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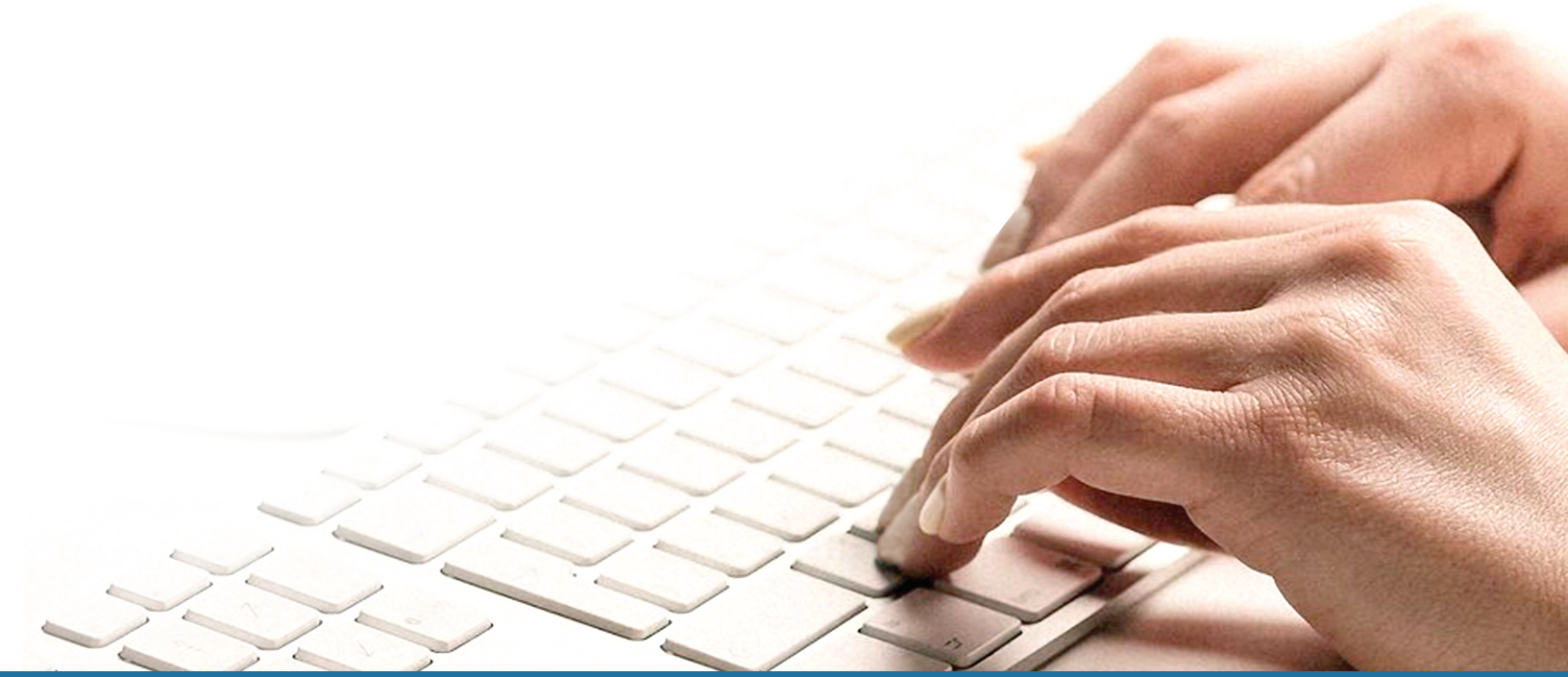
Subscription Details and Module List



www.citiprogram.org

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Sales:
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Support:
888.529.5929 - support@citiprogram.org

Organizational Subscriptions

A base subscription fee includes access to all core subjects for users at each of your organization's sites. Inquire about pricing for additional facilities and large institutions.

- Animal Care and Use
- Conflicts of Interest
- Good Clinical Practice
- Human Subjects Research
- Information Privacy & Security
- Responsible Conduct of Research

Subscription Pricing

BASE SUBSCRIPTION - INCLUDES 6 COURSES LISTED ABOVE

Government / Non-profit organizations
$4,000 USD per year / per site

For-profit organizations
$4,500 USD per year / per site

NEW CUSTOM SUBSCRIPTION - SELECT YOUR OWN 6 COURSES *(Restrictions apply)*

Government / Non-profit organizations
$5,000 USD per year / per site

For-profit organizations
$5,500 USD per year / per site

Add to Your Base Subscription

Offer learners more than the courses included in the base subscription for an additional fee. You can add these courses or specific webinars during the subscription process and at any time to your active subscription.

