

IBC SOP:	Statement on Institutional Biosafety Committee	
SOP#100.00	IBC Approval: 6/26/2024	IO Approval: 6/27/2024

1.0 Introduction

Texas A&M University – San Antonio (A&M-SA) is committed to the safety of students, faculty, staff, the community at large, and the environment through oversight of teaching and research activities involving the use of potentially hazardous biological materials and biological toxic materials.

1.1 Purpose of the IBC

The purpose of the A&M-SA Institutional Biosafety Committee (IBC) is to review and approve research and teaching activities with recombinant or synthetic nucleic acid molecules (r/sNA) and other hazardous biological agents, materials or biological toxins being conducted at or sponsored by A&M-SA. Principal investigators (PIs) and/or laboratory teaching faculty at A&M-SA who either store or conduct research or teaching activities involving potentially biohazardous materials or biological toxins must obtain approval from the IBC prior to beginning work. See [SOP 200.00](#) for guidance on IBC membership, [SOP 300.00](#) for guidance on Roles and Responsibilities and [SOP 400.00](#) for guidance on protocol submission & Review.

1.2 Authority

Institutions that receive support from the National Institutes of Health (NIH) for r/sNA research are required to establish and register an IBC with the NIH Office of Science Policy (OSP) in compliance with the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules \(NIH Guidelines\)](#). The NIH requires all institutions receiving federal research funds to have all the r/sNA research conducted at that institution reviewed by the IBC regardless of whether that research is directly supported by the NIH or not. If research is conducted without approval, the NIH has the authority to withdraw research support for that project, the laboratory, or the entire university.

The A&M-SA IBC has been established in compliance with the above requirements.

1.3 Scope

The scope of the Texas A&M-SA IBC oversight includes any activities involving: collection and/or use (in field or on university property), receipt, storage, transfer, or disposal of known or potentially biohazardous agents, materials or biological toxins including r/sNA molecules that may potentially pose a risk to humans, animals, public health and/or the environment. Research involving Gene Drive Modified Organisms [GDMO] may require risk assessments that incorporate a broader scope of considerations because of greater uncertainty of the technology and potential uncertainty of the impact of the newly modified organism.

The activities encompass research and teaching conducted by faculty, staff, students, and others under the jurisdiction of A&M-SA. The A&M-SA IBC oversight includes activities conducted on Texas A&M-SA campus, facilities, or property or conducted by A&M-SA Investigators off-site. Activities may be funded or not funded.

Per the system regulation 15.99.06, all studies conducted at TAMUSA by their faculty, staff, or students, irrespective of the source of funding require IBC approval.

- [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#), most current edition, developed by the Center for Disease Control (CDC) and the National Institutes of Health (NIH).
- [Pathogen Safety Data Sheets](#) produced by the Public Health Agency of Canada (PHAC)



1.4 Work Requiring Review and Approval from the IBC Prior to Starting Work

Research or teaching activities that use any of the materials listed below must receive approval from the IBC prior to starting work: **Recombinant/synthetic nucleic acid molecules**, as covered by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf. Approved protocols are subject to Post Approval Monitoring. [See SOP 700.00](#) for details.

This includes but is not limited to:

- **Infectious agents** (viruses, bacteria, fungi, parasites, prions, etc.) that can cause diseases in healthy humans and/or has significant environmental or agricultural impacts, as covered by the Biosafety in Microbiological and biomedical laboratories (BMBL) guidelines. <https://www.cdc.gov/labs/BMBL.html>
- **Human materials** (including all fluids, tissues, excretions, secretions, or cell lines) as covered by the Texas Department of State Health Services (DSHS), Bloodborne Pathogen Control Rule Texas Administrative Code Title 25 Part 1 Chapter 96, [https://texreg.sos.state.tx.us/public/readtac\\$ext.ViewTAC?tac_view=4&ti=25&pt=1&ch=96&rl=Y](https://texreg.sos.state.tx.us/public/readtac$ext.ViewTAC?tac_view=4&ti=25&pt=1&ch=96&rl=Y)
Texas Health & Safety Code, Chapter 81, Subchapter H. <https://statutes.capitol.texas.gov/Docs/HS/htm/HS.81.htm>
- **Nonhuman primate materials** (including live animals, all fluids, tissues, excretions, secretions, or cell lines) as covered by the BMBL and DSHS Bloodborne Pathogen Standard
- **Genetically Modified Organisms [GMO]** as covered by NIH guidelines https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf
- **Gene Drive Modified Organisms [GDMO]**
- **Regulated plant pest or pathogens** as covered by USDA-APHIS https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/SA_Regulations
- **Biological select agents and toxins** A&M-SA currently does not work with any select agents as defined by HHS and USDA guidelines. Before embarking on any research involving such agents, A&M-SA will have a certificate of registration for Select Agents and Select Agent Toxins with the Federal Select Agent Program for the possession, use, receipt, or transfer of listed select agents or select agent toxins. For more information visit <http://www.cdc.gov/od/sap/>

