Introduction

Welcome to the National Institutes Health (NIH) Guidelines for Recombinant and Synthetic Nucleic Acid Molecules (BIO305) Course.

The ultimate goal of this course is to help all Principal Investigators (PIs) and laboratory staff know and understand their roles and responsibilities as it pertains to the *NIH Guidelines*.

All institutions that receive NIH funding for research involving recombinant or synthetic nucleic acid molecules must comply with the ***NIH Guidelines.***

WARNING!!!

Failure to comply to the *NIH Guidelines* may result in one or more of the following:

- Suspension, limitation, or termination of financial assistance for the non-compliant NIH-funded research project
- Suspension, limitation, or termination of financial assistance for NIH funds for **OTHER** recombinant or synthetic nucleic acid molecule research at the institution
- Requirement for prior NIH approval of any or all recombinant or synthetic nucleic acid molecule projects at the institution

Objectives

After completing this course you should be able to:

1. Identify those regulatory agencies involved in the oversight of research involving recombinant or synthetic nucleic acid molecules.
2. Recognize how regulators, including the Institutional Biosafety Committee (IBC) and the Biosafety Officer (BSO), impact this research.

3. Demonstrate the responsibilities of PIs regarding their research involving recombinant or synthetic nucleic acid molecules.
4. Understand the consequences of noncompliance set forth in the *NIH Guidelines*.
5. Know where to locate information regarding research involving recombinant or synthetic nucleic acid molecules – regulations, forms, processes/procedures, etc.
6. Know when and how to report any significant research-related accidents, illnesses or environmental releases.

Why you are required to take this training?

PI's and research staff who conduct in research involving recombinant or synthetic nucleic acid molecules must be able to apply the responsibilities set forth for them by the National Institutes of Health (NIH) and the Office of Biotechnology Activities (OBA).

This course satisfies the training requirement set forth in the ***NIH Guidelines.***

The NIH

Program of Biosecurity and Biosafety Policy (PBBP)

The PBBP serves to foster an awareness and compliance of the standards and practices set forth in the *NIH Guidelines*.

What are the NIH Guidelines?

The *NIH Guidelines* provide detailed procedures and practices involving the containment and safe conduct of various forms of research involving recombinant and synthetic nucleic acid molecules.

This includes, but is not limited to, research involving:

- Genetically modified plants and animals

- Genetically modified cells, organisms, and viruses
- Synthetically generated nucleic acid molecules
- Human gene transfer research
- Plants

Researchers at institutions that are subject to the *NIH Guidelines* must comply with the requirements even if their own projects are not funded by NIH.

Institutional Biosafety Committee

Oversight

The UAB Vice President of Research and Economic Development appoints members to the UAB IBC.

The NIH mandates that all research utilizing non-exempt recombinant and/or synthetic nucleic acid molecules, regardless of funding agency, be reviewed and approved by the UAB IBC prior to initiation. At UAB, all research projects that involve the use of Risk Group/Biosafety Level 2 or higher agents are also reviewed and approved by the UAB IBC prior to work with these agents.

The Committee has the authority to impose disciplinary measures in cases where there is violation of UAB's established practices and procedures.

Membership

Membership includes:

- Representation from faculty, UAB staff, scientists, lab tech staff, and non-UAB community members
- Committee members expertise includes microbiology and infectious disease, chemistry, occupational health and safety, biosafety, recombinant and synthetic nucleic acid technology, human gene transfer trials, veterinary care and use, public health, law, plants, and UAB policy

Purpose

The Committee is structured to ensure that it includes the necessary collective experience and expertise to evaluate the potential risks associated with the wide variety of research conducted at UAB.

The UAB IBC and the Department of Occupational Health and Safety (OH&S) have been charged with the planning and implementation of the campus Biosafety Program. The Committee has the authority to impose disciplinary measures in cases where there is violation of UAB's established practices and procedures.

For more information on the IBC at UAB please visit their **website**.

Responsibilities

The IBC:

- Consults, collaborates, reviews, and approves all institutional research activities involving the use of the following:
    - Recombinant or synthetic nucleic acid molecules as defined as non-exempt by the *NIH Guidelines*
    - Material classified as Risk Group 2 or above

  - Human Gene Transfer experiments
  - Potential **Dual Use Research of Concern** (DURC)
  - Other as deemed necessary or as required
- Increases and decreases Biosafety Levels dependent upon the project specific risk assessment
- Analyzes accidents or near-accidents, make recommendations, determine cause/effect, and make safety recommendations to mitigate potential exposures
- Adopts emergency plans to cover accidental hazardous material spills and personnel contamination
- Reports any significant accidents, incidents, environmental releases, or violations
- Provides applicable training
- Enforces disciplinary measures in cases where there is violation of UAB's established policies and procedures
- Plans and implements campus safety programs

Principal Investigator (PI)

Roles and Responsibilities

Compliance

PIs are responsible for full compliance with the *NIH Guidelines* while performing research with recombinant or synthetic nucleic acid molecules. As a PI, he/she should:

