

## Responsible and Ethical Conduct of Research

### CITI Optional Training Courses

RESEARCH INVOLVING HUMAN SUBJECTS					
<a href="#">1</a>	Human Subject Research Course – Social/Behavioral	<a href="#">3</a>	Decisionally Impaired Persons	<a href="#">5</a>	Research with Older Adults
<a href="#">2</a>	Human Subject Research Course – Biomedical	<a href="#">4</a>	CITI Program – Socially or Economically Disadvantaged Persons	<a href="#">6</a>	Adults with Disabilities & Impairments
RESEARCH INVOLVING ANIMALS					
<a href="#">7</a>	Working with the IACUC	<a href="#">10</a>	Working with Fish in Research	<a href="#">12</a>	Working with Mice in Research
<a href="#">8</a>	Animal Biosafety	<a href="#">11</a>	Working with Amphibians in Research	<a href="#">13</a>	Post-Procedure Care of Mice and Rats in Research: Minimizing Pain & Distress
<a href="#">9</a>	Wildlife Research				
BIOSAFETY/BIOSECURITY					
<a href="#">14</a>	Introduction to Biosafety	<a href="#">18</a>	Shipping and Transport of Regulated Biological Materials	<a href="#">22</a>	NIH Recombinant DNA Guidelines
<a href="#">15</a>	Basic Biosafety Training	<a href="#">19</a>	OSHA Bloodborne Pathogens	<a href="#">23</a>	Gene Transfer Trials
<a href="#">16</a>	OSHA PPE Training	<a href="#">20</a>	Dual Use Research of Concern	<a href="#">24</a>	Nanotechnology
<a href="#">17</a>	Emergency and Incident Response to Biohazard Spills and Releases	<a href="#">21</a>	Select Agents, Biosecurity and Bioterrorism	<a href="#">25</a>	USDA Permits
RESEARCH INVOLVING CONTROLLED PRODUCTS					
<a href="#">26</a>	Export Compliance				

### 1. Human Subjects Research – Social-Behavioral-Educational Basic

The SBE Basic course provides an introduction to social-behavioral-educational research with a focus on the protection of human subjects. It offers historic and current information on regulatory and ethical issues important to the conduct of research involving human subjects. Case studies are used within the modules to present key concepts. This course has been updated to reflect the 2018 Requirements of the Common Rule.

#### Required Modules

Students in Research
Populations in Research Requiring Additional Considerations and/or Protections
Conflicts of Interest in Human Subjects Research
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research

History and Ethical Principles
Defining Research with Human Subjects
The Federal Regulations
Assessing Risk
Informed Consent
Privacy and Confidentiality
The University of Tennessee at Chattanooga

### **Optional Modules**

Research and HIPAA Privacy Protections
Vulnerable Subjects - Research Involving Workers/Employees
Hot Topics
Research with Prisoners - SBE
Research with Children - SBE
Research in Public Elementary and Secondary Schools - SBE
International Research - SBE
Internet-Based Research - SBE
Cultural Competence in Research
Research with Older Adults
Research with Persons who are Socially or Economically Disadvantaged
Research with Critically Ill Subjects
Research with Decisionally Impaired Subjects
Illegal Activities or Undocumented Status in Human Research
Research with Subjects with Physical Disabilities & Impairments
Research Involving Subjects at the End-of-Life
Consent and Subject Recruitment Challenges: Remuneration
Cultural Competence in Research
Research with Older Adults
Introduction To Community-Engaged Research (CEnR)
Introduction to Community-Based Participatory Research (CBPR)
Ethical and Practical Considerations in Community-Engaged Research (CEnR)
Consent in the 21st Century
Consent with Subjects Who Do Not Speak English
Consent and Cultural Competence
Disaster and Conflict Research, Part 1: PI Responsibilities

Disaster and Conflict Research, Part 2: Best Practices and Recommendations
Single Institutional Review Board (sIRB) Use and Administration: When Relying on a sIRB
Single Institutional Review Board (sIRB) Use and Administration: When Serving as a sIRB of Record
Single Institutional Review Board (sIRB) Use and Administration: Authorization Agreements
Mobile Apps and Human Subjects Research
Are You Thinking About Being in a Research Study?