ADDITIONAL COURSES - Pricing is per year/per site

- Bioethics - $500 USD
- Biomedical PI - $500 USD
- Biosafety and Biosecurity - $500 USD
- CRC Foundations & CRC Advanced - $800 USD
- CRC Foundations Only - $500 USD
- CRC Advanced Only - $500 USD
- Clinical Trial Billing Compliance - $500 USD
- Disaster Planning for the Research Enterprise - $500 USD
- Essentials of Grant Proposal Development - $500 USD
- Essentials of Research Administration - $500 USD
- Essentials of Statistical Analysis - $1250 USD
- Export Compliance - $500 USD
- Good Laboratory Practice - $500 USD
- Healthcare Ethics Committee - $500 USD
- IRB Administration - $500 USD
- Laboratory Chemical Safety - $300 USD
- Protocol Registration and Results Summary Disclosure in ClinicalTrials.gov - $650 USD
- Research Study Design - $500 USD
- Semiannual Evaluations In Depth - $300 USD

WEBINARS - $300 USD per year/per site

- The Challenge of Medicare Advantage Plans and Local Coverage Determinations
- GDPR & Human Subject Research in the U.S.
- FERPA: A Quick Review of the Law for Researchers and IRBs
- Transitioning Research to the Revised Common Rule: The What, How, and Why
- Revised Common Rule Webinar: Overview of Revisions
- Research with Native American Communities: Important Considerations When Applying Federal Regulations
- Ethics & Policy Issues in CRISPR Gene Editing

CE/CME credits are available for purchase by CITI Program learners for eligible courses. Check the "CE/CMEs" tab on our home page.

Independent Learner Subscriptions

If individuals are not affiliated with a subscribing organization, they can register as an independent learner. Learners may also purchase individual courses not offered by their organization to fulfill training needs or to expand their knowledge.

Prices for Independent Learners

Animal Care and Use
$99 USD per course

Bioethics
$99 USD

Biomedical PI
$99 USD

Biosafety and Biosecurity
$110 USD per course

CRC Foundations and CRC Advanced
$300 USD

CRC Foundations Only
$165 USD

CRC Advanced Only
$165 USD

Clinical Trial Billing Compliance
$137.50 USD

Communicating Research Findings *(see RCR)*
$29 USD

Conflicts of Interest
$110 USD per course

Disaster Planning for the Research Enterprise
$165 USD

Essentials of Grant Proposal Development
$99 USD

Essentials of Public Health Research *(see HSR)*
$50 USD

Essentials of Research Administration
$137.50 USD

Essentials of Statistical Analysis
$249 USD

Export Compliance
$110 USD

Good Clinical Practice
$129 USD per course

Good Laboratory Practice
$220 USD

Healthcare Ethics Committee
$165 USD

Human Subjects Research
$129 USD per course

Information Privacy and Security
$110 USD per course

IRB Administration
$165 USD

Laboratory Chemical Safety
$99 USD

Research Study Design
$99 USD

Responsible Conduct of Research
$99 USD per course

Revised Common Rule *(see HSR)*
$129 USD

Semiannual Evaluations In Depth
$99 USD

Webinars
$49 USD per webinar

Courses & Modules List

Animal Care and Use

Included with base subscription

These courses cover the general principles of the ethical care and use of animals in research, training, and testing.

Working with the IACUC

- Working with the IACUC: Introduction
- About the IACUC
- Federal Laws, Policies, and Guidelines
- Planning Research and Completing the Protocol Form
- Procedures: Surgery, Antibody Production, and Blood Collection
- Personnel and Their Welfare
- Special Animal Welfare Considerations
- Making Changes to an Approved Animal Use Protocol
- Reporting Animal Use Concerns

Additional Modules of Interest

- Aseptic Surgery
- Antibody Production in Animals

Essentials for IACUC Members

- Essentials for IACUC Members: Introduction
- Federal Laws, Policies, and Guidelines
- IACUC and IACUC Member Responsibilities
- IACUC Membership Requirements
- Quorum, Alternate Members, and Telecommunications
- The IACUC, CEO, and IO
- Protocol Review
- Suspending Animal Activities
- Types of IACUC Review: Initial, Annual, Triennial
- Documenting IACUC Actions
- Semiannual Evaluations – An Overview
- Facility Inspections and Program Review
- Identifying, Documenting, and Correcting Deficiencies

IACUC Community Member

- Ethics, Regulations, and the IACUC
- IACUC Basics
- Full-committee Meetings and DMR
- Other Responsibilities of IACUC Members
- Additional Tips for Community Members

Post-Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress

- 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

Wildlife Research

- 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

Post-Approval Monitoring (PAM)

- Post-Approval Monitoring (PAM)

Institutional Official: Animal Care and Use

- Introduction to the Challenges of Being an IO: Animal Care and Use Program
- What the IO is Required to Know
- IO Responsibilities
- What Works: A Word from Experienced IOs

IACUC Chair

- Roles and Responsibilities of an IACUC Chair
- The IACUC Chair's Meeting Responsibilities
- The IACUC Chair's Role Outside the IACUC Meeting

Please visit our website to see module lists for our animal specific courses. You will also find module lists for the *Working with the IACUC Refresher* and the *IACUC Member Refresher Case Studies* courses.

