**Purpose**: Understanding federal, state, local, institutional, and protocol requirements is vital when conducting research involving human subjects. Training related to these requirements and the documentation thereof helps to ensure research personnel are aware of the requirements, understand the requirements and agree to adhere to such. This SOP defines the process for the completion and documentation of required training at this investigative site.

**Scope:** This SOP applies to Investigators and clinical research team members conducting human subjects research at UNC.

**Definitions:**

International Conference on Harmonization Good Clinical Practices (ICH GCP) – international and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects

Health Insurance Portability and Accountability Act (HIPAA) – US law designed to provide privacy standards to protect patients’ medical records/health information

Collaborative Institutional Training Initiative (CITI) - platform utilized by UNC to allow faculty/staff to complete specific institutionally required education

Office of Human Research Ethics (OHRE) – responsible for ethical and regulatory oversight of research at UNC-Chapel Hill involving human subjects

Institutional Review Board (IRB) – a committee which prospectively reviews and makes decisions concerning all human research conducted at UNC-CH

**Procedures:**

1. Prior to conducting any research activity involving human subjects, staff will have completed (and demonstrated proficiency of) the following training requirements (include or delete as applicable):
   1. HIPAA
   2. Human Subjects Protection
   3. Good Clinical Practice
   4. Protocol
   5. Investigational Product/Intervention
   6. Specimen Processing
   7. Data Management/Electronic Data Capture
2. Training will be documented by certificates provided by CITI or by signatures attesting to the completion.
3. Documentation of training will be located (state where the information is located):

**Applicable Policies and Guidelines:**

* 21 CFR 50 – Protection of Human Subjects
* 45 CRF 46 – HHS Policy for Protection of Human Research Subjects
* ICH Good Clinical Practices E6 (R2)
* OHRE/IRB Standard Operating Procedures

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| **Revision History** | |
| Date of Revision: | Revision Description: |
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