

Core Training

COURSE OVERVIEW

This training is comprised of multiple independent (standalone) modules aimed at cultivating an advanced understanding of various research-related topics and responsibilities. The modules are a component of the [OHSP Education & Training Framework](#) and the content is meant to build upon remaining components of the framework, including the [Orientation to Conducting Human Subject Research](#) and [Research Boot Camp](#) courses. The modules, listed below (with links to respective course content and enrollment information), are available for all University of Rochester (UR) faculty, staff and students via Blackboard.

Available Modules:

- [Study Design](#)
- [Principal Investigator Oversight](#)
- [Study Operations](#)
- [Recruitment & Retention](#)

Note:

The following modules are currently unavailable: Informed Consent; Investigational Products; Subject Safety; Essential Documentation; and Quality Management & Non-Compliance. These courses are in the process of being transitioned to an online format. In the interim, consider using the following as supplemental training material:

- [Society for Clinical Research Site \(SCRS\)/Transcelerate Informational Programs for Site Staff Conducting Clinical Research](#) – These modules are available online at no cost (use the ‘Non-Member Access’ option to access modules from the link above). Available modules include: Principal Investigator Oversight; Adverse Events and Safety; Clinical Research Overview; Clinical Practice vs. Clinical Research; Conducting a Study; IRB/IEC Responsibilities and Informed Consent; Delegation and Training; Source Documentation; Investigational Product; Essential Documents for a Clinical Study; Facilities and Equipment; and Monitoring and Auditing.
- Previously recorded UR Human Research Protection Program (UR-HRPP) Educational Forums – OHSP hosts UR-HRPP Educational Forums on salient research topics routinely throughout the academic year; most sessions are recorded and available in Blackboard for all UR faculty, staff and students. A searchable index of recordings is available [here](#). To access the recordings, follow the steps provided in the [OHSP’s Blackboard Self-Enrollment Instructions](#) (in step 2 of the instructions, search for the course title ‘UR-HRPP Educational Materials’).

CORE TRAINING: STUDY DESIGN

To enroll in this module, follow the steps provided in the [OHSP’s Blackboard Self-Enrollment Instructions](#) (in step 2 of the instructions, search for the course title ‘OHSP Core Training: Study Design’).

Learning Objectives:

- Describe basic elements of observational and experimental study designs

- Summarize key elements of ethical study design
- Evaluate study protocols against feasibility standards

Approximate Length:

2 hours

JTF Core Competency Alignment:

The content included within this course supports the knowledge and skills needed to meet the following [Joint Task Force \(JTF\) Core Competencies](#): 1.2, 1.3, 2.3, 2.8, 3.3, 4.1, 5.2, 6.1, 7.3.

Content Outline:

- I. Study Design Basics
 - a. Types of Research
 - b. Other Types of Reviews
 - c. Phases of Clinical Research
 - d. General Classes of Research
- II. Ethical Study Design
 - a. Relevant Question
 - b. Scientific Validity
 - c. Appropriate Selection of Subjects
 - d. Favorable Risk-Benefit Ratio
 - e. Respect for Subjects
- III. Evaluating Study Protocols (aka Study Feasibility)
 - a. Operational 'Do-Ability'
 - b. Scientific Merit

CORE TRAINING: PRINCIPAL INVESTIGATOR (PI) OVERSIGHT

To enroll in this module, follow the steps provided in the [OHSP's Blackboard Self-Enrollment Instructions](#) (in step 2 of the instructions, search for the course title 'OHSP Core Training: PI Oversight').

Learning Objectives:

- Identify sources that define the responsibilities of a Principal Investigator
- Describe general responsibilities of a Principal Investigator
- Summarize common errors in conducting human subject research
- Reflect on mechanisms for overseeing the conduct of human subject research

Approximate Length:

2 hours

JTF Core Competency Alignment:

The content included within this course supports the knowledge and skills needed to meet the following [Joint Task Force \(JTF\) Core Competencies](#): 4.2, 5.1, 5.3, 7.3, 8.1.

Content Outline:

- I. The Principal Investigator Role
 - a. Definition of a PI
 - b. PI Oversight
 - II. Principal Investigator Responsibilities
 - a. Levels of Compliance
 - b. OHSP Policy 901 Investigator Responsibilities
 - III. Common Problem Areas
 - IV. Best Practices in PI Oversight
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CORE TRAINING: STUDY OPERATIONS

To enroll in this module, follow the steps provided in the [OHSP's Blackboard Self-Enrollment Instructions](#) (in step 2 of the instructions, search for the course title 'OHSP Core Training: Study Operations').

Learning Objectives:

- Describe how organizational structure affects day-to-day study activities
- Summarize study activities occurring prior to the initiation of a study, during protocol implementation and at study close-out
- Identify study management strategies and tools that aid in running compliant studies
- Summarize roles and activities in multi-site research

Approximate Length:

2 hours

JTF Core Competency Alignment:

The content included within this course supports the knowledge and skills needed to meet the following [Joint Task Force \(JTF\) Core Competencies](#): 3.2, 4.2, 5.2, 5.4.

Content Outline:

- I. Organizational Structure of a Study
 - II. Study Start-Up
 - a. Planning for Study Procedures/Tasks
 - b. Planning for Data Management
 - c. Study Team Establishment & Training
 - d. Compliance Strategies
 - III. Study Conduct
 - a. Subject Enrollment
 - b. Study Visit Management
 - c. Subject Completion
 - d. Non-Compliance
 - IV. Study Close-Out
 - a. Types of Study Closures
 - b. Storage & Retention
 - V. Multicenter Research
 - a. Roles & Responsibilities
 - b. Study Monitoring
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CORE TRAINING: RECRUITMENT & RETENTION

To enroll in this module, follow the steps provided in the [OHSP's Blackboard Self-Enrollment Instructions](#) (in step 2 of the instructions, search for the course title 'OHSP Core Training: Recruitment and Retention').

Learning Objectives:

- Summarize various recruitment methods and factors that affect recruitment
- Describe how to assess study feasibility as it relates to subject recruitment and retention
- Apply best practices for subject recruitment and retention throughout the course of a study

Approximate Length:

1 hour

JTF Core Competency Alignment:

The content included within this course supports the knowledge and skills needed to meet the following [Joint Task Force \(JTF\) Core Competencies](#): 5.2, 5.4.

Content Outline:

- I. Recruitment & Retention Factors
 - a. Recruitment Funnel
 - b. Barriers to Recruitment & Factors of Study Participation
 - c. Determining Study Feasibility (as it relates to Recruitment & Retention)
 - II. Recruitment Strategies
 - III. Retention Strategies
 - IV. Planning for Recruitment & Retention
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