Courses & Modules List

Bioethics

This course provides learners with a review of contemporary bioethics issues.

- History of Bioethics
- Ethical Frameworks
- Ethics and Clinical Practice: Pediatrics
- Ethics and Clinical Practice: Adults
- Reproductive Ethics and Start-of-Life Issues
- Aging and End-of-Life Issues
- Genetics and Ethics
- Gender and Bioethics
- Justice and Healthcare
- Human Enhancement
- Additional Resources

Biomedical PI

This course focuses on key topics essential to the biomedical investigator's role and responsibilities in conducting a clinical investigation of a product regulated by the FDA.

- Ethical Frameworks
- Ethics and Clinical Practice: Pediatrics
- Ethics and Clinical Practice: Adults
- Reproductive Ethics and Start-of-Life Issues
- Aging and End-of-Life Issues
- Genetics and Ethics
- Gender and Bioethics
- Justice and Healthcare
- Human Enhancement
- Additional Resources

Biosafety and Biosecurity

17 courses that cover the principles of biosafety and biosecurity, including the safe use and containment of biohazardous agents.

Basic Introduction to Biosafety

- Biosafety and Biosecurity (BSS) Introduction
- Biosafety Course Overview
- Risk Management: Work Practices

Initial Biosafety Training

- Biosafety Course Overview
- Laboratory-Acquired Infections
- Biohazard Risk Assessment
- Medical Surveillance
- Risk Management: Work Practices
- Risk Management: Personal Protective Equipment
- Risk Management: Emergency and Spill Response
- Risk Management: Engineering Controls
- Risk Management: Laboratory Design
- Work Safely with Sharp Instruments
- Disinfection and Sterilization
- Safe Sharps Devices
- Centrifuge Precautions
- Engineering Controls and Containment Devices
- Dual Use Research of Concern (DURC)
- Biosafety and Biosecurity (BSS) Introduction

Biosafety Retraining

- Risk Management: Work Practices
- Risk Management: Personal Protective Equipment
- Risk Management: Emergency and Spill Response
- Risk Management: Engineering Controls
- Risk Management: Laboratory Design
- Work Safely with Sharp Instruments
- Disinfection and Sterilization
- Safe Sharps Devices
- Centrifuge Precautions
- Engineering Controls and Containment Devices
- Dual Use Research of Concern (DURC)
- Biosafety and Biosecurity (BSS) Introduction

Biosafety Officer Training – Basic/Initial

- Biosafety and Biosecurity (BSS) Introduction
- Biosafety Course Overview
- Laboratory-Acquired Infections
- Biohazard Risk Assessment
- Medical Surveillance
- Risk Management: Work Practices
- Risk Management: Personal Protective Equipment
- Risk Management: Emergency and Spill Response
- Risk Management: Engineering Controls
- Risk Management: Laboratory Design
- Work Safely with Sharp Instruments
- Disinfection and Sterilization
- Safe Sharps Devices
- Centrifuge Precautions
- Engineering Controls and Containment Devices
- OSHA Bloodborne Pathogens Standard
- Hepatitis B Virus (HBV) Vaccination
- Labels and Engineering Controls
- Universal Precautions and Work Practices
- Emergency Response Procedures
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Human Gene Transfer Research

Courses & Modules List

- Select Agents
- Biosecurity
- Bioterrorism
- Shipping Regulated Biological Materials: Overview
- Shipping Regulated Biological Materials: Classifications
- Shipping Regulated Biological Materials: Packaging Requirements
- Shipping Regulated Biological Materials: Shipping Papers
- Shipping Regulated Biological Materials: Permits for Restricted Shipments and Transfers
- Shipping Regulated Biological Materials: Security Awareness
- Shipping Regulated Biological Materials: Emergency Response Information
- Shipping Regulated Biological Materials: Refrigerants
- Shipping Regulated Biological Materials: Appendix
- Animal Biosafety
- Understanding Nanotechnology and Its Implications
- Dual Use Research of Concern (DURC)
- USDA Permits: Plant Pest
- USDA Permits: Soils
- USDA Permits: Veterinary Services (VS)