This list is not exhaustive. Please contact ibc@tamusa.edu with further questions.

1.5 Student Research

Research conducted by students that involves biological materials, toxins is covered under IBC purview. Dissertation, thesis, or other research projects, must be supervised by a faculty PI and applications for proposed research activities must be submitted to the IBC for review. IBC review and final approval shall take place during the proposal stage of the dissertation or thesis research. All students and staff need to be trained as outlined in [SOP 900.00](#).

1.6 Research Requiring Review by Other Texas A&M-SA Committees (IACUC, IRB)

No work can be undertaken until all other relevant committee approvals have been obtained. See [SOP 400.00](#) for guidance on protocol submission.

1.7 Occupational Health Program

The A&M-SA Occupational Health Program (OHP) provides occupational health services to personnel at risk of exposure to animals or infectious biohazards (BSL-2 and higher) in the course of their participation in IBC, IRB or IACUC permitted research, teaching, or diagnostic activities. The OHP provides eligible participants with access to educational resources, occupational health services, and to an occupational health provider. Specifically, the OHP addresses exposure to the following:

1. Biohazardous materials handled in IBC permitted research, teaching, or diagnostic laboratories at BSL-2 or higher including:
 - Human pathogens or zoonotic pathogens of animals;
 - Materials potentially containing human pathogens (e.g. human or non-human primate blood, body fluids, unfixed tissues, or cell lines- including commercially available lines);
 - Recombinant or synthetic nucleic acid molecules and cells, organisms, and viruses containing such molecules; and
 - Biological select agents and toxins.
 - Gene Drive Modified Organisms
2. Animals, or their tissues, body fluids, or waste

Contact the Research and Academic Environmental Health & Safety (RAEHS) Office (210.784.2822), vpantusa@tamusa.edu for more information.

1.8 A&M-SA Laboratory Specific Biosafety Plan

The A&M-SA Biosafety Plan is intended as a resource for information, guidelines, policies, and procedures that will enable and encourage those working in the laboratory environment to work safely and to eliminate, or reduce, the potential for exposure to biological hazards. The information presented also reflects the requirements and guidelines of federal and state regulations. It is intended that the PI and supervisory personnel will supplement this information with instruction and guidance regarding specific practices and procedures unique to the work being conducted in their laboratories/under their supervision. The most current version of the Plan is available on-line on the RAEHS website at <https://www.tamusa.edu/graduate-studies-research/research/research-academic-environmental-health-safety-office/index.html> . See [SOP 900.00](#) for training requirements.

1.9 Addition of a New Funded Project to an Approved Protocol

The IBC approval letter is not specific to a particular grant and therefore, there is no need to submit multiple applications for different grants that fund the same research. When a new grant is funded, an amendment to the existing approved IBC letter should be made to add the new source of funding and any new work involving biohazardous materials resulting from the approved grant. The amendment form should describe any new materials and any changes in research activities involving those materials. New or revised standard operating procedures (SOPs) or biohazardous agent reference documents (BARs) also must be submitted for review and approval. Protocol/Grant comparison will be performed by the DRC. [See SOP 1000.00](#) for information regarding recordkeeping and retention.

1.10 Biosecurity and Export Control

The security of biological materials is of significant concern and importance. In addition to the standard IBC approval, export or import of biological agents will also need the approval of the Exports Control Officer Dr. Rani Muthukrishnan (rmuthukrishnan@tamusa.edu).

History:

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