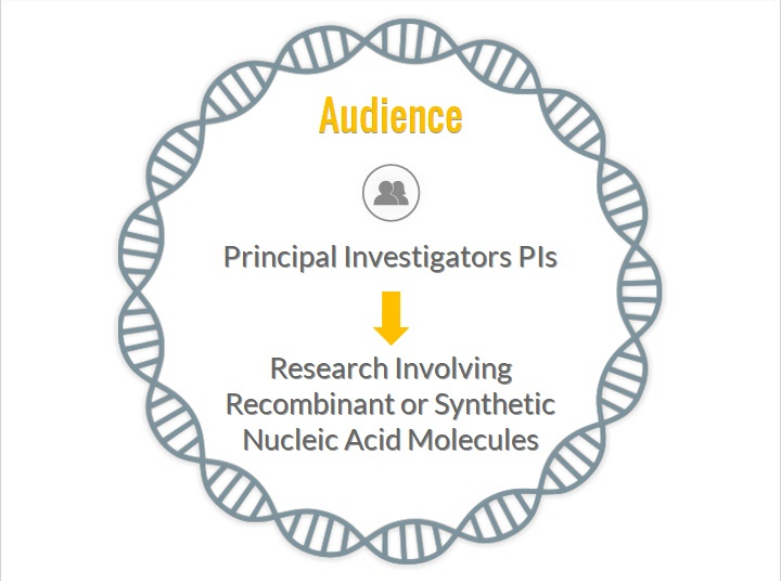
NIH Guidelines for Research Involving Recombinant/Synthetic Nucleic Acids

1.1 Intro

Notes:

Welcome to the "UC Davis NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids" informational training. Please click "Start Course" to begin.

1.2 Who Should Take this Course



Notes:

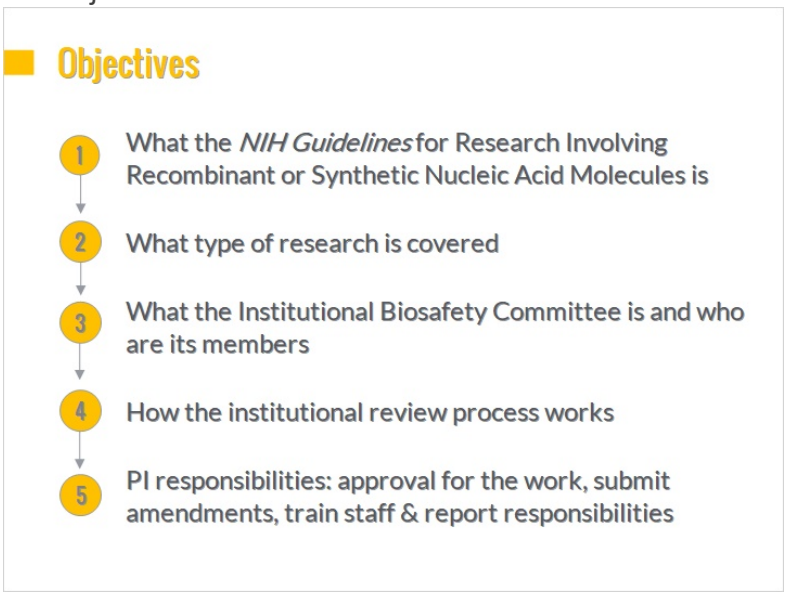
This training module is for Principal Investigators, or PIs, whose research involves recombinant or synthetic nucleic acids as described in Sections IIIA through IIIE of the *NIH Guidelines*. It is designed to provide a basic introduction to the NIH Guidelines, and discusses the framework in place at the University of California Davis to ensure that research involving these materials is conducted safely.

1.3 How to Use this Course

Notes:

Before we begin, please note that you can read a script of the information presented at any time by clicking on the closed captions button. You can also download a PDF of this course by clicking on the download link on the screen. To disable the audio at any time, click on the sound icon at the bottom of screen.