Animal Biosafety

- Animal Biosafety
- Biosafety and Biosecurity (BSS) Introduction

Shipping and Transport of Regulated Biological Materials

- Shipping Regulated Biological Materials: Overview
- Shipping Regulated Biological Materials: Classifications
- Shipping Regulated Biological Materials: Packaging Requirements
- Shipping Regulated Biological Materials: Shipping Papers
- Shipping Regulated Biological Materials: Permits for Restricted Shipments and Transfers
- Shipping Regulated Biological Materials: Security Awareness
- Shipping Regulated Biological Materials: Emergency Response Information
- Shipping Regulated Biological Materials: Refrigerants
- Shipping Regulated Biological Materials: Appendix

OSHA Bloodborne Pathogens

- OSHA Bloodborne Pathogens Standard
- Hepatitis B Virus (HBV) Vaccination
- Labels and Engineering Controls
- Universal Precautions and Work Practices
- Emergency Response Procedures

Select Agents, Biosecurity, and Bioterrorism

- Select Agents
- Biosecurity
- Bioterrorism

Emergency and Incident Response to Biohazard Spills and Releases

- Risk Management: Emergency and Spill Response
- Biosafety and Biosecurity (BSS) Introduction

NIH Recombinant DNA Guidelines

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Biosafety and Biosecurity (BSS) Introduction
- Dual Use Research of Concern (DURC)

Personal Protective Equipment

- Risk Management: Personal Protective Equipment
- Biosafety and Biosecurity (BSS) Introduction

Human Gene Transfer

- Human Gene Transfer Research
- Biosafety and Biosecurity (BSS) Introduction

Nanotechnology

- Understanding Nanotechnology and Its Implications

Dual Use Research of Concern (DURC)

- Dual Use Research of Concern (DURC)
- Biosafety and Biosecurity (BSS) Introduction

Institutional Biosafety Committee Member Training

- Biosafety Course Overview
- Laboratory-Acquired Infections
- Biohazard Risk Assessment
- Medical Surveillance
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Human Gene Transfer Research
- Dual Use Research of Concern (DURC)
- Biosafety and Biosecurity (BSS) Introduction

USDA Permits

- USDA Permits: Plant Pest
- USDA Permits: Soils
- USDA Permits: Veterinary Services (VS)

Hazard Communication

- Hazard Communication

Courses & Modules List

Clinical Research Coordinator

These courses focus on key topics essential to the conduct of clinical research. They are specifically tailored to the needs of clinical research coordinators.

CRC Foundations

- CRC Course: Overview
- Planning Research
- Funding, Financial Management, and Budgeting
- Working with the Institutional Review Board (IRB)
- Protocol Review and Approvals
- Principal Investigator (PI) Responsibilities
- Clinical Research Coordinator (CRC) Responsibilities
- Sponsor Responsibilities
- Informed Consent
- Site Management, Quality Assurance, and Public Information
- CRC Resources
- CRC Organization-Specific Module

Additional Modules of Interest

- Overview of the Clinical Trial Agreement (CTA)
- Understanding the Terms of the Clinical Trial Agreement (CTA)
- Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)
- Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites

CRC Advanced

- Project Management for Clinical Trials
- Preventing and Identifying Misconduct and Noncompliance
- Training and Mentoring
- Financial Management of Clinical Trials
- Subject Recruitment and Retention
- Statistics and Data Management of Clinical Trials
- Specialty Areas and Regulatory Requirements

Clinical Trial Billing Compliance

This course focuses on developing the knowledge and skills necessary to maintain compliance and best practices associated with clinical research billing.

- Before the National Coverage Determination/The Clinical Trial Policy and Its Meaning
- Understanding the Term "Qualifying Clinical Trial" for Investigational Drugs and Devices
- Implementing a Clinical Trial Billing Compliance Program
- Study Document Synchronization
- Using a Coverage Analysis to Enhance Billing Accuracy and Claims Processing
- Coding Clinical Trial Activity Through the Insurance Claim

Conflicts of Interest

Included with base subscription

These courses cover the U.S. Public Health Service (PHS) regulations on financial conflicts of interest and an investigator's responsibilities related to the disclosure of "Significant Financial Interests."

Conflicts of Interest Basic

- Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (COI-Basic)
- Institutional Responsibilities as They Affect Investigators (COI-Basic)
- Conflicts of Commitment and Conscience (COI-Basic)
- Institutional Conflicts of Interest (COI-Basic)
- Organization-Specific Policies (Basic Level)

Please visit our website to see module list for the *Conflict of Interest Refresher* course.

Disaster Planning for the Research Enterprise

This course offers information about disaster planning and business continuity to those responsible for research oversight.

