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

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**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

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
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