

## 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

- The *NIH Guidelines* requires that a Biosafety Manual be prepared for laboratories working at the BSL2 level of containment or higher. The Department of Environmental Health & Safety ([EH&S](#)) prepared a Biosafety Manual for ASU laboratories. Lab specific standard operating procedures (SOPs) are required. [EH&S](#) has a [template](#) to generate SOPs.
- Biological Hazardous Waste Management [Compliance Guidelines](#)

### Applicable Regulations

**NIH Guidelines for Research Involving Recombinant DNA Molecules:** Though technically not a regulation, NIH requires that any institution receiving NIH funding comply with this document for all rDNA research, regardless of funding source.

### Summary of Requirements

- Compliance is a condition for funding, regardless of the source;
- Every institution must establish an [IBC](#);
- The Principal Investigator completes and submits [EHS form 112](#) located on the ASU [Office for Research Integrity and Assurance](#) website;
- Containment level for work with rDNA is determined by [IBC](#) based on a risk assessment and recommendations in the BMBL;
- ASU policy requires registration of all experiments involving genetically engineered organisms, including those exempt from the *NIH Guidelines*.

## Training

The National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) regulates the use of recombinant DNA in government sponsored research and teaching activities in the United States. The NIH OBA developed the [NIH Guidelines](#) as a comprehensive set of rules for the use of recombinant DNA. One component of these rules is a requirement to ensure all personnel working with recombinant DNA are properly trained. The Biosafety group in EHS has developed a training in Blackboard to help meet this requirement. You can access the Blackboard training module through your [MyASU webpage](#). Search for “NIH Guidelines” in Blackboard to locate this training.

If you have any questions about this training, please contact [Biosafety@asu.edu](mailto:Biosafety@asu.edu).

## Reporting

- The Principal Investigator 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, unless the [IBC](#) determines that a report has already been filed by the Principal Investigator.
- Post-exposure treatment should be started as soon as possible following an exposure incident. If an exposure occurs, the employee 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 Integrity and Assurance maintains records of registrations approved by the [IBC](#).

## Technical Contacts

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