Research Boot Camp Objectives & Course Outline
Approximate Length: 5 hours

Objectives:
- Describe the purpose of a study protocol.
- Identify the elements of a study protocol.
- Describe the informed consent process, including components of an ethically valid consent process.
- Describe regulatory and institutional requirements regarding the informed consent process.
- Identify elements of consent that must be included in the informed consent process, as defined by the federal regulations.
- Summarize alterations of informed consent.
- Describe factors that impact the informed consent process.
- Describe the Research Subjects Review (RSRB) role and scope.
- Describe the RSRB review process.
- Distinguish between a Reviewing Institutional Review Board (IRB) and a Relying IRB.
- Summarize the responsibilities of the Principal Investigator.
- Describe essential study documentation.
- Determine when a modification must be submitted to the Reviewing IRB for review.
- Describe IRB reporting requirements, including research event reporting and annual reporting.

Course Outline:
I. Study Protocol Basics: Elements & Development Considerations (Approximate Length: 70 minutes)
   a. Purpose of a Study Protocol
   b. Elements of a Study Protocol
      • Purpose & background
      • Study design
      • Study population
      • Recruitment & consent
      • Study procedures
      • Costs & payments
      • Potential risks & benefits
      • Data & safety monitoring
      • Privacy & confidentiality
      • Data analysis
   c. Lessons Learned in Protocol Development
II. Informed Consent: Federal Regulations, Institutional Policy & Good Practice (Approximate Length: 100 minutes)
   a. Basic Informed Consent Requirements
      • Federal regulations, state laws and institutional policies pertaining to informed consent
   b. Variations of Informed Consent
      • Waiver of consent
      • Alteration of consent elements
      • Waiver of documentation of consent
      • Written short form
   c. Special Consideration in Informed Consent
      • Vulnerable populations
      • Children
      • Decisionally impaired adults
      • Students & employees
   d. Planning & Implementing the Informed Consent Process
      • Process planning considerations
      • Assessing subject understanding
• Best practices for drafting informed consent documents
• Documentation of informed consent
• Re-Consent of subjects
• Consent retention & storage

III. IRB Review Processes (Approximate Length: 80 minutes)
   a. University of Rochester (UR) Institutional Review Board (IRB) Overview
      • UR IRB structure and scope
      • UR IRB composition and key players
   b. IRB Review Processes
      • IRB review pathways
      • Levels of IRB review (exempt, expedited & full board)
      • IRB approval determinations
      • IRB follow-on submissions
   c. IRB Review of Multi-Site Research
      • IRB reliance model review pathways and requirements

IV. Study’s Approved... What’s Next? (Approximate Length: 55 minutes)
   a. Roles & responsibilities
   b. Regulatory & protocol compliance
   c. Essential documentation
   d. Data & safety monitoring and research event reporting
   e. Progress reports/continuing reviews & study closure