1.4 Objectives

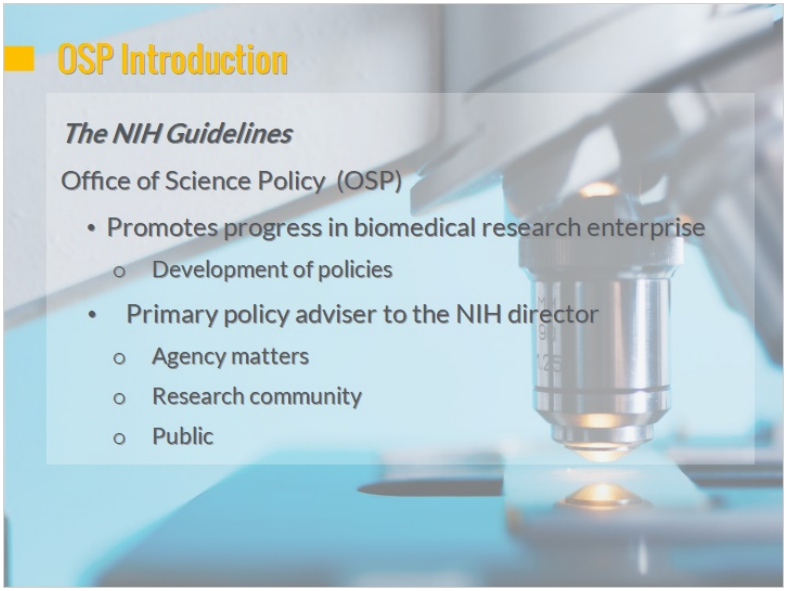


Notes:

By the end of this training, you should have a basic understanding of:

1. What the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules is*
2. What type of research is covered.
3. What the Institutional Biosafety Committee is and who are its members.
4. How the institutional review process works.
5. The PI responsibilities as outlined in the NIH Guidelines, as they pertain to obtaining approval for the work, submitting amendments to reflect progress, training of staff, and reporting responsibilities.

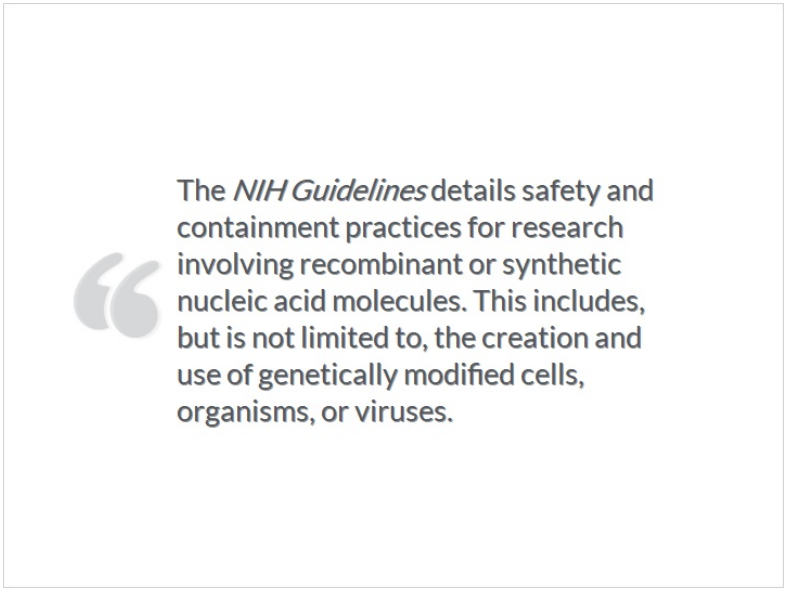
1.5 OSP Introduction



Notes:

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,* hereafter referred to as the *NIH Guidelines*, is administered by the NIH Office of Science Policy (OSP). The scope of this federal agency is to promote progress in the biomedical research enterprise through the development of sound and comprehensive policies. The OSP also is the primary policy adviser to the NIH Director on matters of significance to the agency, the research community, and the public interest.
In the next few slides, we will discuss the scope of the *NIH Guidelines* and the research that is covered.

