications%2Fbmbl5%2Findex.htm);

c. the [U.S. Department of Health and Human Services and USDA Rules for the Possession, Use, and Transfer of Select Agents and Toxins 42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121](https://www.selectagents.gov/regulations/); and

d. the [CDC and USDA Federal Select Agent Program (42 CFR Part 73)](http://www.cdc.gov/od/sap/).

02.05 As a condition for receiving funding from the NIH, institutions must ensure that all research conducted at the institution complies with the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules from NIH’s Office of Science Policy (OSP)](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf). Texas State hereby gives assurance that it complies with OSP. OSP is applicable to all research, research training, experimentation, biological testing, instructional, and related activities involving recombinant or synthetic nucleic acid molecules conducted at Texas State or at another institution as a consequence of the sub-granting or subcontracting of a supported activity by Texas State.

 Additionally, Texas State is committed to ensuring research and education involving the use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins are compliant with the [Texas State Biosafety Manual](https://gato-docs.its.txstate.edu/jcr%3A92d280a9-9b48-4d5e-9c27-cd2e32172a5a/BioManual-IBC.pdf), the [BMBL](https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2020-P.pdf), and [any other pertinent regulations](https://osp.od.nih.gov/biotechnology/biosafety-guidance-and-resources/).

02.06 Texas State, including its researchers, faculty, students, and staff, accepts responsibility for determining that research and education involving the use of recombinant or synthetic nucleic molecules and biohazardous materials, agents, and toxins meet the standards of, and fulfills the principles outlined in, the aforementioned documents.

02.07 The purpose of this university policy is to establish and standardize compliance procedures concerning the safe use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins for education and research purposes by Texas State.

02.08 The policy set forth in this document will be updated as needed to comply with changes in federal laws regulations.

**03. INSTITUTIONAL** **RESPONSIBILITIES AND AUTHORITY**

03.01 The IO has assigned the IBC the responsibility of reviewing, approving, and providing oversight and guidance to research personnel who seek to use recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins in research or teaching.

03.02 IBC members, the IBC chair, and BSO will be appointed by the IO.

03.03 One voting member of the IBC should be from EHSRM. Additionally, this individual will serve as BSO.

**04. INSTITUTIONAL BIOSAFETY COMMITTEE RESPONSIBILITIES**

04.01 The responsibility of the IBC is to review, approve, and provide oversight and guidance to those individuals at the university who seek to use rDNA and biohazardous materials, agents, and toxins in research or teaching. Any possession or use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins at the university must be conducted with appropriate safeguards and in accordance with university policies and federal guidelines and regulations.

04.02 The IBC will be collectively capable of assessing the risks to laboratory personnel, the public, or the environment of research or teaching activities involving rDNA and biohazardous materias, agents, and toxins. The IBC should consist of of persons with experience and expertise in recombinant or synthetic nucleic acid technology, biological safety, and physical containment.

04.03 The IBC will notify the PI of the results of the IBC's review, approval, or disapproval.

04.04 The IBC will make final determination of physical and biological containment for recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins research and will modify containment levels as necessary. The IBC will only approve research conducted at laboratories at a BSL-1 or BSL-2 category.

04.05 The IBC will assess the facilities, procedures, practices, training, and expertise of personnel involved in research utilizing recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins.

04.06 The IBC will review and report any significant problems, violations of NIH guidelines, and any significant research-related accidents or illnesses to the IO and to the NIH and OSP per NIH guidelines.

04.07 The IBC will be directly involved in the development of appropriate procedures as required by NIH, OSP, CDC, and USDA regulations to oversee the possession or use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins.

04.08 The IBC has the authority to suspend or terminate protocol approval for the possession or use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins where the IBC finds noncompliance, or that such use or possession poses undue risk to research personnel, or that it poses a threat to the health and safety of the community.

04.09 The IBC will periodically review IBC policies and procedures and will modify them as necessary to ensure appropriate biosafety measures and adherence with federal and state requirements.

04.10 The IBC is only authorized to approve research protocols and laboratories at a BSL-1 or BSL-2 category.

**05. PRINCIPAL INVESTIGATOR AND INSTRUCTOR RESPONSIBILITIES**

05.01 PIs who wish to perform research using biological materials must [submit an application](https://gato-docs.its.txstate.edu/jcr%3Aa298a3bd-d3c7-45e8-b224-dbf01bfabb19) to the IBC.

05.02 PIs and instructors are responsible for activities conducted within their respective laboratories or research facilities, carrying out all activities in accordance with IBC approved protocols and in a lab approved for the proposed work, for promptly reporting biohazard incidents to the IBC Chair and EHSRM, and if possible, assisting in any decontamination, inquiry, and reporting of incidents, as may be required.

05.03 PIs and instructors are ultimately responsible for the instruction and training provided to all staff and students engaged in potentially biohazardous activities. This includes ensuring all lab personnel complete training outlined in Section 06.01.

05.04 PIs and instructors are responsible for supervising laboratory staff and students to ensure that appropriate safety techniques and procedures are employed.

**06. TRAINING REQUIREMENTS**

06.01 Training is required for all personnel working with recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins. Courses can be registered through EHSRM and will be completed on CANVAS. EHSRM will designate the appropriate courses according to the biosafety level labs designated. Completion of courses is a requirement for the approval of new and continuing IBC protocols.

06.02 All IBC members will complete and receive initial training regarding IBC policies.

06.03 PIs should maintain a record of all required training for lab personnel involved in research activities.

**07. REVIEWERS OF THIS UPPS**

 07.01 Reviewers of this UPPS include the following:

 Position Date

Assistant Vice President for Sept 1 E5Y

Research and Sponsored

Programs

Director, Research Integrity Sept 1 E5Y

and Compliance

Director, Environmental Health Sept 1 E5Y

Safety, and Risk Management

Chair, Institutional Biosafety Sept 1 E5Y

Committee

**08. CERTIFICATION STATEMENT**

This UPPS has been approved by the following individuals in their official capacities and represents Texas State policy and procedure from the date of this document until superseded.

Assistant Vice President for Research and Federal Relations; senior reviewer of this UPPS

Associate Vice President for Research and Federal Relations

Provost and Vice President for Academic Affairs

President