

EXPERIMENTS INVOLVING RECOMBINANT DNA

Introduction

The *National Institutes of Health Guidelines for Experiments Involving Recombinant DNA Molecules (NIH Guidelines)* was published in the 1970s in response to scientists' concerns about the dangers of creating recombinant organisms. It has been revised and updated many times but is still the standard for classifying recombinant DNA (rDNA) experiments. The classification is based on potential hazards of organisms expressing rDNA and the appropriate containment for those organisms. All work with rDNA 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 405 - Shipping and Receiving Hazardous Materials

Applicable ASU Guidelines

- Biosafety Manual
- Lab-specific standard operating procedures (SOPs) are required; EH&S has a template on the [Biosafety website](#) that can be used to generate SOPs.

Applicable Regulations

- NIH Guidelines for Research Involving Recombinant DNA Molecules

Summary of Requirements

- ASU policy requires registration of all experiments involving genetically engineered organisms, including those exempt from the *NIH Guidelines*;
- Compliance is a condition for the university to receive any NIH funding, regardless of the source of individual project funding;
- Every institution must establish an IBC;
- The Principal Investigator completes and submits [EHS form 112AB](#) located on the ASU [Office for Research and Sponsored Projects Administration](#) website;
- Containment level for work with rDNA is determined by IBC based on a risk assessment and recommendations in the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, provided by the Centers for Disease Control and Prevention (CDC) and the NIH.

Training

The Principal Investigator (PI) provides or arranges appropriate training of all employees, students, and visitors. For experiments with rDNA only, with no infectious agents, the PI can provide training. For research involving infectious agents, Biosafety Training (provided by EH&S) is required.

Reporting

- The PI must report all research-related accidents or illnesses to EH&S 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.

- **Post-exposure treatment must be started as soon as possible following an exposure incident.** If an exposure occurs, the individual should immediately go to Campus Health Service. If Campus Health is closed, follow-up care may be obtained at the nearest emergency room and reported to Campus Health Service and EH&S the next business day.

Recordkeeping

The ASU Office for Research and Sponsored Projects Administration maintains records of registrations approved by the IBC.

Technical Contacts

Karen Kibler, Co-Assistant Director, Biosafety and Biosecurity, Biosafety Officer
Environmental Health & Safety (480) 727-0457

Shelley Jones, Co-Assistant Director, Biosafety and Biosecurity
Environmental Health & Safety (480) 965-5389

Christine Carlson, Biosafety Associate, Biosafety and Biosecurity
Environmental Health & Safety (480) 965-1344

Updated 02/09/09