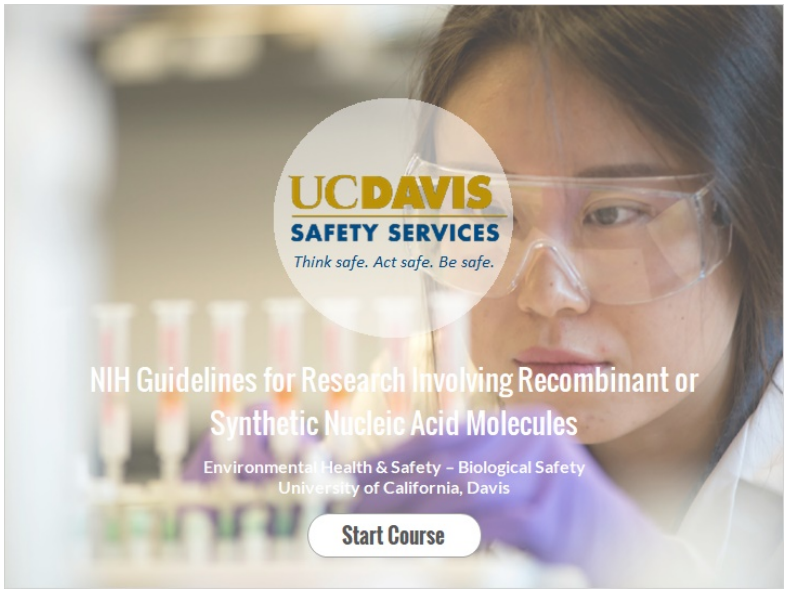
NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Mole

1.1 Introduction



NOTES:

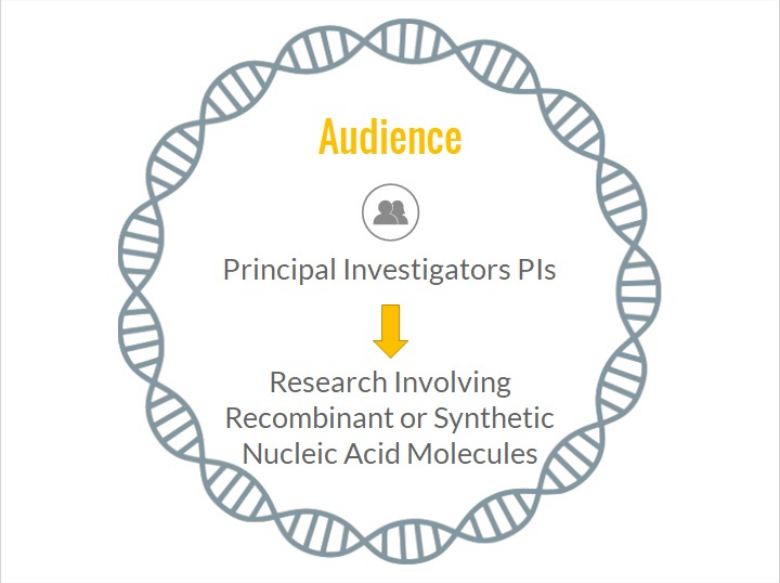
Welcome to UC Davis's Medical Waste Management training. This training was designed for research and teaching activities at UC Davis and covers proper methods for handling and disposing of medical waste, as required by local, State and Federal regulations.

1.2 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 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 the screen. Because this is an interactive training, you will be prompted to click in an area or make a decision before proceeding to the next section of the course.

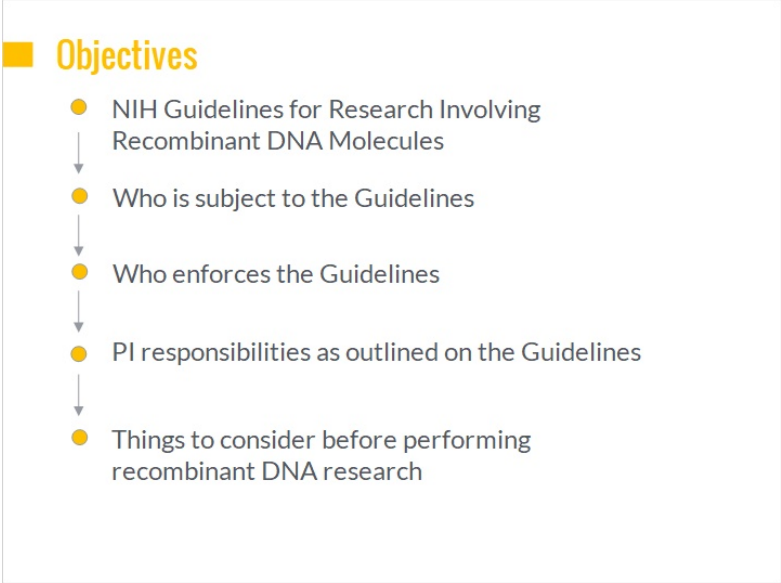
1.3 Audience



NOTES:

This training module is for Principal Investigators (P Eyes) whose work involves research as described in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules", Section III A to section III E.

