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
   a. Purpose of a Study Protocol
   b. Elements of a Study Protocol
      - Purpose & background,
      - Characteristics of the research population,
      - Subject identification & recruitment,
      - Process of consent,
      - Methods & procedures,
      - Costs & payments,
      - Risk/benefit assessment,
      - Reportable events,
      - Data analysis & monitoring,
      - Confidentiality of data & information storage,
      - Data analysis
   c. Lessons Learned in Protocol Development

II. Informed Consent: Federal Regulations, Institutional Policy & Good Practice
   a. Basic Requirements for Informed Consent
      - Process description & key components
      - Federal regulations pertaining to informed consent
      - Institutional expectations regarding the informed consent process
   b. The Informed Consent Process
      - Process development consideration
      - Best practices for drafting informed consent documents
      - Assessing subject understanding
      - Documentation of informed consent
      - Consent retention & storage
      - Re-Consent of subjects
      - Consent storage requirements
   c. Managing & Avoiding Errors in Informed Consent
      - Common errors
      - Reporting consent errors
Corrective and preventative actions
General preventative actions

III. IRB Review Processes
   a. University of Rochester Institutional Review Board (IRB) Overview
      • Institutional IRB structure
      • IRB composition
      • Basic IRB submission components
   b. IRB Review Processes
      • IRB submission pathway
      • Levels of IRB review (exempt, expedited & full board)
      • IRB review process
      • Criteria for IRB approval

IV. Study's Approved... What's Next?
   a. General principles concerning roles & responsibilities
   b. Regulatory & protocol compliance
   c. Principal Investigator oversight
   d. Study documentation
   e. Data & safety monitoring and reporting research events
   f. Progress reports/continuing reviews