- Disaster Planning for the Research Enterprise: Overview
- Disaster Planning: Responsibilities of the Principal Investigator in Human Subjects Research
- Disaster Planning: Animal Care and Use Research
- Disaster Planning: Human Subjects Research
- Disaster Planning: Data Security
- Disaster Planning: Biohazards, Valuable Biological Materials, and Select Agents

Essentials of Grant Proposal Development

This course provides a step-by-step guide to help simplify the grant writing process.

- An Introduction to Grants
- Getting Started in Grant Writing
- Finding and Selecting Funding Opportunities
- Crafting a Proposal Development Plan
- Creating the Proposal Narrative
- Tables, Forms, and Documents
- Preparing the Budget and Budget Justification
- Understanding the Proposal Review Process
- Bringing it All Together

Courses & Modules List

Essentials of Research Administration

This course provides an overview of research administration.

- Elements of Research Administration
- Elements of Research Development
- Elements of Pre-Award
- Elements of Award Negotiation and Acceptance
- Elements of Post-Award

Additional Modules of Interest

- Overview of the Clinical Trial Agreement (CTA)
- Understanding the Terms of the Clinical Trial Agreement (CTA)
- Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)
- Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites

Essentials of Statistical Analysis

These courses teach learners the essentials of statistical analysis via an interactive online experience.

EOSA: Part 1

- Introduction
- Population and Sample
- Central Tendency and Variability
- Sensitivity and Specificity
- Distribution and Probability
- Probability and Odds
- Normal Distribution and Z-Scores
- Skewness and Kurtosis

EOSA: Part 2

- Standard Error and Type I/II Errors
- The Four Horsemen
- Confidence Intervals and Degrees of Freedom
- Comparing Two Independent Means
- Wilcoxon Rank-Sum Test
- Paired Samples T-Test
- Nonparametric Methods for Paired Sample Data

EOSA: Part 3

- Analysis of Variance
- Following Up a Significant ANOVA
- Kruskal-Wallis Nonparametric ANOVA
- Proportions
- Comparing Two Independent Proportions
- Contingency Tables and Chi-Square Tests
- Other Contingency Table Analyses
- Correlations
- Comparing Correlation Coefficients
- Simple Linear Regression
- Multiple Regression

EOSA: Complete is also available and includes *EOSA: Part1, Part 2,* and *Part 3* .

Export Compliance

This course provides an overview of export compliance regulations along with information specifically tailored to certain roles, responsibilities, and activities.

- Introduction to Export Compliance
- Export Compliance for Researchers: Part I
- Export Compliance for Researchers: Part II
- Export Compliance for Research Administrators
- Export Compliance and Biosafety
- Export Compliance for Operational Departments
- Export Compliance for International Shipping
- Export Compliance and Purchasing
- Export Compliance and International and Foreign Waters
- Export Compliance and Collaborations
- Export Compliance and United States Sanctions Programs
- Export Compliance and Distance Education
- Export Compliance When Using Technology in Research

Please visit our website to see module list for the *Export Compliance Refresher* course.

Courses & Modules List

Good Clinical Practice

Included with base subscription

These courses that provide essential good clinical practice training for research teams involved in clinical trials of drugs, biologics, and devices, as well as those involved in behavioral intervention and social science research studies.

GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)

- The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices
- Overview of New Drug Development
- Overview of ICH GCP
- ICH – Comparison Between ICH GCP E6 and U.S. FDA Regulations
- Conducting Investigator-Initiated Studies According to FDA Regulations and GCP
- Investigator Obligations in FDA-Regulated Clinical Research
- Managing Investigational Agents According to GCP Requirements
- Overview of U.S. FDA Regulations for Medical Devices
- Informed Consent in Clinical Trials of Drugs, Biologics, and Devices
- Detecting and Evaluating Adverse Events
- Reporting Serious Adverse Events
- Monitoring of Clinical Trials by Industry Sponsors
- Audits and Inspections of Clinical Trials
- Completing the CITI GCP Course

GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)

- The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Biologics
- Overview of New Drug Development
- Overview of ICH GCP
- ICH – Comparison Between ICH GCP E6 and U.S. FDA Regulations
- Conducting Investigator-Initiated Studies According to FDA Regulations and GCP
- Investigator Obligations in FDA-Regulated Research
- Managing Investigational Agents According to GCP Requirements
- Informed Consent in Clinical Trials of Drugs and Biologics
- Monitoring of Clinical Trials of drugs by Industry Sponsors
- Audits and Inspections of Clinical Trials of Drugs and Biologics
- Detecting and Evaluating Adverse Events
- Reporting Serious Adverse Events in Investigations of Drugs and Biologics
- Completing the CITI GCP Course

