Orientation Objectives & Course Outline

Objectives:
- Identify the various departments and committees that comprise the University of Rochester’s Human Research Protection Program
- Describe the role of the Office for Human Subject Protection (OHSP), Office of Research and Project Administration (ORPA) and Privacy Officer/HIPAA Security Official in the oversight of human subject research at the University of Rochester.
- Identify sources for conflict of interest training and how to meet disclosure requirements.
- Recognize when Ancillary Committee review and approval is required for human subject research.
- Identify University research-related resources and services.

Course Outline:
I. Background – The HRPP at the UR
   a. Purpose of the HRPP
   b. HRPP Oversight
   c. Departments/Committees that comprise the HRPP

II. Basic Review Processes/Requirements
   a. Office for Human Subject Protection
      - OHSP Structure & Divisions
      - Research Subjects Review Board Structure
   b. Office of Research and Project Administration (ORPA)
      - Services Provided by ORPA
      - Overview of Web-Site Contents/Resources
      - Establishing a PIVOT account
   c. Conflicts of Interest
      - Summary of Policy Purpose and Content
      - Training – Course Description and Accessibility Instructions
      - Annual Disclosure (minimum) – Where to Disclose and How to Disclose
   d. Privacy and Information Security Offices
      - Privacy Officer & HIPAA Security Official Roles and Responsibilities
      - HIPAA Intranet Site (Privacy & Security policies, training materials & resources; Research guidance documents & forms)
      - Key Concepts (1. Access to clinical system, 2. Data must be safeguarded & 3. Report breaches)
   e. Ancillary Committees
      - Clinical Trials Office, Emergency Medicine Research Committee, Perinatal Research Committee, Institutional Biosafety Committee, Surgical Pathology, Human Use of Radiation Committee & Rochester Center for Brain Imaging

III. Summary of Basic Steps for Initiating Human Subject Research
   a. Determining Human Subject Research, Human Subjects Training & Requesting a ROSS Account, Who can be a PI, Protocol Development, ORPA Review, COI Disclosure, ROSS Submission, Department Review

IV. Resources @ UR
   b. Additional: Investigational Drug Service, Environmental Health & Safety, Emergency Medicine Research Associate Program, Imaging Sciences Clinical Trial Services, URMC Labs Services & Clinical Trials Processing Lab & Cold Storage Core Facility

V. Group Competency Check via Scenario Presentations/Case Studies