### Core Training Outline

Available Modules:
- **Study Design**
- **PI 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. Announcements will be made via the Office for Human Subject Protection listserv as they become available. 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. 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 University of Rochester Human Research Protection Program Educational Forums. All recorded sessions are available in Blackboard for all University of Rochester faculty, staff and students; information on accessing the sessions is available [here](#). A searchable directory of recordings is available [here](#).

<table>
<thead>
<tr>
<th>Module</th>
<th>Objectives &amp; Course Outline</th>
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</table>
| **Study Design**            | **Objectives:**<br>  - Describe basic elements of observational and experimental study designs  
  - Summarize key elements of ethical study design  
  - Evaluate study protocols against feasibility standards  
  **Content Outline:**<br>  I. Study Design Basics  
  - Types of Research  
    - Observational  
    - Experimental  
  - Other Types of Reviews  
  - Phases of Clinical Research  
  - General Classes of Research  
  II. Ethical Study Design  
  - Relevant Question  
  - Scientific Validity  
  - Appropriate Selection of Subjects  
  - Favorable Risk-Benefit Ratio  
  - Respect for Subjects  
  III. Evaluating Study Protocols (aka Study Feasibility)  
  - Operational ‘Do-Ability’  
  - Scientific Merit  
    - OHSP Policy 505 Scientific Review for Human Subjects Research |
| **PI Oversight**            | **Objectives:**<br>  - Identify sources that define the responsibilities of a Principal Investigator  
  - Describe general responsibilities of a Principal Investigator |
<table>
<thead>
<tr>
<th><strong>Study Operations</strong></th>
<th><strong>Objectives:</strong></th>
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<tbody>
<tr>
<td>• Summarize common errors in conducting human subject research</td>
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<td>• Reflect on mechanisms for overseeing the conduct of human subject research</td>
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**Content Outline:**

<table>
<thead>
<tr>
<th>I. The Principal Investigator Role</th>
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<tbody>
<tr>
<td>a. Definition of a PI</td>
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<td>b. PI Oversight</td>
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<tr>
<th>II. Principal Investigator Responsibilities</th>
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<tbody>
<tr>
<td>a. Levels of Compliance</td>
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<td>b. OHSP Policy 901 Investigator Responsibilities</td>
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<th>III. Common Problem Areas</th>
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<td>IV. Best Practices in PI Oversight</td>
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<th><strong>Study Operations</strong></th>
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<tr>
<td>• Describe how organizational structure affects day-to-day study activities</td>
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<td>• Summarize study activities occurring prior to the initiation of a study, during protocol implementation and at study close-out</td>
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<td>• Identify study management strategies and tools that aid in running compliant studies</td>
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<tr>
<td>• Summarize roles and activities in multi-site research</td>
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<thead>
<tr>
<th>I. Organizational Structure of a Study</th>
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<tr>
<th>II. Study Start-Up</th>
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<tr>
<td>a. Planning for Study Procedures/Tasks</td>
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<tr>
<td>b. Planning for Data Management</td>
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<tr>
<td>c. Study Team Establishment &amp; Training</td>
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<tr>
<td>d. Compliance Strategies</td>
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<tr>
<th>III. Study Conduct</th>
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<tbody>
<tr>
<td>a. Subject Enrollment</td>
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<tr>
<td>b. Study Visit Management</td>
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<tr>
<td>c. Subject Completion</td>
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<tr>
<td>d. Non-Compliance</td>
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<tr>
<th>IV. Study Close-Out</th>
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<tbody>
<tr>
<td>a. Types of Study Closures</td>
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<tr>
<td>b. Storage &amp; Retention</td>
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<tr>
<th>V. Multicenter Research</th>
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<tbody>
<tr>
<td>a. Roles &amp; Responsibilities</td>
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<tr>
<td>b. Study Monitoring</td>
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<tr>
<th><strong>Recruitment &amp; Retention</strong></th>
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<tr>
<td>• Summarize various recruitment methods and factors that affect recruitment</td>
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<tr>
<td>• Describe how to assess study feasibility as it relates to subject recruitment and retention</td>
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<tr>
<td>• Apply best practices for subject recruitment and retention throughout the course of a study</td>
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**Content Outline:**