GCP - Social and Behavioral Research Best Practices for Clinical Research

- Research Protocol
- Recruitment and Retention
- Informed Consent Communication
- Privacy and Confidentiality
- Participant Safety and Adverse Event Reporting
- Quality Control and Assurance
- Research Misconduct

GCP for Clinical Investigations of Devices

- The CITI Good Clinical Practice Course for Clinical Investigations of Devices
- Overview of U.S. FDA Regulations for Medical Devices
- Investigator Obligations in FDA-Regulated Clinical Research
- Conducting Investigator-Initiated Cinical Investigations of Devices
- Managing Investigational Devices According to GCP Requirements
- Informed Consent in Clinical Investigations of Devices
- Monitoring Clinical Investigations of Devices
- Audits and Inspections of Clinical Investigations of Devices
- Reporting Requirements for Clinical Investigations of Devices
- Completing the CITI Program's GCP Course for Clinical Investigations of Devices

Additional Modules of Interest

- Humanitarian Use Devices (HUDs)
- Phase I Research: Understanding Phase I Research
- Phase I Research: Protecting Phase I Subjects
- Overview of the Clinical Trial Agreement (CTA)
- Understanding the Terms of the Clinical Trial Agreement (CTA)
- Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)
- Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites
- Hot Topics in Clinical Research
- Overview of ICH GCP E6(R2) Revisions

Please visit our website to see module lists for the *GCP FDA Refresher*, *GCP ICH Refresher*, *GCP Device Refresher, and GCP SBR Advanced Refresher* courses.

Courses & Modules List

Good Laboratory Practice

This course provides training on good laboratory practice for non-clinical laboratory studies that reflects regulations and best practices established by key regulatory agencies and guidelines.

- CITI GLP Course: Overview
- History of the Good Laboratory Practices: A Breach of Trust
- Here & There: U.S. and Global Regulatory Agencies
- Let's Be Clear: Words Matter in GLP
- Components of Compliance
- GLP Requirements of Personnel
- The Responsible Use of Laboratory Animals (LA) – Part 1
- The Responsible Use of Laboratory Animals (LA) – Part 2
- Standard Operating Procedures (SOPs) and Equipment Operation
- Understanding Raw Data and Reconstruction
- Required Reading: Study Protocols
- Archiving Study Data and Specimens
- The Quality Assurance Unit (QAU)
- Chemicals, Test Articles, and Solutions
- Reporting of Study Results and Regulatory Decisions on Study Disqualification

Healthcare Ethics Committee

This course focuses on developing the knowledge and skill base necessary for being a successful healthcare ethics committee member.

- Introduction: Healthcare Ethics Committee (HEC) Course
- Healthcare Ethics Committee (HEC): Definition, Mission, and Organizational Structure
- Healthcare Ethics Committee (HEC) Membership
- Ethical Theories and Principles for Healthcare Ethics
- Ethical Problem Identification, Analysis, and Solving
- Informed Consent in the Clinical Setting
- End-of-Life Issues: Capacitated Patients
- Advance Directives (Living Wills)
- Decision Making for Incapacitated Patients
- End-of-Life Issues: Cultural Issues, Medical Futility, and Resuscitation
- End-of-Life Issues: Brain Death, Palliative Sedation, Physician-Assisted Suicide, and Other Related Issues
- Medical Confidentiality
- Neonatal Ethics and Maternal-Fetal Ethical Issues
- Overview of Allocation
- Healthcare Ethics Committee (HEC) Educational Activities and Policy Development and Review
- Clinical Ethics Consultation: Part 1
- Clinical Ethics Consultation: Part 2

Human Subjects Research

Included with base subscription

HSR provides foundational training in human subjects research and includes the historical development of human subject protections, ethical issues, and current regulatory and guidance information.

Biomedical (Biomed) Basic

- History and Ethics of Human Subjects 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
- Populations in Research Requiring Additional Considerations and/or Protections
- Research Involving Prisoners
- Research Involving Children
- Research Involving Pregnant Women, Fetuses, and Neonates
- Avoiding Group Harms - U.S. Research Perspectives
- Avoiding Group Harms - International Research Perspectives
- FDA-Regulated Research
- Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research
- Research and HIPAA Privacy Protections
- Vulnerable Subjects - Research Involving Workers/Employees
- Conflicts of Interest in Human Subjects Research

