1. Purpose

To outline the required training for investigators and study staff for conducting research at UTHealth.

2. Scope and Responsibility

This SOP applies to all individuals participating in the conduct of clinical research at UTHealth. All staff to whom an investigator assigns a study task are required to follow this SOP.

3. Definitions

3.1 **CITI Training:** The Collaborative Institutional Training Initiative (CITI Program) offers web-based educational courses in research, ethics, regulatory oversight, responsible conduct of research, research administration.

4. Policy

4.1 The Principal Investigator (PI) is responsible for ensuring that all individuals assisting with the clinical research study are adequately informed about:

- 4.1.1 The protocol
- 4.1.2 The investigational products (if any)
- 4.1.3 Trial related duties and functions
- 4.1.4 Good clinical practice

4.2 The PI is responsible for ensuring that all individuals have adequate training and education to fulfil their role on the study.

5. Procedures

5.1 The PI should ensure that all individuals assisting with the clinical research study have completed:

- 5.1.1 Protocol Specific Training
- 5.1.2 Any Sponsor Required Training
- 5.1.3 CITI Human Subjects Training – required for any role in clinical research.
- 5.1.4 CITI GCP Training – required for any role in clinical trials.

5.2 The lead study coordinator or program manager will maintain training certificates or documentation of training in the regulatory binder including but not limited to:

- 5.2.1 Current licensure and/or professional certification
- 5.2.2 Curriculum vitae, updated every three years (initialed and dated)
- 5.2.3 Training completion certificates.

5.3 The lead study coordinator or program manager will ensure that these documents are made available upon request by monitors, auditors and inspectors.

5.4 Non-study specific training documents maybe maintained in a common file for all personal in the department. A note to file maybe maintained in the study specific regulatory binders explaining the availability of this folder upon request

6. References

6.1 CPHS Training Requirements: https://www.uth.edu/cphs/for-researchers/training.htm

7. Appendices

7.1 Training Log

If you find errors in this document, contact clinicaltrials@uth.tmc.edu

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