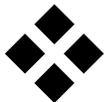


Northwestern University

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# **Recombinant DNA Safety Program**

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**Office of Research Safety**

Office of the Vice President for Research and Graduate Studies

## 1.0 Introduction

Research involving recombinant deoxyribonucleic acid (DNA) shall comply with the National Institute of Health's "Guidelines for Research Involving Recombinant DNA Molecules" (NIH Guidelines) as published in the *Federal Register* ([www.nih.gov/od/orda/toc.htm](http://www.nih.gov/od/orda/toc.htm)). The recombinant DNA guidelines are applicable to all recombinant DNA research within the United States or its territories, which is conducted at or sponsored by an institution that receives any support for recombinant DNA research from NIH. Any individual receiving support for research involving recombinant DNA must be associated with or sponsored by an institution that can and does assume the responsibilities assigned in the guidelines.

The safe conduct of experiments involving recombinant DNA depends on the individual conducting such activities. The guidelines cannot anticipate every possible situation. The NIH guidelines are intended to assist the institution, institutional biosafety committee (designated as the Recombinant DNA Safety Committee [RDSC] at Northwestern), Chemical and Biological Safety Officer, and principal investigator in determining safeguards that should be implemented. It is the responsibility of Northwestern University and those associated with it to adhere to the intent of the NIH guidelines as well as to its specifics.

The purpose of the *NIH Guidelines* is to specify practices for constructing and handling

- recombinant DNA molecules
- organisms and viruses containing recombinant DNA molecules

In the context of the *NIH Guidelines*, recombinant DNA molecules are defined as

- molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell
- molecules that result from the replication of those described above

Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed *in vivo* as a biologically active polynucleotide or polypeptide product it is exempt from the NIH guidelines. Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the NIH guidelines unless the transposon itself contains recombinant DNA.

## **2.0 Responsibilities**

General responsibilities relating to health and safety at the University are described in *Chemical and Biological Safety in Laboratories*, which is distributed to deans, department heads, center directors, and principal investigators.

Northwestern University is responsible for ensuring that the research is conducted in full conformity with the provisions of the NIH guidelines. This section describes and assigns those responsibilities.

### **2.1 University President**

The President of Northwestern University, upon recommendation of the Vice President for Research and Graduate Studies, shall appoint the RDSC.

### **2.2 Office of Research Safety**

The Office of Research Safety (ORS) is responsible for coordinating the recombinant DNA safety program for the University.

### **2.3 Recombinant DNA Safety Committee**

The RDSC has established and implemented policies that provide for the safe conduct of recombinant DNA research and that ensure compliance with the NIH guidelines. The RDSC comprises at least five members who collectively have experience and expertise in recombinant DNA technology. They possess the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment. Two members are not affiliated with the University (apart from their membership on the RDSC) and represent the interest of the surrounding community with respect to health and protection of the environment. The Chemical and Biological Safety Officer and a laboratory technical staff member also serve as members.

The RDSC is responsible for reviewing recombinant DNA research conducted at or sponsored by the University for compliance with the NIH guidelines as specified in Section III of the guidelines. The committee approves those research projects that are found to conform to the NIH guidelines. This review shall include

- an independent assessment of the containment levels required by the NIH guidelines for the proposed research
- assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research

- notifying the principal investigator of the results of the committee's review
- reviewing recombinant DNA research conducted at Northwestern University to ensure compliance with the NIH guidelines
- adopting emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research
- reporting any significant problems with or violations of the NIH guidelines and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/Office of Recombinant DNA Activities (ORDA) within 30 days
- establishing subcommittees or ad hoc committees as necessary to carry out its overall responsibilities

#### **2.4 Chemical and Biological Safety Officer**

The Chemical and Biological Safety Officer's duties include, but are not limited to

- periodic inspections to ensure that laboratory standards are rigorously followed (Note: laboratories are periodically inspected as part of the laboratory safety program)
- reporting to the RDSC and the University any significant problems, violations of the NIH guidelines, and any significant research-related accidents or illnesses
- developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant DNA research
- providing advice on laboratory security
- providing technical advice to principal investigators and the RDSC on laboratory safety procedures

#### **2.5 Principal Investigator**

The principal investigator is responsible for full compliance with the NIH guidelines in the conduct of recombinant DNA research. As part of this responsibility, the principal investigator shall

- make an initial determination of the required levels of physical and biological containment in accordance with the NIH guidelines
- select appropriate microbiological practices and laboratory techniques to be used for the research

