Research Boot Camp

COURSE OVERVIEW
This course is comprised of four learning modules aimed at understanding and applying key considerations, requirements, and best practices related to study protocol development, the informed consent process, Institutional Review Board (IRB) review, and post-IRB approval responsibilities. This course is a component of the OHSP Education & Training Framework and is available for all University of Rochester (UR) faculty, staff and students via Blackboard.

Self-Enrollment Instructions:
To enroll in the course, follow the steps provided in the OHSP’s Blackboard Self-Enrollment Instructions (in step 2 of the instructions, search for the course title listed in the heading above or ‘OHSP.ResearchBootCamp’).

Learning 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.

Approximate Length:
5 hours

JTF Core Competency Alignment:
The content included within this course supports the knowledge and skills needed to meet the following Joint Task Force (JTF) Core Competencies: 1.2, 1.3, 2.3, 2.4, 2.5, 2.7, 2.8, 4.2, 4.4, 4.6, 4.7, 5.3, 5.5, 5.6, 7.3.

CONTENT OUTLINE
I. Study Protocol Basics: Elements & Development Considerations (Approximate Length: 70 minutes)
   a. Purpose of a Study Protocol
   b. Elements of a Study Protocol
c. Lessons Learned in Protocol Development

II. Informed Consent: Federal Regulations, Institutional Policy & Good Practice (Approximate Length: 100 minutes)
   a. Basic Informed Consent Requirements
   b. Variations of Informed Consent
   c. Special Consideration in Informed Consent
   d. Planning & Implementing the Informed Consent Process

III. IRB Review Processes (Approximate Length: 80 minutes)
   a. University of Rochester (UR) Institutional Review Board (IRB) Overview
   b. IRB Review Processes
   c. IRB Review of Multi-Site Research

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