Social-Behavioral-Educational (SBE) Basic

- History and Ethical Principles - SBE
- Defining Research with Human Subjects - SBE
- The Federal Regulations - SBE
- Assessing Risk - SBE
- Informed Consent - SBE
- Privacy and Confidentiality - SBE
- Research with Prisoners - SBE
- Research with Children - SBE
- Research in Public Elementary and Secondary Schools - SBE
- International Research - SBE
- Internet-Based Research - SBE
- Unanticipated Problems and Reporting Requirements in Social and Behavioral Research
- Vulnerable Subjects - Research Involving Workers/Employees
- Populations in Research Requiring Additional Considerations and/or Protections
- Conflicts of Interest in Human Subjects Research

Courses & Modules List

Additional Modules of Interest

- Are You Thinking About Being in a Research Study?
- Cultural Competence in Research
- Hot Topics
- Humanitarian Use Devices (HUDs)
- International Studies
- Data and Safety Monitoring in Human Subjects Research
- Human Subjects Considerations and Big Data Research

Consent Modules

- Consent and Biobanks and Associated Databases
- Consent and Cultural Competence
- Informed Consent and Incidental Findings in Research with Human Subjects
- Consent and Subject Recruitment Challenges: Remuneration
- Consent and Subject Recruitment Challenges: Therapeutic Misconception
- Consent in the 21st Century
- Consent Tools Used by Researchers
- Consent with Subjects Who Do Not Speak English

Clinical Trial Agreement (CTA) Modules

- Overview of the Clinical Trial Agreement (CTA)
- Understanding the Terms of the Clinical Trial Agreement (CTA)
- Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)
- Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites

Community-Engaged Research (CEnR) Modules

- Introduction to Community-Engaged Research (CEnR)
- Introduction to Community-Based Participatory Research (CBPR)
- Ethical and Practical Considerations in Community-Engaged Research (CEnR)

Disaster and Conflict Research Modules

- Disaster and Conflict Research, Part 1: PI Responsibilities
- Disaster and Conflict Research, Part 2: Best Practices and Recommendations

Family Educational Rights and Privacy Act (FERPA) Modules

- FERPA: An Introduction
- FERPA for Researchers
- FERPA for Institutional Review Boards (IRBs)

Phase I Research Modules

- Phase I Research: Understanding Phase I Research
- Phase I Research: Protecting Phase I Subjects

Population-Specific Modules

- Gender and Sexuality Diversity (GSD) in Human Research
- Illegal Activities or Undocumented Status in Human Research
- Research Involving Subjects at the End-of-Life
- Research with Critically Ill Subjects
- Research with Decisionally Impaired Subjects
- Research with Older Adults
- Research with Persons who are Socially or Economically Disadvantaged
- Research with Subjects with Physical Disabilities & Impairments
- Students in Research

IRB Focused Modules

- External IRB Review
- I Have Agreed to be an IRB Community Member. Now What?
- The IRB Administrator's Responsibilities
- The IRB Member Module - "What Every New IRB Member Needs to Know"
- 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

Stem Cell Research Modules

- Stem Cell Research Oversight (Part I)
- Stem Cell Research Oversight (Part II)

Essentials of Public Health Research

- Introduction to Public Health Research
- Public Health Research and Public Health Practice
- Informed Consent and Confidentiality in Public Health Research
- Ethical Issues in Public Health Research

Institutional/Signatory Official: Human Subjects Research

- Introduction to Being an Institutional Official (IO)
- IO Knowledge Requirements: Human Subject Protections
- Expectations of the IO
- Challenges of Being an IO: Human Subject Protections

IRB Chair

- Role and Responsibilities of an IRB Chair
- IRB Chair Meeting Responsibilities
- The IRB Chair's Role Outside of the IRB Meeting

Courses & Modules List

Revised Common Rule

- Overview of the Final Rule Revisions
- New and Revised Definitions
- Informed Consent - Changes and Additions to Consent Processes
- Informed Consent - Changes to the Documentation of Consent
- Understanding Broad Consent
- Secondary Research with Identifiable Information and Biospecimens
- Effect of Revised Common Rule on Research Roles
- Updates to Exemption Categories
- Limited IRB Review
- Updates to Expedited Review Procedures

Please visit our website to see module lists for the *Biomedical (Biomed)* and *Social-Behavioral-Educational (SBE) Refreshers*. Legacy versions of our Biomed Basic and SBE Basic are also available for those who need training on the Common Rule's pre-2018 requirements.

Information Privacy & Security

Included with base subscription

These courses cover the principles of data protection, focusing on the healthcare-related privacy and information security requirements of HIPAA and the educational records and data-related requirements of FERPA.