1.4 Objectives



NOTES:

The objective of this training is to develop awareness of:

The NIH Guidelines for research involving recombinant DNA molecules,

Who is the subject to the guidelines,

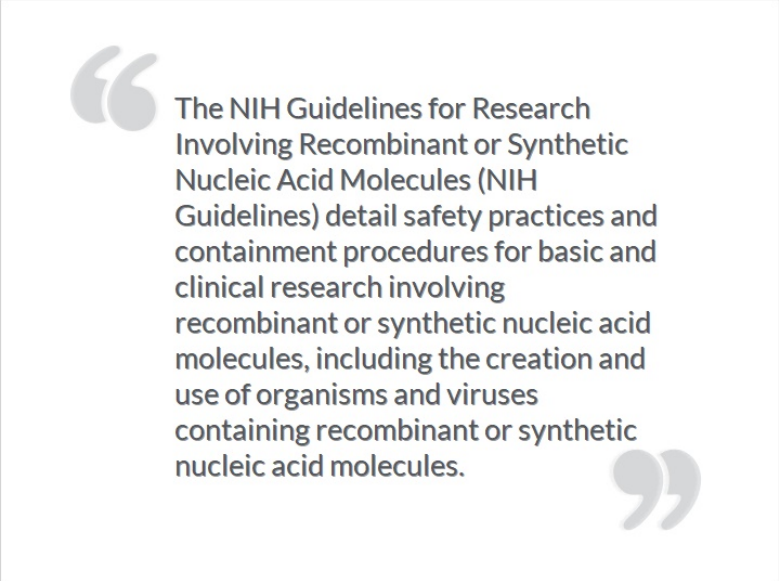
Who enforces the guidelines,

PI responsibilities as outlined in the guidelines and

Things that need to be considered before performing recombinant DNA research.

Let's get started!

1.5 Guidelines



NOTES:

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) detail safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules.

1.6 Complying to the Guidelines

NOTES:

All institutions that receives NIH funding for rDNA research must comply with the NIH guidelines.

This includes researchers at institutions receiving NIH funding even if their individual projects are not funded by NIH.

If the researcher involves Human Gene Transfer, or HGT, additional training must also be completed.

1.7 Institutional Biosafety Committee (IBC)

NOTES:

Institutional Biosafety Committees, or IBC, provide local review and oversight of nearly all forms of research utilizing recombinant or synthetic nucleic acid molecules.

They ensure that recombinant DNA research conducted at, or sponsored by, the institution is in compliance with the NIH Guidelines.

A requirement of the NIC guidelines is that an IBC must review and approve all research that is covered under the NIH guidelines.

1.8 UC Davis IBC

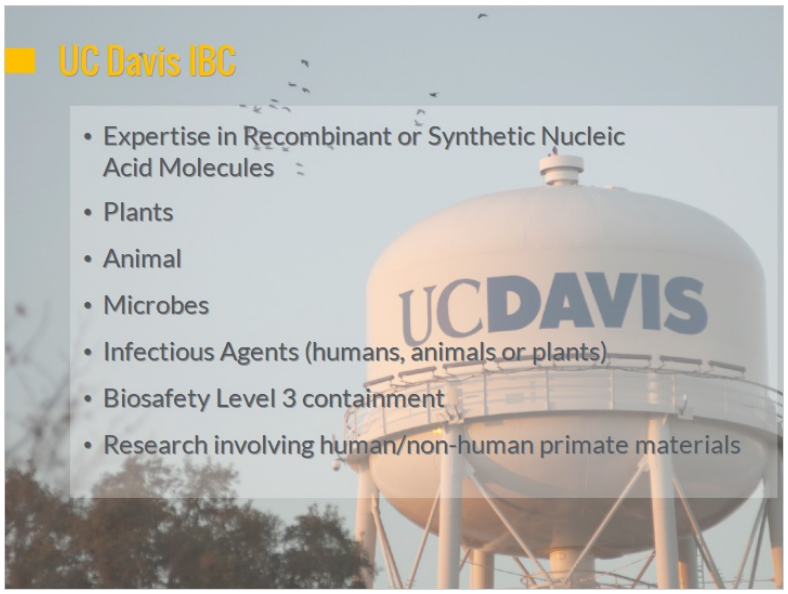
NOTES:

At the University of California, Davis, the IBC is comprised of Tenured or tenure-track, faculty,

subject matter experts, safety professionals, occupational health physicians

It also includes unaffiliated individuals who represent community interests in the safe conduct of r-DNA research.

