Core Training Outline

Modules:

1) Study Design
2) PI Oversight
3) Financial Management
4) Study Operations
5) Recruitment & Retention
6) Informed Consent
7) Investigational Products
8) Subject Safety
9) Essential Documentation
10) Quality Management & Non-Compliance

Module	Objectives, Content Outline & MyPath Access
1) Study Design	Objectives: • Describe basic elements of observational and experimental study designs • Summarize key elements of ethical study design • Evaluate study protocols against feasibility standards Content Outline: I. Study Design Basics a. Types of Research ➢ Observational ➢ Experimental 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 ➢ OHSP Policy 505 Scientific Review for Human Subjects Research **Instructions for Accessing Course in MyPath**: Click here
2) PI Oversight	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 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 **Instructions for Accessing Course in MyPath**: Click here
3) Financial Management	NOTE: This training module is currently fulfilled by pre-existing content developed by the Office of Research & Project Administration (ORPA). Course completion requirements include: • CT-01 Overview of UR Clinical Research Billing Policy and Standard Operating Procedures: This course is available online through MyPath. To access the course: ➢ Log in to MyPath ➢ Type 'CT-01' in the search box in the upper left-hand corner of the main menu; click on the name of the course once it automatically populates. ➢ Click 'Request'. From there, MyPath will automatically direct you to your Learning Transcript. Click 'Open Curriculum' to the left of the course title to begin. • CTFBI Budgeting Workbook Self-Study: Review the workbook in its entirety.
4) Study Operations	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 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 **Instructions for Accessing Course in Blackboard**: Click here

5) Recruitment & Retention	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 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 **Instructions for Accessing Course in Blackboard**: Click here
6) Informed Consent	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 IV. Resources
7) Investigational Products	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 c. Surveillance Studies d. Preventing Incidents of Non-Compliance
8) Subject Safety	Objectives: • 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
9) Essential Documentation	Objectives: • 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
10) Quality Management & Non-Compliance	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