Health Privacy (HIPAA)

- Basics of Health Privacy
- Health Privacy Issues for Clinicians
- Health Privacy Issues for Fundraisers
- Health Privacy Issues for Marketers
- Health Privacy Issues for Researchers
- Health Privacy Issues for Students and Instructors

Information Security

- Basics of Information Security, Part 1
- Basics of Information Security, Part 2
- Picking and Protecting Passwords
- Protecting Your Computer
- Protecting Your Identity
- Protecting Your Portable Devices
- Safer Emailing and Messaging, Part 1
- Safer Emailing and Messaging, Part 2
- Safer Social Networking
- Safer Web Surfing
- Security for Work/Workers Off-Site

Family Educational Rights and Privacy Act (FERPA)

- FERPA: An Introduction
- FERPA for Instructors
- FERPA for Students
- FERPA for Researchers
- FERPA for Institutional Review Boards (IRBs)
- FERPA for Educational Administrators

IRB Administration

This course offers a comprehensive review of the critical areas associated with IRB and IRB office operations.

- HRPP/IRB Policies and Procedures
- Reporting to Federal Agencies
- Communicating with Subjects
- Internal Quality Assurance and Quality Improvement of the HRPP
- External Oversight of the HRPP/IRB: Monitoring and Inspections

Additional Modules of Interest

- 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

Laboratory Chemical Safety

This course covers the fundamental safety practices for working with hazardous chemicals in the laboratory.

- Fundamental Concepts of Laboratory Chemical Safety
- Chemical Storage and Segregation
- Emergency Planning
- Chemical Fume Hoods
- Hazard Identification and Risk Assessment
- Personal Protective Equipment (PPE) When Using Hazardous Chemicals
- Laboratory Waste Management
- Transporting Hazardous Chemicals
- Chemical Security
- Compressed Gas Cylinders

Courses & Modules List

Protocol Registration and Results Summary Disclosure in ClinicalTrials.gov

This course provides a video-enhanced guide to compliance with the FDAAA Final Rule and NIH Policy on clinical trial disclosure in ClinicalTrials.gov.

- Overview: Protocol Registration and Results Summary Disclosure in ClinicalTrials.gov
- Transparency in Clinical Research: ClinicalTrials.gov in Context
- Protocol Registration and Results System (PRS): Structure, Access, and Roles
- Applicable Clinical Trials (ACTs) and Responsible Party (RP) Identification
- Protocol Registration
- Summary Results Information Submission
- ClinicalTrials.gov and Informed Consent

Research Study Design

This course provides learners with an understanding of how to improve study design, collect and analyze data, and promote reproducible research.

- Introduction to Scientific Research
- Observational Research
- Interventional Research
- Quantitative Research: Statistical Reasoning and Hypothesis Testing: Part 1
- Quantitative Research: Statistical Reasoning and Hypothesis Testing: Part 2
- Survey Research: Designing the Instrument
- Survey Research: Conducting the Research
- Qualitative Research
- Mixed Methods
- Data Management
- Reproducibility of Research Results

Responsible Conduct of Research

Included with base subscription

RCR covers core norms, principles, regulations, and rules governing the practice of research.

RCR Basic

- Introduction to RCR (RCR-Basic)
- Authorship (RCR-Basic)
- Collaborative Research (RCR-Basic)
- Conflicts of Interest (RCR-Basic)
- Data Management (RCR-Basic)
- Financial Responsibility (RCR-Basic)
- Mentoring (RCR-Basic)
- Peer Review (RCR-Basic)
- Plagiarism (RCR-Basic)
- Research Involving Human Subjects (RCR-Basic)
- Research Misconduct (RCR-Basic)
- Using Animal Subjects in Research (RCR-Basic)

Additional Modules of Interest

- Export Controls and National Security (RCR)
- Research, Ethics, and Society (RCR)
- Environmental and Social Dimensions of Engineering Research (RCR)
- Reproducibility of Research Results

Communicating Research Findings

- Communicating with the Public
- Presentation of Research Findings

Please visit our website to see the module list for the *RCR Refresher* course.

Semiannual Evaluations In Depth

This course provides IACUC members and administrators with more in-depth information about the conduct of semiannual evaluations.

Overview and Regulations
Facility Inspections
Program Review
The Semiannual Report to the Institutional Official (IO)
Follow-Up and Follow-Through
Keeping it Fresh

Courses & Modules List

Webinars

- The Challenge of Medicare Advantage Plans and Local Coverage Determinations
- GDPR & Human Subject Research in the U.S.
- FERPA: A Quick Review of the Law for Researchers and IRBs
- Transitioning Research to the Revised Common Rule: The What, How, and Why
- Revised Common Rule Webinar: Overview of Revisions
- Research with Native American Communities: Important Considerations When Applying Federal Regulations
- Ethics & Policy Issues in CRISPR Gene Editing

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