Research Boot Camp Objectives & Course Outline

Objectives:
- Describe the purpose of a study protocol.
- Identify the elements of a study protocol.
- Describe the consent process, including components of an ethically valid consent process.
- Identify elements that must be included in informed consent documents, as defined by the federal regulations.
- List alterations of informed consent.
- Describe institutional expectations regarding the informed consent process.
- Distinguish between studies reviewed by the RSRB and studies reviewed by WIRB.
- Describe the RSRB review process.
- Summarize responsibilities of the Principal Investigator.
- Describe study documentation requirements.
- Determine when an amendment must be submitted for RSRB/WIRB review.
- Describe annual reporting requirements.
- Summarize research event reporting requirements.

Course Outline:
I. Study Protocol Basics: Elements & Development Considerations (~45 minutes)
   a. Protocol Basics: What is the purpose of the protocol and how does it relate to the IRB application, recruitment material and consent documents
   c. Protocol Development Considerations
II. Informed Consent: Federal Regulations, Institutional Policy & Good Practice (~60 minutes)
   a. Informed Consent Basics
      • Process definition & key components
      • Required & additional elements as defined by federal regulations
      • Alterations of the consent process
      • Institutional expectations regarding the informed consent process
      • Consent issues as they relate to vulnerable populations
   b. Informed Consent Processes
      • Process development consideration (including best practices for writing informed consent documents and methods for assessing understanding)
      • Best practices for documenting informed consent
      • Re-Consent of subjects
      • Consent storage requirements
      • Process example
   c. Managing Consent Errors
III. BREAK (~15 minutes)
IV. RSRB & WIRB Review Processes (~30 minutes)
   a. RSRB Structure & Composition (including both the RSRB office and the boards)
   b. RSRB vs. WIRB Review: Who reviews what?
   c. Documents requiring submission (e.g., IRB application, protocol, consent, recruitment material, etc.)
   d. WIRB Review Processes
   e. RSRB Review Processes
      • Levels of Review (exempt, expedited & full board)
• Process of RSRB Review: Department Review, Board Assignment, Board Specialist Review, Full Board Review, Requesting Changes
• Criteria for RSRB Approval

V. Study’s Approved... What’s Next? (~60 minutes)
   a. PI Oversight & Responsibilities
      • Protecting the rights, safety & welfare of the subjects
      • Supervise the conduct of the investigation
   b. Study Documentation
      • Regulatory File
      • Protocol Compliance Documentation (Consent, Source Documentation, Event Monitoring, etc.)
      • Overall Conduct of the Study
   c. Protocol Compliance
   d. Amendments
   e. Continuing Reviews/Progress Reports
   f. Reportable Events
      • Definitions: Research Event, Unanticipated, Serious, Related
      • RSRB Reporting Requirements (local vs. non-local events, UPIRTSOs)

VI. Group Competency Check via Scenario Presentations/Case Studies (~15 minutes)