1. Be adequately trained in good microbiological techniques
2. Supervise lab staff to ensure that good microbiological techniques and required safety practices and techniques are applied
3. Make sure that everyone involved with the protocol is enrolled in and complies with the requirements set forth by OH&S Employee Health
4. Inform the lab staff of the reasoning behind any required or recommended precautionary medical practices (e.g., vaccinations or medical screenings)

5. Provide lab research staff with protocols describing potential biohazard's and necessary precautions
6. Correct work errors and conditions that may result in the release of materials or organisms containing recombinant or synthetic nucleic acid molecules
7. Ensure the integrity of physical containment (e.g., biological safety cabinets) and biological containment (e.g. host-vector systems that preclude survival of the agent outside the lab)
8. Comply with permits and shipping requirements for all materials including recombinant or synthetic nucleic acid molecules
9. Report **ALL** releases and/or exposures to OH&S. After review, OH&S will work with the PI to ensure that all reporting requirements are satisfied

Research

Before Research Begins

Before initiating research with recombinant or synthetic nucleic acid materials, the PI must:

1. Determine whether the research is subject to Section III-A, III-B, III-C, III-D, or III-E of the *NIH Guidelines*
2. Obtain UAB IBC approval before initiating non-exempt research subject to the *NIH Guidelines*
3. Propose appropriate microbiological practices and lab techniques to be used for the research
4. Propose physical and biological containment levels in accordance with the *NIH Guidelines* when registering with the UAB IBC
5. Submit a research protocol to the UAB IBC (via OH&S Project Registration) for review and approval
6. Obtain IBC and NIH approval before conducting experiments specified in Section III-A and III-B of the *NIH Guidelines*

7. Contact the UAB IBC Director for proposed new exemptions from the *NIH Guidelines*
8. Obtain UAB IBC approval prior to enrolling patients in research that involves human gene transfer

For more information on how to submit a research protocol, go to the **Project Registration Form** located on the OH&S website.

Timing for Review

How do I get my project reviewed and approved by the IBC?

Please visit the UAB IBC web page to find the Project Registration Form and other pertinent Committee-related information. Download and complete the Project Registration Form, then submit it along with a copy of your grant to projects@uab.edu. Complete submissions received by the last working day of the month are reviewed at the next monthly meeting.

As long as the Project Registration Form is submitted by the PI from their UAB email account (this requires a unique BlazerID and strong password) the signature on the last page is not required.

While Conducting Research

The PI must:

- Remain in communication with the UAB IBC throughout the duration of the project
- Determine the need for UAB IBC review before modifying recombinant or synthetic nucleic acid research already approved by the UAB IBC

- Submit any subsequent changes (e.g., changes in the source of DNA or host-vector system) to the UAB IBC for review and approval
- Provide the UAB IBC with periodic project updates
- Report any significant research-related accidents, illnesses, or environmental releases immediately to the UAB OH&S

What to do when something goes wrong

A PI must:

1. Adhere to approved emergency plans for handling accidental spills and personnel contamination
2. Ensure that the staff understands the procedures for dealing with accidents
3. Instruct and train laboratory staff in:
    a. The practices and techniques required to ensure safety
    b. The procedures for dealing with accidents

You, as the PI, are expected to report:

1. Problems pertaining to the operation and implementation of containment practices and procedures
2. *NIH Guidelines* compliance violations
3. Any significant research-related accidents, illnesses or environmental releases (spills and personnel contamination)

Who to tell when something goes wrong

PIs should report these accidents, illnesses, or environmental releases immediately to the UAB IBC.

The UAB IBC will determine who should be notified. This may include:

- NIH PBBP (for violations of the *NIH Guidelines*)
- The IACUC (if non-human animals are involved)
- Other appropriate authorities as deemed necessary

If you need to report an accident, illness, or environmental release, please call the UAB IBC at 205-934-2487. For more information on incident reporting click **here**.

Human Gene Transfer Trials

The **Recombinant DNA Advisory Committee** (RAC) is responsible for reviewing submitted protocols. They will also determine if further public review is needed.

Before Enrolling Patients

PIs conducting human gene transfer research subject to Section III-C of the *NIH Guidelines* must:

- Complete the RAC Review Process and provide the UAB IBC with a copy of the RAC Determination Letter.
- Submit site specific answers to all aspects of Appendix M from the *NIH Guidelines* to the UAB IBC for review.
- Comply with all UAB IBC recommendations regarding in-service training, handling and transport of study material, waste handling and disposal, containment conditions for administration, etc.
- Have the RAC Review Process completed, UAB IBC approval, Institutional Review Board (IRB) approval, and all the applicable regulatory authorization(s) **BEFORE** enrolling the first patient in any human gene transfer trial.
- Comply with reporting requirements for human gene transfer experiments (see Appendix M –I-C of the *NIH Guidelines*).

During The Study

The PI must:

- Report all serious adverse events (SAEs) in an appropriate time period to the UAB IBC.
- Provide UAB IBC with any amendments or updates

Conclusion

This concludes the *NIH Guidelines* for Recombinant and Synthetic Nucleic Acid Molecules course. Please take the assessment at this time. 80% or higher is required to pass.

You may take the assessment two times. If you fail all attempts, you will fail the course and have to take it again.

For further assistance or information contact The Institutional Biosafety Committee (IBC) at 205-934-2487 or visit the OH&S **website**.