I. An Introduction to Human Subject Research

Objectives: Explore the history of research ethics and emerging ethical considerations as new fields emerge. Learn what lead to the formation of current regulations governing human subject research, their implications, and how research is governed.

- The Clinical Research Coordinator
- An Introduction to the IRB
- COI/Research Integrity
- Ethics/Behavioral Research: Definitions, Data Collection/Management
- Overview of Research at WU
- Living with HIPAA at WU

II. Necessary Elements – Good Clinical Practice

Objective: Provide an overview of the research process from study origination through data collection an analysis.

- Protocols
- Case Report Forms and Study Phases
- Billing, Devices, Matrix
- Informed Consent
- Study Budgets
- Writing a Protocol
- Risk Assessment

III. Necessary Elements - Institutional and Investigator Responsibilities

Objectives: Explain responsibilities from study initiation through closure.

- Case Studies in Compliance
- Recruitment and Retention
- Audits