## 2. Human Subject Research – Biomedical

This course provides an introduction to the protection of human subjects in biomedical research. It offers historic and current information on regulatory and ethical issues important to the conduct of research involving human subjects. Case studies are used within the modules to present key concepts. This course has been updated to reflect the 2018 Requirements of the Common Rule.

### Required Modules

Conflicts of Interest in Human Subjects Research
Students in Research
Basic Institutional Review Board (IRB) Regulations and Review Process
Informed Consent
Social and Behavioral Research (SBR) for Biomedical Researchers
Records-Based Research
Genetic Research in Human Populations
Research Involving Children
Research and HIPAA Privacy Protections
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in
Populations in Research Requiring Additional Considerations and/or Protections
History and Ethics of Human Subjects Research
The University of Tennessee at Chattanooga

### Optional Modules

International Studies
Avoiding Group Harms - U.S. Research Perspectives
Avoiding Group Harms - International Research Perspectives
Vulnerable Subjects - Research Involving Workers/Employees
Hot Topics
Research Involving Pregnant Women, Fetuses, and Neonates

FDA-Regulated Research
Research Involving Prisoners
Consent and Subject Recruitment Challenges: Remuneration
Consent Tools Used by Researchers
Introduction To Community-Engaged Research (CEnR)
Introduction to Community-Based Participatory Research (CBPR)
Ethical and Practical Considerations in Community-Engaged Research (CEnR)
Consent in the 21st Century
Consent and Subject Recruitment Challenges: Therapeutic Misconception
Consent with Subjects Who Do Not Speak English
Consent and Cultural Competence
Disaster and Conflict Research, Part 1: PI Responsibilities
Disaster and Conflict Research, Part 2: Best Practices and Recommendations
Single Institutional Review Board (sIRB) Use and Administration: When Relying on a sIRB
Single Institutional Review Board (sIRB) Use and Administration: When Serving as a sIRB of Record
Single Institutional Review Board (sIRB) Use and Administration: Authorization Agreements
Cultural Competence in Research
Humanitarian Use Devices (HUDs)
Research with Older Adults
Research with Persons who are Socially or Economically Disadvantaged
Gender and Sexuality Diversity (GSD) in Human Research
Research with Critically Ill Subjects
Research with Decisionally Impaired Subjects
Illegal Activities or Undocumented Status in Human Research
Research with Subjects with Physical Disabilities & Impairments
Research Involving Subjects at the End-of-Life
Mobile Apps and Human Subjects Research
Are You Thinking About Being in a Research Study?
The IRB Administrator's Responsibilities

### 3. HSR – Decisionally Impaired Persons

Provides an overview of the nature and sources of decisional impairment. Discusses the obligations imposed on institutional review boards (IRBs) and researchers to ensure that appropriate protections are in place when research involves adult subjects who are or may be decisionally impaired and may have impaired consent capacity. Reviews additional safeguards, discusses assessment of consent capacity, and defines who can provide consent on behalf of an adult subject who lacks consent capacity.

## 4. Human Subjects Research – Socially or Economically Disadvantaged Persons

Discusses subject's social and economic disadvantage as a potential vulnerability in research. Describes barriers to participation, the ethical and regulatory mandates for the inclusion of these populations in research, as well as the additional protections that may be used to minimize risk. It also explains considerations for IRBs and researchers when planning, reviewing, or conducting research with socially or economically disadvantaged persons.

## 5. Human Subjects Research – Research with Older Adults

Provides education and training regarding the conduct of research with older adults. It discusses information for both researchers and IRBs in order to begin the process of addressing underrepresentation of older adults in research, while at the same time providing critical information to consider when conducting research with this group. It also covers the demographic and social issues concerning the exclusion of older adults in research, barriers to inclusion, and research design considerations to enhance inclusion and protect this potentially vulnerable population.