1.6 Guidelines



Notes:

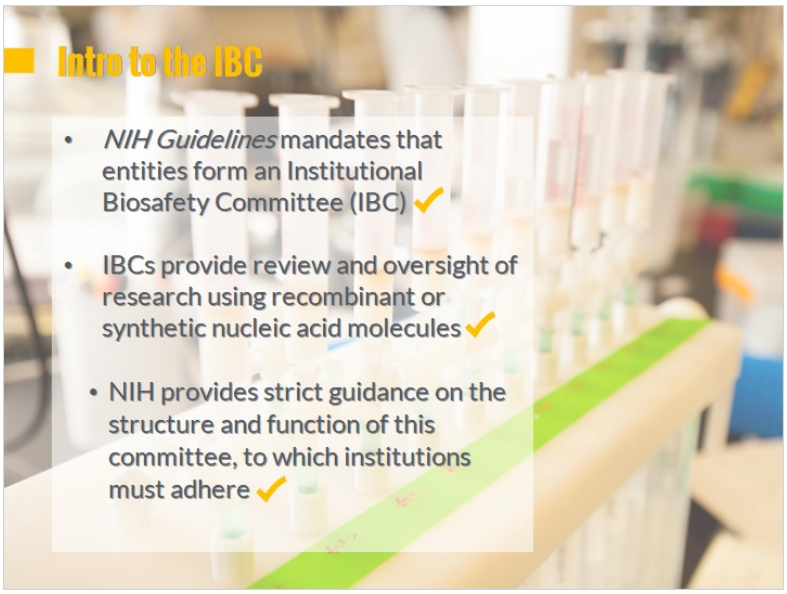
The *NIH Guidelines* details safety and containment practices for research involving recombinant or synthetic nucleic acid molecules. This includes, but is not limited to, the creation and use of genetically modified cells, organisms, or viruses.

1.7 Who Must Comply

Notes:

Entities that receive NIH funding for research involving recombinant or synthetic nucleic acid molecules must comply with the *NIH Guidelines*. This applies to all researchers working at the institution, even if individual projects are not funded by the NIH.

1.8 Intro to the IBC



Notes:

The NIH Guidelines mandates that those entities form an Institutional Biosafety Committee, or IBC, to provide local review and oversight for all non-exempt forms of research utilizing recombinant or synthetic nucleic acids. The NIH provides strict guidance on the structure and function of this committee, to which institutions must adhere.

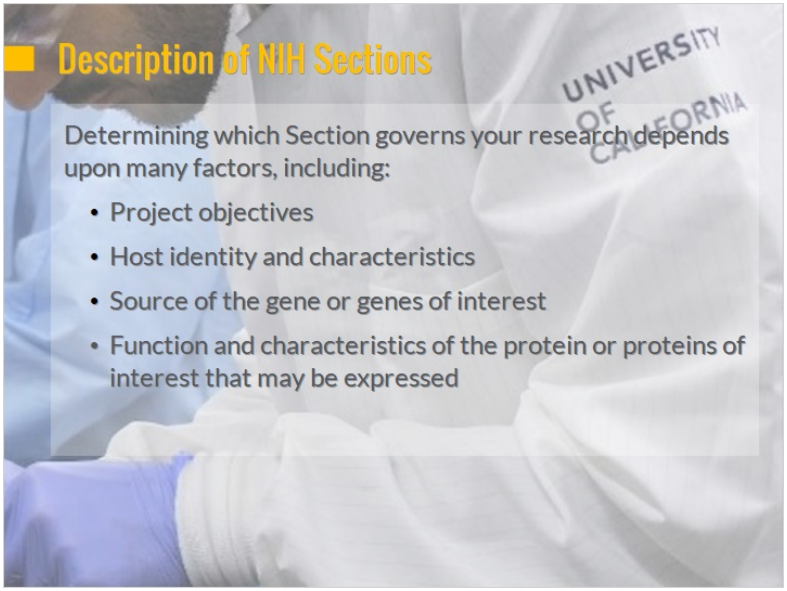
1.9 Who Reviews the Research?

