| Requirements for Human Research Protections Training | Effective Date | |
|---|---|---|
| | Revisions Date | 01.15.2021 |

## 1.0 Purpose:

The purpose of this standard operating practice (SOP) is to inform faculty, staff, and students at East Carolina University and all other researchers that rely on ECU's IRBs of the mandatory requirements for education in human research protections. This SOP applies to all research involving the use of human subjects regardless of funding or sponsorship.

## 2.0 Individuals Required to Complete Education:

2.1 Education in human research protections is required for all faculty, staff, and students directly involved in the conduct of research with humans, including anyone who does any of the following:

- 2.1.1 Obtains informed consent of humans for research;
- 2.1.2 Collects information from or about humans for research purposes;
- 2.1.3 Conducts research procedures, interventions or interactions with humans; or
- 2.1.4 Obtains private identifiable information or biospecimens for research.

2.2 Researchers not employed by or affiliated with ECU must either provide up-to-date documentation of completion of human research protections training within at their respective institutions or complete the ECU foundation requirement.

2.3 Education in human research protections is highly recommended for individuals conducting Humanitarian Use Device (HUD) projects. HUD projects do require initial review and continuing review from an IRB.

## 3.0 Education Requirements:

3.1 **Completion of the Education Requirement**.

- 3.1.1 The foundation requirement is a one-time requirement that must be completed before the individual first becomes directly involved in the conduct of human research at ECU
- 3.1.2 This requirement consists of completing either the biomedical or behavioral/social sciences modules of the CITI Training which is found at **http://www.citiprogram.org/**.
- 3.1.3 Completion of the foundation requirement meets the education requirement for a three-year period;

3.2 **IRB-approved Continuing Education Requirement**.

- 3.2.1 Continuing education must be completed after three years as long as the individual is involved in human research.
- 3.2.2 The CITI **Refresher Course** is the preferred continuing education course to meet ECU's requirements. This course may be repeated because new content is continuously being added.

3.2.3 Other continuing education in human protections will be considered on a case by case basis.

3.3 **National Institutes of Health (NIH) Education Requirement**.

3.3.1 The NIH requires that primary investigators and clinical trial staff involved in all new and ongoing NIH-defined clinical trials complete Good Clinical Practice (GCP) training.

3.3.2 The UMCIRB offers GCP training under its CITI subscription for those that may need to take this training.

3.3.3 GCP training would be in addition to the required human research protections training required at ECU.

3.4 **Failure to Comply**

3.4.1 Failure to complete the education requirements will delay initial IRB approval. Also, the IRB has the authority to suspend or withhold approval from any project that involves study personnel who fail to meet these education requirements.

**Revision History:**

| Date | Change | Reference Section(s) |
|---|---|---|
| 10.01.2014 | Created information in SOP format | All |
| 01.21.2019 | 2018 Common Rule revisions | |
| 1.15.2021 | Clarifications for training requirements for outside investigators; recommendation for training for HUD projects; describe NIH GCP training requirement. | 1; 2.3; 3.3 |