

ASU FACT SHEET

Experiments Involving Recombinant or Synthetic Nucleic Acid Molecules

Introduction

The National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regulates the use of recombinant and synthetic nucleic acid (r/sNA) molecules in government-sponsored research and teaching activities in the United States. The NIH OBA developed the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) in the 1970s in response to scientists' concerns about the dangers of creating recombinant and synthetic organisms. It has been revised and updated many times but is still the standard for classifying r/sNA molecule experiments. The classification is primarily based on potential hazards of organisms expressing r/sNA molecules and the appropriate containment for those organisms. NIH requires that any institution receiving government funding comply with the NIH Guidelines for all r/sNA molecule research. All work with r/sNA molecules at ASU must be approved by the [Institutional Biosafety Committee](#) (IBC).

Applicable ASU Policies

[EHS 112](#) - Biosafety and the Possession, Use, and Transfer of Select Agents and Toxins

[EHS 406](#) - Shipping and Receiving Hazardous Materials

ASU Guidelines

[Biosafety Manual](#)

[Biological Hazardous Waste Handling Procedures](#)

Laboratory-specific biosafety standard operating procedures (SOPs); EH&S has a [template](#) that may be used to create SOPs.

Regulations

[Biosafety in Microbiological and Biomedical Laboratories](#) (CDC/NIH)

[Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#) (NIH)

Summary of Requirements

IBC registration and approval of all work with r/sNA molecules is required. The containment level for work with r/sNA molecules is determined by IBC based on a risk assessment and recommendations in the BMBL and NIH Guidelines. Compliance is a condition for funding, regardless of the source. The Principal Investigator must complete and submit an IBC disclosure for all experiments involving genetically engineered organisms, including those exempt from the NIH Guidelines.

Biosafety Training

ASU Biosafety Training must be taken prior to initial work with biohazardous materials and then at least every four years thereafter. More frequent training may be required if there are any significant findings during an inspection, after an accident or injury involving biohazards, when biosafety procedures or policies change, or after an adverse event in the laboratory. The ASU Biosafety Training is available through ASU Blackboard.

Recombinant and Synthetic Nucleic Acid Molecules Training

The Recombinant and Synthetic Nucleic Acid Molecules Training is included in the ASU Biosafety Training or is available as standalone training in Blackboard. The Recombinant and Synthetic Nucleic Acid Training must be taken prior to working with r/sNA molecules.

Reporting

The Principal Investigator must report all research-related accidents or illnesses to Biosafety & Biosecurity and the IBC. The IBC is responsible for reporting any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to NIH within 30 days unless the IBC determines that a report has already been filed by the Principal Investigator.

It is highly recommended that post-exposure treatment be started as soon as possible following an exposure incident. If an exposure occurs, the individual should immediately go to ASU Health Service. If ASU Health is closed, follow-up care may be obtained at the nearest emergency room and reported to ASU Health Service and Biosafety & Biosecurity the next business day.

Records

The ASU Office for Research Integrity and Assurance maintains records of registrations approved by the IBC. Training records must be kept for 3 years.