Orientation to Conducting Human Subject Research

COURSE OVERVIEW
The aim of the course is to provide a general overview of review processes and requirements concerning the conduct of human subject research at the University of Rochester (UR). This course is a component of the OHSP Education & Training Framework and is available for all 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.Orientation’).

Learning Objectives:
- Summarize the purpose of the University’s Human Research Protection Program (HRPP).
- Describe key components of the University’s Human Research Protection Program (HRPP).
- Recognize factors that impact the process for initiating research.
- Identify research-related resources and services available within the University.

Approximate Length: 1 hour

CONTENT OUTLINE
I. The HRPP at the UR (6 minutes):
   a. Purpose of the HRPP
   b. HRPP Oversight
   c. HRPP Components
II. Institutional Review Board (IRB) Review (12 minutes)
   a. Office for Human Subject Protection
   b. IRB Scope & Review Process
   c. IRB Reliance Model
III. Contracts, Grants & Agreements (7 minutes)
   a. Office of Research and Project Administration (ORPA)
   b. Clinical Research Billing Compliance
IV. Privacy & Data Security (10 minutes)
   a. Data Security Assessment Form
   b. HIPAA Compliance
   c. International Regulations
V. Additional Requirements (8 minutes)
   a. HRPP Training Requirements
   b. Conflicts of Interest
   c. UR-HRPP Ancillary Committees
VI. Steps for Getting Started (13 minutes)