

**Institutional Handbook of Operating Procedures  
Policy 11.03.01**

Section: Research Policies	Responsible Vice President: Executive Vice President and Provost
Subject: Clinical Research	Responsible Entity: Research Services

**I. Title**

*Good Clinical Practice (GCP) Training Required for Conducting Clinical Trials*

**II. Overview**

The National Institutes of Health (NIH) “[Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials](#)” establishes the expectation that, effective January 1, 2017, all NIH funded investigators and clinical trial staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference of Harmonisation (ICH) E6 (R2)., UTMB is extending this requirement to apply **to all investigators and clinical trial staff working on a new or existing clinical trial irrespective of the funding source of the clinical trial and** regardless of whether any employee is receiving direct salary support from the clinical trial.

**III. Policy**

This policy applies to all investigators (e.g., PI, Co-PI, and/or Co-I/SubInvestigator) and clinical trial site staff who are responsible for the conduct, management, and oversight of clinical trials. The policy requires basic GCP training and refresher GCP training every three (3) years.

**IV. Procedures**

To satisfy this training requirement all research investigators and staff at all UTMB locations who are involved in a study meeting the definition of a clinical trial (as defined by the NIH below), will be required to complete GCP training by completing a Collaborative Industrial Training Initiative (CITI) training course. Once successfully completed, research investigators and staff will be required to complete refresher training every three (3) years thereafter.

**V. Definitions**

**Clinical Trial:** Specific to this policy, a clinical trial is defined by the NIH as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

**Clinical trial staff:** Individuals, identified by the Principal Investigator, who are responsible for study coordination, data collection and data management. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and collect and record information from research participants. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

**Principal Investigator:** A Principal Investigator (PI) is responsible for the overall conduct of a project, including all technical, programmatic, financial, compliance, and administrative aspects, and for the management and integrity of the design, conduct, and reporting of the project as well as assurance with applicable laws, regulations, and institutional policies governing the project. The PI is the only person who can request study changes through the institution’s IRB.

**Co-Investigator:** A Co-Investigator (Co-I), is key personnel that collaborates on the study along with the PI, but does not share any responsibility or accountability for the conduct of the study. A Co-Investigator can also be named a Sub-Investigator.

**Co-Principal Investigator:** A Co-Principal Investigator (Co-PI) is person that shares responsibility and accountability for the conduct of the study with the PI. For example, a Co-PI can sign study documents in the investigator’s absence. The IRB does not recognize Co-Principal Investigators, thus only the PI may request study changes through the IRB.

**VI. Relevant Federal and State Statutes**

[NIH Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials](#)

**VII. Related UTMB Policies and Procedures**

IHOP – 11.01.07 - *Principal Investigator Roles and Responsibilities* (policy posted upon approval)

**VIII. Dates Approved or Amended**

<i>Originated: 05/18/2018</i>	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>

**IX. Contact Information**

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