UTHealth Houston

Title: SOP Development and Maintenance	Version: 1.0	Effective Date: 1 Aug 2020	Page 1 of 2

1. Purpose

To establish a standardized format for Standard Operating Procedures for clinical research conducted by UTHealth investigators and research staff and to describe the process for creation, revision and maintenance of SOPs

2. Scope and Responsibility

This procedure applies to all investigators and study team members involved in conducting clinical research at UTHealth.

3. Definitions

3.1 **Standard Operating Procedure:** Detailed, written instructions to achieve uniformity of the performance of a specific function.

4. Procedures

4.1 A template of the approved SOP format will be retained electronically on a shared drive for access involved in the preparation of new SOPs. The following format will be used when completing the template:

- 4.1.1 Calibri Font
- 4.1.2 Font Size – 11 pt body
- 4.1.3 Single Spacing

4.2 The individual(s) designated to create an SOP will do so and will circulate the working draft among the team members charged with implementing it. Once team member comments have been incorporated, the SOP will be provided to the study team lead for review.

4.3 The Principal Investigator will denote approval by signature and date.

4.4 The study team lead is responsible for document control, storage and distribution of all SOPs.

4.5 All the investigators and research staff in the study team will be trained on SOPs either individually or in a group in-service. Documentation of training will be kept in the regulatory files.

4.6 SOPs will be reviewed and revised as necessary. Upon revision, the revision history table at the end of this document will need to be added to the SOP in order to track changes.

4.7 New versions will be distributed to faculty and research staff and documentation of training will be retained in the regulatory files.

5. References

5.1 Clinical Trials Resource Center - Good Clinical Practice policies - https://www.uth.edu/ctrc/gcp-policies

6. Appendices

6.1 SOP Template

6.2 SOP Training Log

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

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