## 6. Human Subjects Research – Adults with Disabilities & Impairments

Provides an overview of physical disabilities and impairments, and the obligations imposed on IRBs and researchers to ensure that appropriate research protections are in place when research involves subjects who are physically disabled and may require additional tailored protections. Additional barriers, vulnerabilities, and challenges that individuals with physical disabilities face when participating in research are identified. It also discusses safeguards and additional protections that IRBs and researchers can implement to protect this potentially vulnerable population, as well as ways to make research studies more accessible to individuals with physical disabilities.

## 7. Animal Research – Working with the IACUC

Working with the IACUC is intended for laboratory research personnel who will write animal-use protocols for review by an Institutional Animal Care and Use Committee (IACUC) member or who will handle animals under such protocols. It provides basic information regarding the U.S. regulations for protection of animal subjects used in research, teaching, and testing. It also describes the sources and applicability of regulations governing animals in these uses.

In addition, it discusses the role, authority, and composition of the IACUC, the types of IACUC review, and the items of information required for the review. It discusses animal surgery, blood sample collection, antibody production, and euthanasia.

General discussions are also provided for requirements for personnel training and experience, and occupational health and safety. It provides recommendations for housing rodents, exercising dogs, enriching the environment of primates, and using human patient care areas for animal procedures. Finally, there is a discussion of the requirements for making changes in a project involving animals and the procedures for reporting inappropriate use of animals.

### **Required Modules**

Introduction to Being an IO: Animal Care and Use Program
What the IO is Required to Know
IO Responsibilities
What works: A word from Experienced IOs

## 8. Animal Research -- Animal Biosafety

Animal Biosafety provides initial training for researchers and animal handlers working with small or conventional animals used in biohazard experiments. It can also be used as periodic refresher training based on the schedule outlined by the host institution.

## 9. Animal Research – Wildlife Research

Wildlife Research describes the types of field studies, methods of animal capture, principles and methods of restraint, animal marking, animal transportation and housing, maintenance of wildlife in captivity, translocation and release, animal surgery, blood sample collection, recognition and management of pain, and euthanasia.

### Required Modules

Introduction to Wildlife Research Course
Oversight, Compliance, and Training
Permits, Pain and Distress Categories, Transportation, and Housing
Conducting Field Research and Teaching Studies
Research Procedures, Recognizing and Managing Pain, and Release

## 10. Animal Research – Working with Fish in Research

This course offers an introduction to working with fish in research settings including the regulatory mandates and biological features of fish.

### Required Modules

Introduction, Taxonomy, Research Mandates, and Occupational Health
Alternatives, Humane Standards, Housing, Source, and Acclimation and Quarantine
Biological Features
Recognizing Pain and Distress, Blood Collection, Identification and Routes of Administration
Anesthesia, Analgesia, Surgery, and Postoperative Care
Euthanasia

## 11. Animal Research – Working with Amphibians in Research

This course offers an introduction to working with amphibians in research settings including the regulatory mandates and biological features of amphibians.

### Required Modules

Introduction to Working with Amphibians in Research Settings
Taxonomy, Research Mandates, and Occupational Health Issues
Alternatives Search, Housing, Source, and Acclimation and Quarantine
Biology, Pain and Distress, Handling, and Pain Relief
Surgery, Supportive Care and Monitoring, Euthanasia, and References

## 12. Animal Research – Working with Mice in Research

This course offers an introduction to working with mice in research settings including the regulatory mandates and biological features of mice.

### Required Modules

Introduction to Working with Mice in Research Settings
Research Mandates and Occupational Health Issues
Alternatives Search, Humane Standards, Housing, Source, and Acclimation and Quarantine
Detecting Pain and Distress, Genetics, and Biological Features
Injections, Blood Collection, and Antibody Production
Surgery, Supportive Care and Monitoring, Euthanasia, and References

## 13. Animal Research – Post-Procedure Care of Mice and Rats in Research: Minimizing Pain & Distress

Discusses the detection of pain and distress in mice and rats during research testing. It also discusses the appropriate surgical techniques, supportive care and monitoring, and euthanasia for mice and rats.