Notes:

At the University of California Davis, the IBC is comprised of representatives qualified to provide a full, comprehensive review of the cutting-edge research that occurs on campus. Members include tenured and tenure-track faculty, as well as non-faculty subject matter experts. These include safety professionals, veterinarians, and physicians. There are also several members of the committee that are not directly affiliated with UC Davis to represent community interests, as mandated by the NIH Guidelines.

The next section of the training will introduce the Biological Use Authorization, or BUA, and the way by which PIs obtain approval for research that is subject to the NIH Guidelines.

1.10 Description of NIH Sections

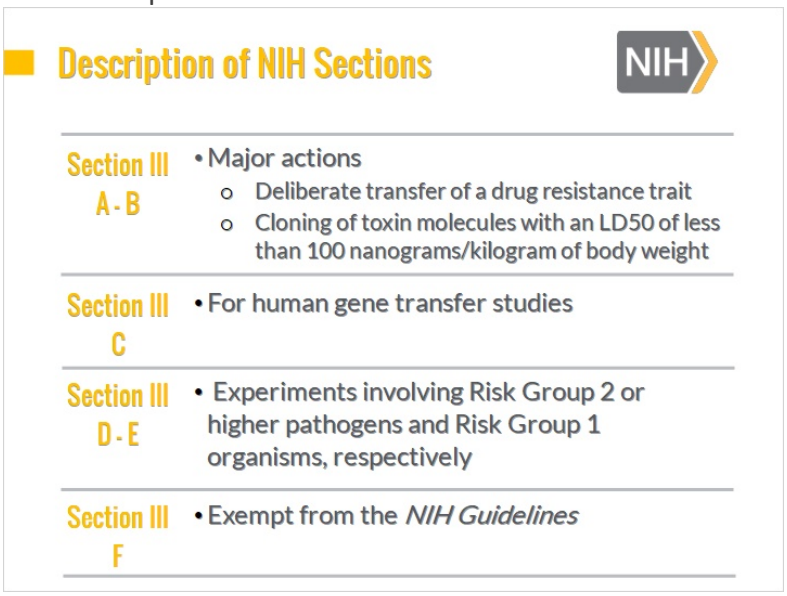


Notes:

Research involving recombinant or synthetic nucleic acids will fall into one of six Sections of the NIH Guidelines. Determining which Section governs your research depends upon many factors, including:

1. Host Identity and Characteristics
2. Source of the Gene or Genes of Interest
3. Function and characteristics of the Protein or Proteins of Interest that may be expressed

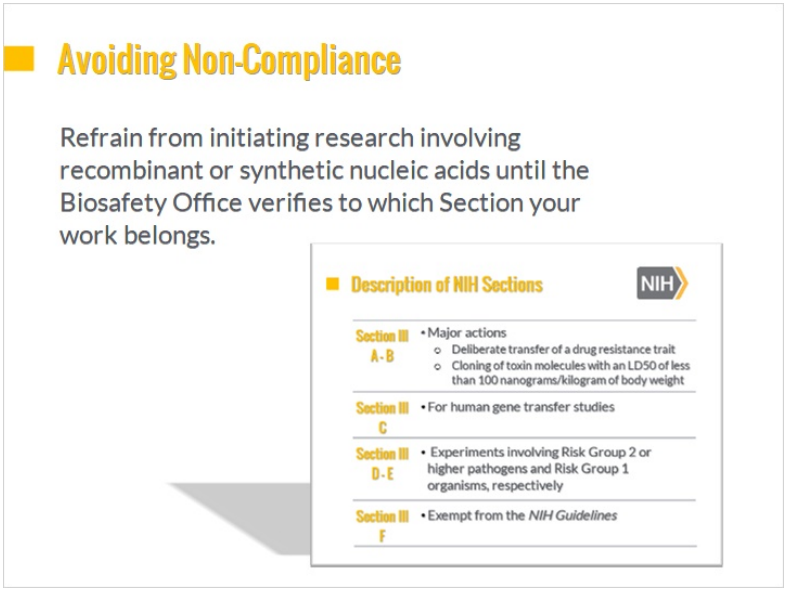
1.11 Description of NIH Sections



Notes:

The Biosafety Office will help determine which sections of the NIH Guidelines apply to your research. Sections III A through B of the NIH Guidelines are for "major actions," such as the deliberate transfer of a drug resistance trait, and for cloning of toxin molecules with an LD50 of less than 100 nanograms/kilogram of body weight, respectively. Section III C is for human gene transfer studies. Sections III D and E are for experiments involving Risk Group 2 or higher pathogens and Risk Group 1 organisms, respectively.
Also noteworthy is that use of certain hosts and vectors falls under Section III F and is exempt from the NIH Guidelines.

