**GUIDANCE: Developing Good Clinical Practice Guidance Documents**

**Policy:** Clinical research conducted at UTHSC-H should comply with the Good Clinical Practice Guidelines. Good Clinical Practice Guidance documents will be maintained and reviewed regularly by the Clinical Trials Resource Center and will be available for all UTHSC-H faculty and staff. Research teams may create Standard Operating Procedures based on these guidance documents.

**Key Terms**

**Good Clinical Practice:** Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

**Procedure for Preparing New Chapters / Revisions -** Based upon changes to applicable regulations, guidelines, or research practice at UTHSC-H*,* the Clinical Trials Resource Center staff will amend or add new chapters to the Good Clinical Practice Guidance documents.

The Good Clinical Practice guidance documents are organized into chapters grouped into general administration, project management and study conduct. Each guidance document should include the following information:

* + 1. The title
    2. Number
    3. Definitions
    4. Applicable Regulations and Guidelines
    5. References
    6. Attachments
    7. The date of the current version
    8. The date of the previous version

The GCP workgroup will be responsible for review of the guidance documents annually. CTRC staff will submit current guidance documents to the workgroup and seek input. If revisions or additions are required, the above procedure shall be followed. If no changes are required, the Clinical Trials Resource Center staff will document the review process and file appropriately.

When an guidance document is revised, CTRC staff will maintain an historical archive of copies of all previous versions of guidance.

**Procedure for Approval and Distribution –** CTRC staff will submit the amended / new chapters to the GCP workgroup. for comments and suggestions. The amended / new chapters will then be submitted to Director, Clinical Trials Resource Center for review and approval.

CTRC staff will maintain a Table of Contents by number and title of the guidance documents and will ensure that any amendments / new chapters are made available to the to the research community by uploading them on the CTRC website.

**Procedure for Training on Implementing -** The department research administrators will ensure that all the key research personnel have access to the latest approved version of the UTHSC-H Good Clinical Practice GUIDANCEs. The department research administrator should ensure that each new employee documents the date of review of the relevant GUIDANCEs.

**Applicable Regulations and Guidance Documents**

* 21 CFR 50
* 21 CFR 56
* 45 CFR 46
* 21 CFR 312
* 21 CFR 812
* ICH Good Clinical Practice Guidelines

**Applicable Institutional Policies and Procedures**

* UT Houston HOOP
* CPHS Policies and Procedures

**ATTACHMENTS**

* Guidance Training Log
* Standard Operating Procedure Template

**If you find errors in this document, contact** [**clinicaltrials@uth.tmc.edu**](mailto:clinicaltrials@uth.tmc.edu)

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