### Required Modules

Introduction to Post-Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress
Investigator Responsibility
Minimizing Sources of Nonexperimental Variation
Systematically Monitoring for Pain and Distress
Detecting Clinical Signs of Pain and Distress
Appearance and Behavior

Physical Exam for Clinical Condition
Body Weight
Fluid and Electrolyte Balance
Body Temperature
Tumors
Alleviation of Pain and Distress
Documentation of Post-Procedure Care
Summary

#### 14. Biosafety/Biosecurity – Introduction to Biosafety

Basic Introduction to Biosafety provides an introduction to biosafety for researchers handling Risk Group 1 agents and working only at Biosafety Level 1 (BSL-1) containment.

#### 15. Biosafety/Biosecurity – Basic Biosafety Training

Initial Biosafety Training provides initial training for researchers handling biohazards in a research or clinical laboratory. The course addresses awareness of biohazards, risk assessment, and key risk management principles including work practices, personal protective equipment (PPE), engineering controls, and emergency response.

#### 16. Biosafety/Biosecurity – OSHA PPE Training

Personal Protective Equipment discusses OSHA PPE training requirements for researchers handling biohazards. A supplemental PPE Training Record Form and PPE Training and Use Table are available to facilitate the documentation of training.

#### 17. Biosafety/Biosecurity – Emergency and Incident Response to Biohazard Spills and Releases

Emergency and Incident Response to Biohazard Spills and Releases provides biohazard emergency response training for employees who are designated as hazardous materials responders and address the biohazard component of their annual training.

#### 18. Biosafety/Biosecurity – Shipping and Transport of Regulated Biological Materials

Shipping and Transport of Regulated Biological Materials is designed as initial training and periodic retraining for employees who package or ship diagnostic and clinical human or animal specimens, human or animal pathogens, and other regulated biohazards. The course is designed to meet requirements of the International Air Transport Association (IATA) and the U.S. Department of Transportation (DOT).



## 19. Biosafety/Biosecurity – OSHA Bloodborne Pathogens

OSHA Bloodborne Pathogens is designed as initial training or annual retraining to meet the requirements of the U.S. Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogen Standard.

## 20. Biosafety/Biosecurity – Dual Use Research of Concern

Dual Use Research of Concern (DURC) offers a detailed training on the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. The course is based on the 2014 United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern, which is required for all National Institutes of Health (NIH) funded entities. It describes the agents and types of experiments that require oversight, individual and organizational responsibilities, and risk mitigation strategies.

## 21. Biosafety/Biosecurity – Select Agents, Biosecurity and Bioterrorism

Select Agents, Biosecurity, and Bioterrorism offers initial and annual retraining options in select agents and laboratory biosecurity as required by U.S. select agent regulations. It must be augmented with site-specific biosecurity information as required by the select agent regulations.

## 22. Biosafety/Biosecurity – NIH Recombinant DNA Guidelines

NIH Recombinant DNA Guidelines provides principal investigators and those responsible for the conduct of recombinant and synthetic nucleic acid research experiments with basic training and an overview of the requirements established by the National Institutes of Health (NIH).

## 23. Biosafety/Biosecurity – Gene Transfer Trials

Human Gene Transfer is designed for principal investigators, clinicians, and IBC members participating in the conduct or review of a human gene transfer clinical study. It reviews the NIH and IBC requirements for human gene transfer clinical trials.

## 24. Biosafety/Biosecurity – Nanotechnology

Nanotechnology offers basic awareness and understanding of nanoparticles, and the unique safety issues associated with their handling.

## 25. Biosafety/Biosecurity – USDA Permits

USDA Permits discusses the import, transit, and release of regulated: plants pests, plant pathogens, plants, and plant products; soils; and animal pathogens, animal products, and etiologic agents.

## 26. Export Compliance

EC Basic includes an introduction to export compliance, as well as information focused on export compliance as it relates to biosafety, operational departments, international shipping, purchasing, international and foreign waters, collaborations and U.S. sanctions programs, distance education, and technology.

It is designed for use by investigators, members of the research team, key personnel across operational departments, and others who work with or may be responsible for federally controlled devices, materials, or technologies.