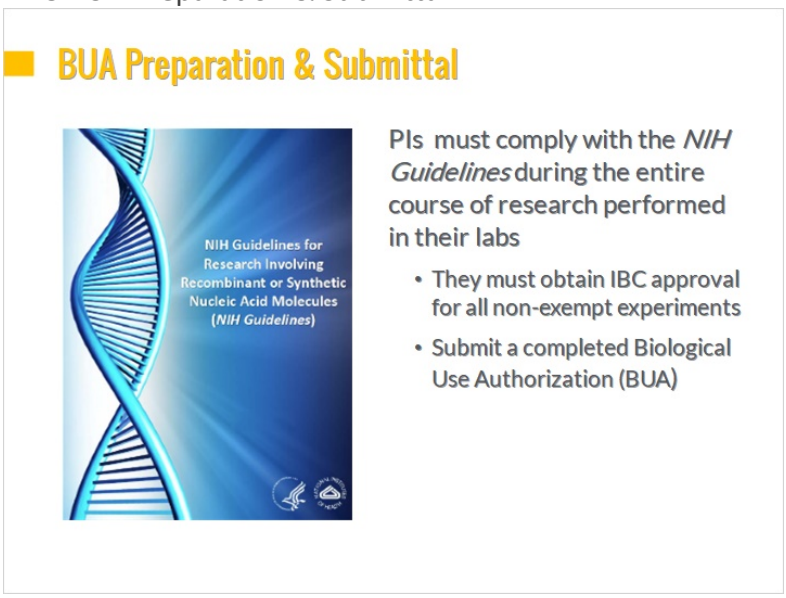
1.12 Avoiding Non-Compliance



Notes:

To avoid having to report an incident to the NIH, it is recommended that you refrain from initiating research involving recombinant or synthetic nucleic acids until the Biosafety Office verifies to which Section your work belongs.

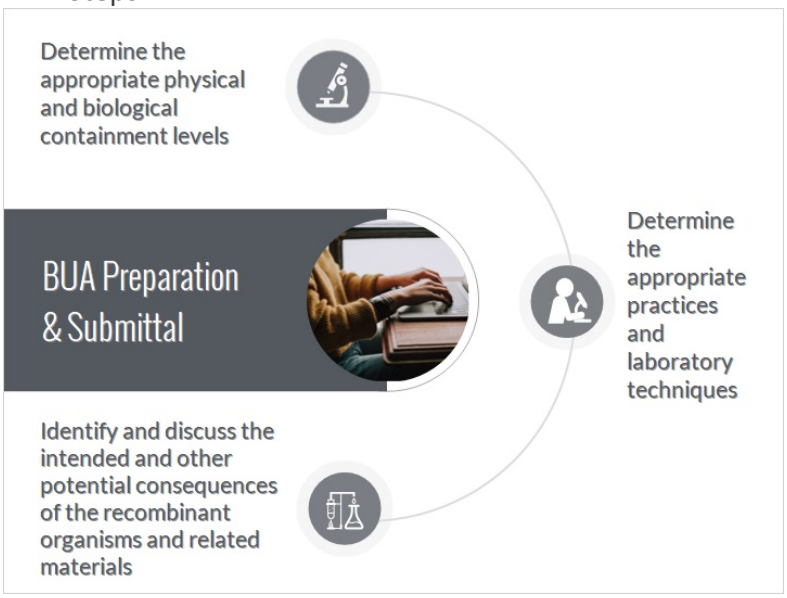
1.13 BUA Preparation & Submittal



Notes:

PIs are responsible for full compliance with the NIH Guidelines during the entire course of research performed in their labs and must obtain IBC approval for all non-exempt experiments. At UC Davis, this is done by submitting a completed Biological Use Authorization, or BUA.