<table>
<thead>
<tr>
<th>I. Recruitment &amp; Retention Factors</th>
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<tr>
<td>a. Recruitment Funnel</td>
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<tr>
<td>b. Barriers to Recruitment &amp; Factors of Study Participation</td>
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<tr>
<td>c. Determining Study Feasibility (as it relates to Recruitment &amp; Retention)</td>
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<th>II. Recruitment Strategies</th>
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<tr>
<td>III. Retention Strategies</td>
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IV. Planning for Recruitment & Retention

**CURRENTLY UNAVAILABLE**

Objectives:
- Analyze factors that influence the quality and effectiveness of the informed consent process
- Respond appropriately to situations where the informed consent process has been or potentially will be compromised
- Use techniques to improve the informed consent process

Content Outline:
I. Current State of the Informed Consent Process
II. Process Practice
   a. Drafting & Reviewing the Consent Document
   b. Critiquing an Informed Consent Process
   c. Process Practice Tips
III. Troubleshooting the Informed Consent Process
   a. Case Studies
   b. Quality Management Practices

Investigational Products

**CURRENTLY UNAVAILABLE**

Objectives:
- Determine the appropriate regulatory pathway for a specific study based on design and objectives
- Describe site and sponsor-investigator responsibilities in the clinical development process for drugs and devices
- Summarize FDA submission and maintenance requirements
- Demonstrate appropriate management and accountability of investigational products

Content Outline:
I. Drug & Device Clinical Development Process
II. Regulatory Framework: What Regs Apply & When
   a. FDA – 312, 812
   b. ICH GCP & FDA
   c. OHSP Policies
III. Key Players: Who’s Responsible for What?
   a. Site Investigators vs. Sponsor-Investigators

IV. Submitting to the FDA
   a. Pre-Submission Considerations
   b. Filing the IND/IDE
   c. IND/IDE Maintenance

V. Investigational Product Management & Accountability
   a. Management of Drugs/Biologics/Supplements
   b. Subject-Specific Accountability
   c. IDS vs. Study Team
   d. Management of Devices

VI. Additional Considerations
   a. Emergency Use of Investigational Products
   b. Expanded Access to Investigational Drugs for Treatment
Subject Safety

Objective:
- Describe methods for identifying, assessing and managing research events.
- Differentiate types of research events and their associated reporting requirements.
- Summarize types of data and safety monitoring and respective roles within the monitoring process.

Content Outline:
I. Safety Basics
   a. Definitions, Classifications & Grading
II. Identifying and Managing Research Events
   a. Mechanisms for Identifying Research Events
   b. PI Review & Oversight
   c. Considerations Regarding Continued Participation
   d. Follow-Up Through Event Resolution
III. Data & Safety Monitoring
   a. Types of Data & Safety Monitoring
   b. Site Responsibilities – Multi-Center vs. Single-Center; Investigator-Initiated
IV. Reporting Requirements
   a. Who’s Responsible for What and When
V. Additional Considerations
   a. Incidental Findings
   b. Safety Outliers

Essential Documentation

Objective:
- Define essential documentation and determine what type of documentation must be maintained, based on the nature of the research
- Differentiate between source documentation and study documentation
- Apply best practices in developing and maintaining study documentation
- Summarize good documentation practices

Content Outline:
I. Essential Documentation: The Basics
   a. Definition of Essential Documentation
   b. Types of Essential Documentation
   c. Required vs. Good Practice Documentation
II. Prepping for Study Implementation
   a. Regulatory File
   b. Subject-Specific Documentation
III. Maintaining Essential Documentation
   a. Regulatory File
   b. Subject-Specific Documentation
IV. Post-Study Considerations: Retention & Archiving

Quality Management & Non-Compliance

** CURRENTLY UNAVAILABLE**
Objectives:
- Describe the review process and reporting requirements related to non-compliance.
- Differentiate types of quality reviews related to the conduct of research.
- Develop corrective and preventative action plans and evaluate their appropriateness based on context.
- Summarize how to implement a quality management plan at the site level.

Content Outline:
I. Non-Compliance
   a. Definitions
   b. Review Process
   c. Reporting
II. Quality Management: What is it and why is it important?
III. Types of Quality-Related Review
   a. Monitoring
   b. Audits, QA/QI Reviews
   c. Regulatory Inspections (OHRP, FDA)
IV. Preparing for Quality-Related Reviews
V. Responding to / Addressing Findings
   a. Common Findings
   b. Root Cause Analysis
   c. Effective & Appropriate CAPAs
VI. Site Quality Management
   a. Developing a Quality Management Plan at the Site
   b. Conducting Self-Reviews
   c. Managing Findings of Self-Reviews