1.9 UC Davis IBC



NOTES:

The committee membership structure complies with the requirements of section IV of the NIH guidelines.

The IBC has faculty expertise in recombinant DNA of plants, animals and microbes, infectious agents to humans, animals or plants, in addition to biosafety level 3 containment, and research involving human ad non-human primate materials.

1.10 What is NIH OSP?

NOTES:

The NIH Office of Science Policy (O S P) promotes progress in the biomedical research enterprise through the development of sound and comprehensive policies.

OSP also is the primary policy adviser to the NIH Director on matters of significance to the agency, the research community, and the public.

1.11 What is NIH OSP?

NOTES:

PIs are responsible for full compliance with the NIH guidelines during the conduct of their r-DNA research.

As part of this general responsibility, the P I should:

Obtain IBC approval for the research if required under the NIH guidelines,

Obtain IBC approval for any changes in personnel,

work locations,

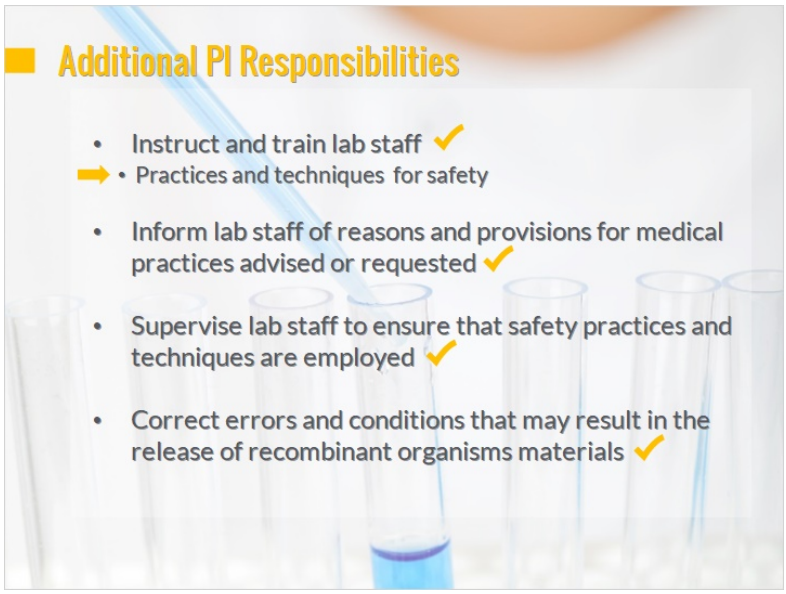
experimental techniques and experimental materials,

before making those changes in the project.

Be well trained in microbiological techniques.

Provide laboratory research staff with protocols describing potential biohazards and necessary precautions

1.12 Additional PI Responsibilities



NOTES:

Additional P I responsibilities under the guidelines are:

Instruct and train laboratory staff in the practices and techniques required to ensure safety and procedures for dealing with accidents,

Inform the laboratory staff of the reasons and provisions for precautionary medical practices advised or requested, for example, vaccinations,

Supervise laboratory staff in order to ensure that the required safety practices and techniques are employed,

Correct the errors and conditions that may result in the release of recombinant organisms.

1.13 Additional PI Responsibilities

NOTES:

Further P I responsibilities under the Guidelines are:

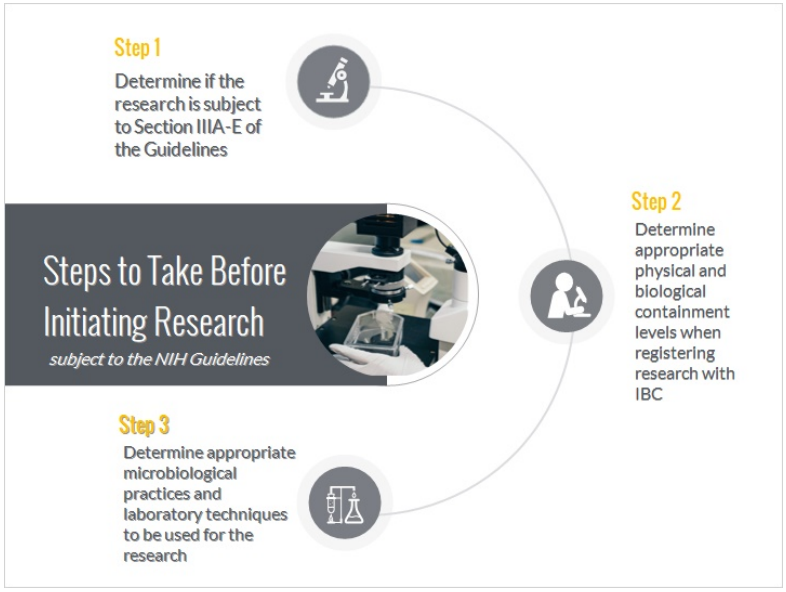
Report release of materials involving recombinant organisms to the Biological Safety Office, for example, spills, needle, sticks, and escaped transgenic animals,