1.14 Steps



Notes:

The BUA is a document in which the PI describes the project, lists organisms and materials involved, assesses the risks of the materials and procedures, and proposes containment and controls to mitigate the risks to staff and the environment. The PI works directly with the Biosafety Office in preparing this document to:

1. Determine the appropriate physical and biological containment levels.
2. Determine the appropriate practices and laboratory techniques.
3. Identify and discuss the intended and other potential consequences of the recombinant organisms and related materials.

Once these topics have been addressed, it is submitted to the IBC for review. The next section of the training will outline the responsibility of the PI to sufficiently train his or her staff.

1.15 Steps

Notes:

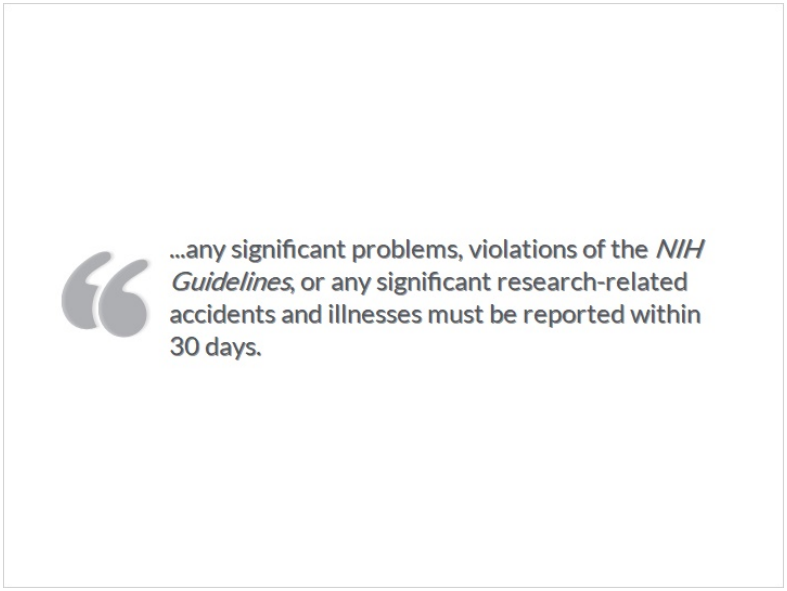
In addition to obtaining IBC approval for research involving recombinant organisms, the PI has a regulatory requirement to provide adequate training to all staff. The BUA acts a training document and staff are required to be trained on it at least annually, or more frequently as needed, such as after an amendment has been approved. Training must be documented, and that documentation must be made available upon request.
It is also the responsibility of the PI to keep the BUA current by submitting amendments after its initial approval. Amendments are necessary for changes to personnel, work locations, experimental techniques or materials.
Research staff must be trained and supervised on the practices and techniques required to ensure safety during hazardous procedures until competence is achieved. Staff must also be made aware of how to respond during an accidental exposure or loss of containment. It is recommended that the rationale behind provisions for precautionary medical practices that have been advised or requested be provided, such as vaccinations.

1.16 Facility Maintenance and Containment Practices

Notes:

An approved BUA dictates the conditions of the work to be performed, such as containment level, engineering controls, personal protective equipment, and work practices required when handling genetically modified materials. The PI must ensure that these conditions are being met and should act without delay to correct any issues or practices that may result in the release of recombinant organisms. Examples would be to ensure that a biosafety cabinet is annually certified and is used correctly, or that recombinant organisms are inactivated before disposal via the appropriate waste stream.