- submit the initial research protocol and any subsequent changes (e.g., changes in the source of DNA or host-vector system), if covered under Sections III-A, III-B, III-C, III-D, or III-E of the guidelines, to the RDSC for review and approval or disapproval
- remain in communication with the RDSC throughout the duration of the project
- make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken
- instruct and train laboratory staff in the practices and techniques required to ensure safety and the procedures for dealing with accidents
- supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed
- investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Chemical and Biological Safety Officer, the RDSC, NIH/ORDA, and other appropriate authorities
- correct work errors and conditions that may result in the release of recombinant DNA materials
- ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics)
- initiate or modify no recombinant DNA research which requires RDSC approval prior to initiation (see Sections III-A, III-B, III-C, and III-D of the guidelines) until that research or the proposed modification thereof has been approved by the RDSC and has met all other requirements of the NIH guidelines
- determine whether experiments are covered by Section III-E of the guidelines and ensure that the appropriate procedures are followed
- report any significant problems, violations of the NIH guidelines, or any significant research-related accidents and illnesses to the Chemical and Biological Safety Officer, RDSC, NIH/ORDA, and other appropriate authorities (if applicable) within 30 days
- report any new information bearing on the NIH guidelines to the RDSC and to NIH/ORDA
- be adequately trained in good microbiological techniques
- adhere to RDSC-approved emergency plans for handling accidental spills and personnel contamination; and

- comply with shipping requirements for recombinant DNA molecules

Submissions by the principal investigator to the NIH/ORDA are covered in section IV-B-7-b of the NIH guidelines. For example, these submissions can cover certification of new host-vector systems or determining level of containment. See the guidelines for exact requirements.

### **3.0 Approval Procedures**

The policies set forth below comply with the NIH Guidelines. They apply to all recombinant DNA research conducted at Northwestern University, without regard to source of funding.

#### **3.1 Registration Document**

Principal investigators intending to use recombinant DNA molecules shall notify the RDSC by contacting ORS for information and the registration form. The principal investigator shall prepare the registration document according to the nature of the research. A copy of the current NIH guidelines should be available for reference ([www.nih.gov/od/orda/toc.htm](http://www.nih.gov/od/orda/toc.htm)). All recombinant DNA research falls into one of six classes, described in the NIH guidelines as follows

- section III-A Experiments that require Institutional Biosafety Committee approval, Recombinant DNA Advisory Committee (RAC) review, and NIH Director approval before initiation
- section III-B Experiments that require NIH/ORDA and Institutional Biosafety Committee approval before initiation
- section III-C Experiments that require Institutional Biosafety Committee approval, Institutional Review Board approval, and NIH/ORDA registration before initiation
- section III-D Experiments that require Institutional Biosafety Committee approval before initiation
- section III-E Experiments that require Institutional Biosafety Committee notice simultaneous with initiation
- section III-F Exempt experiments

If an experiment falls into section III-A, III-B, or III-C and one of the other sections as well, the rules pertaining to section III-A, III-B, or III-C shall be followed. If an experiment falls into section III-F alone, or into section III-F and into section III-D or III-E as well, the experiment is considered exempt from the NIH guidelines.

### **3.2 Status Report**

Principal investigators are required to file an annual Status Report for all recombinant DNA research. In addition, principal investigators must file a new or amended registration document when there are changes in their research protocols that require reclassification.

### **3.3 Training**

Principal investigators performing recombinant DNA experiments covered by Sections III-A through III-E under the NIH guidelines shall file Statement of Training and Experience forms with the RDSC for all active researchers.

### **3.4 Changes in Approved Research**

Principal investigators wishing to modify approved research regulated under the NIH guidelines are responsible for notifying the RDSC. Modifications to research conducted under Sections III-A, III-B, III-C, and III-D must be approved prior to implementing new procedures. The RDSC must be notified of modifications under Section III-E at the time they are implemented. Notification of modifications to exempt research conducted under Section III-F is not required; however, the annual Status Report will reflect the changes.

### **4.0 Laboratory Inspections**

Laboratory inspections are required for recombinant DNA experiments that are regulated by the NIH guidelines. ORS will inspect newly registered laboratories working at biosafety level 2 (BL2) as part of its normal laboratory inspection functions. Inspection and certification of newly registered laboratories by the RDSC are required for recombinant DNA experiments performed at biosafety level 3 (BL3). The RDSC inspection team is comprised of two members of the RDSC and a representative of ORS. BL3 laboratories are inspected annually by the RDSC.

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