Ensure the integrity of physical containment, for example, biosafety cabinets; and biological containment, such as vector production in the absence of the host,

Comply with permit and shipping requirements for recombinant organisms and

Adhere to the IBC-approved emergency plans for handling accidental spills and personnel contamination.

1.14 Steps



NOTES:

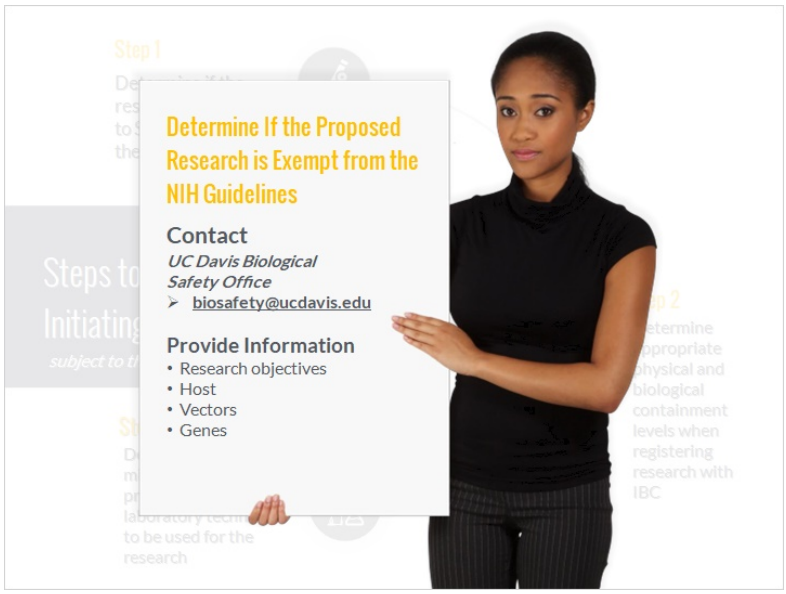
Before initiating any recombinant DNA research NIH requires that the P I:

Determine whether the research is subject to section III-A to E of the guidelines.

Determine appropriate physical and biological containment levels in accordance with the NIH guidelines when registering research with the IBC,

Determine appropriate microbiological practices and laboratory techniques to be used for the research.

1.15 Steps

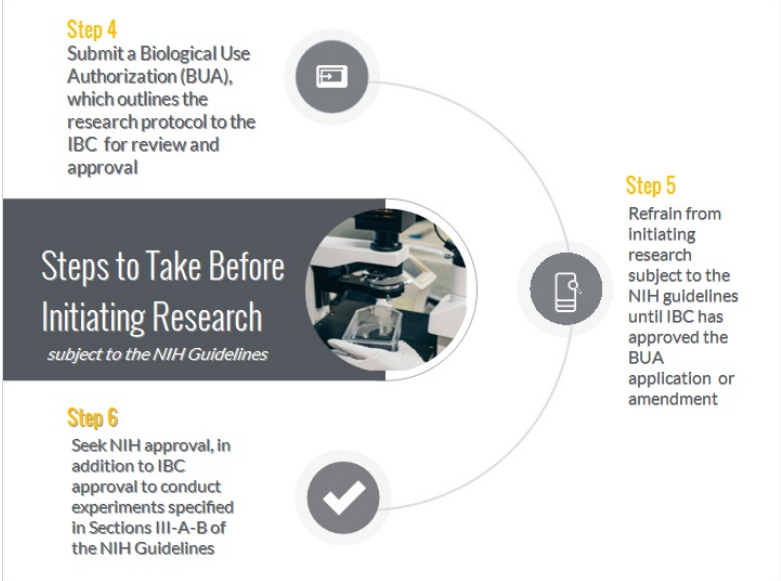


NOTES:

Please note that Section II-F lists the types of recombinant DNA molecules which are exempt from the NIH Guidelines. Appendix C provides further information regarding exempt hosts and vector systems.

