The Columbia Human Subjects Protection Training Course requires completion of five individual modules within the online CITI (Collaborative IRB Training Initiative) system. Three specific modules are required: History and Ethical Principles; Basic IRB Regulations and Review Process; and Informed Consent for all learners. The remaining two modules may be selected by the learner from the list of CITI modules, with two caveats: 1) if conducting research with minors, the Vulnerable Populations - Research with Minors module must be one of the electives; and 2) if conducting a study which involves a drug, device, biologic, or other biomedical intervention in a study of its potential therapeutic use, or a diagnostic test or procedure to study its potential clinical utility, completion of the FDA-Regulated Research module is required. Refresher training is required every three years, and involves completion of three CITI modules.

The objectives for each required module are provided below.

**History and Ethical Principles:**
- Discuss why ethics are necessary when conducting research involving human subjects.
- Describe the major historical events that have influenced how research involving human subjects is conducted.
- Identify problems with past studies that have violated ethical standards.
- Describe the Belmont Principles.
- Discuss the ethical standards for research that guide us today.

**Basic IRB Regulations and Review Process:**
- Describe the role, authority, and composition of the IRB.
- List the IRB requirements for conducting research involving human subjects.
- Describe the types of IRB review.
- Describe the process of working with the IRB.
- Identify other regulations and regulatory groups that require compliance based on the type of research being conducted.

**Informed Consent:**
- Describe the requirements for complying with informed consent regulations.
- Describe the process for obtaining informed consent.
- Describe the regulations for waiving informed consent.

**FDA-Regulated Research:**
This training module addresses FDA-regulated clinical research and the responsibilities of investigators, IRBs, and sponsors when they participate in a study of an FDA-regulated product.

**Vulnerable Populations - Research with Minors:**
- Describe the major historical events that influenced how research with children as subjects is currently conducted.
- Identify problems with research involving children that may violate ethical standards.
- Understand the assent and informed consent requirements on different types of studies involving children.
- Understand the current efforts by the FDA to ensure the inclusion of children in studies on the safety and efficacy of new drugs.