1.17 Untitled Slide



Notes:

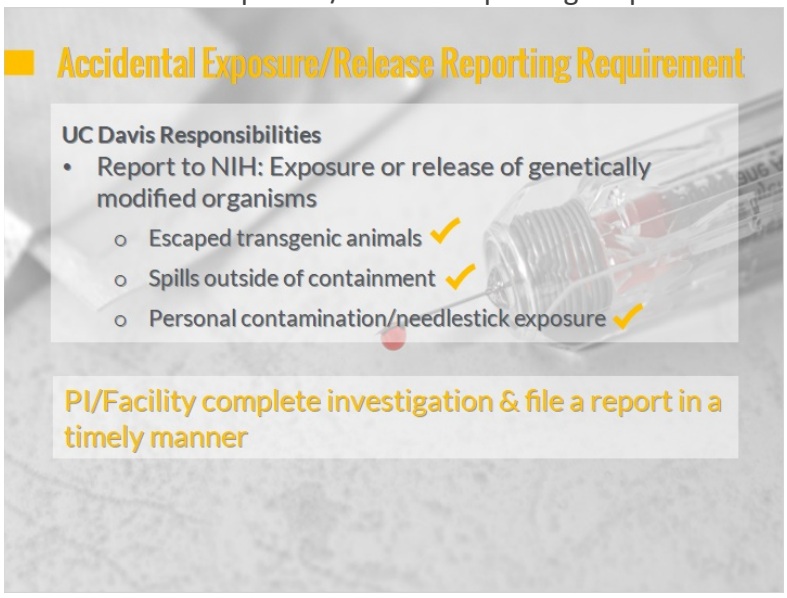
The NIH Guidelines states that "...any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days.

1.18 Accidental Exposure/Release Reporting Requirement

Notes:

Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in a Biosafety Level 2 laboratory resulting in an overt exposure must be immediately reported to NIH.
Spills or accidents occurring in high containment, such as a Biosafety Level 3 laboratory resulting in an overt or potential exposure must also be immediately reported to NIH.

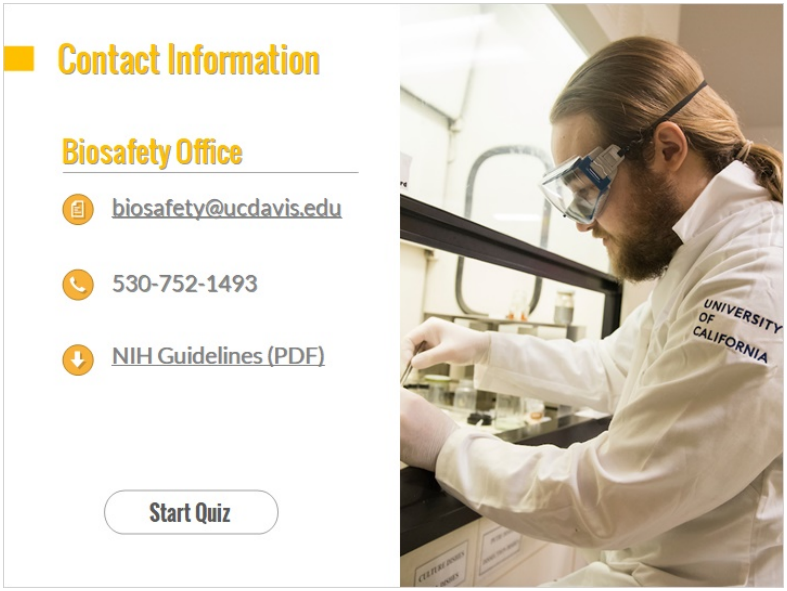
1.19 Accidental Exposure/Release Reporting Requirement



Notes:

UC Davis has an institutional responsibility to report any exposure to, or release of, genetically modified organisms to the NIH OSP. Examples of a reportable exposure or release include escaped transgenic animals, spills outside of containment, personal contamination or needle stick exposure.
After an exposure or release, the PI or facility will work with the Biosafety Office to complete an investigation and file the report in a timely manner.

1.20 Contact Information



Notes:

This concludes the informational training regarding the *NIH Guidelines.* Please contact the Biosafety Office if you have questions about any topic presented in this course.
Email- biosafety@ucdavis.edu <mailto:biosafety@ucdavis.edu>
Phone-530-752
NIH Guidelines PDF link