To determine if the proposed research us exempt from the NIH Guidelines, contact the U C Davis Biological Safety Office and provide specific information about the research objectives and the host, vectors ad genes to be used.

1.16 Steps



NOTES:

In addition, once a P I determines their research is subject to the guidelines they should

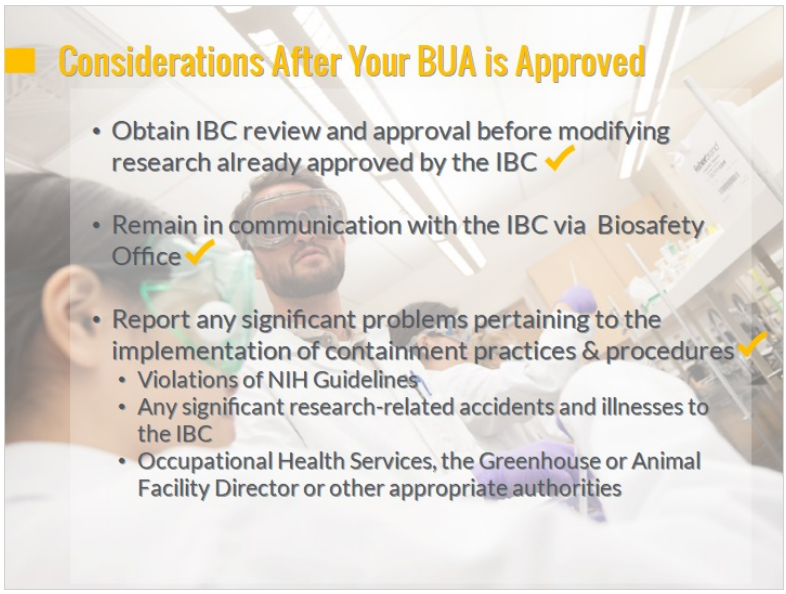
Submit a biological use authorization, or B U A, which outlines the research protocol to the IBC for review and approval

Refrain from initiating research subject to N I H Guidelines, projects described in the section 3 A through D of the guidelines until I B C has approved the B U A application or amendment

and seek NIH approval, in addition to the IBC approval to conduct experiments specified in sections 3A and B of the NIH guidelines.

Human gene transfer experiments under section III A through B of the guidelines are also subject to additional approvals and greatly expanded training.

1.17 Considerations After Your BUA is Approved



NOTES:

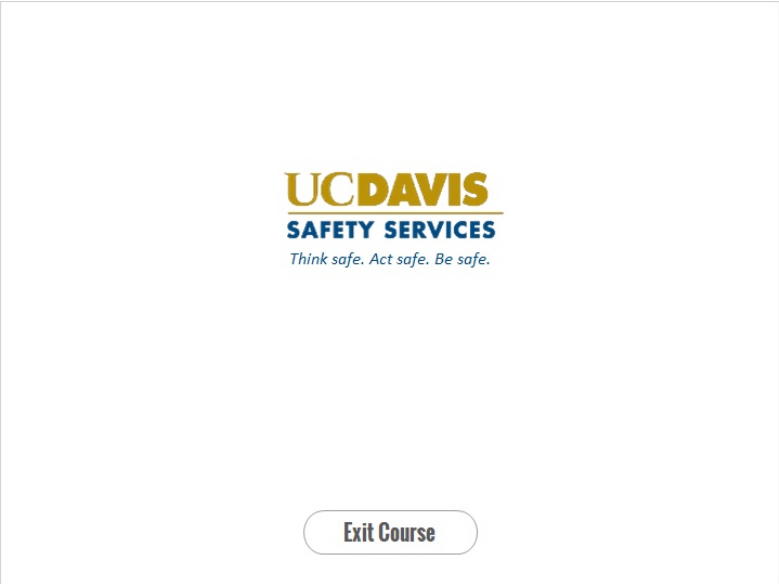
Thins a P I needs to consider after their B U A has been approved include:

Obtaining IBC review and approval before modifying research already approved by the IBC

Remaining in communication with the I B C via the Biosafety office throughout the project in regards to changes to or questions approved by B U A

Reporting any significant problems pertaining to the operation and implementation of containment practices and procedures, violations of the NIC guidelines, or any significant research-related accidents and illnesses to the I B C through the Biosafety Office, and, as applicable, to Occupational Health Services, the Greenhouse or Animal Facility Director or other appropriate authorities.

1.24 Exit Course



NOTES:

Congratulations, you've completed this course. You can exit now.