IOWA STATE UNIVERSITY
Office for Responsible Research

Good Clinical Practice (GCP) Training – NIH-funded Clinical Trials

Effective January 1, 2017, training in Good Clinical Practice (GCP) is required for all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials. Training must be consistent with the principles of the International Conference on Harmonization (ICH).[1] The principles of GCP help assure the safety, integrity, and quality of clinical trials.

A **clinical trial** is defined by 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.*[2]

GCP training complements required training on human subjects protection—both types of training must be completed.

Applicability

NIH requires Good Clinical Practice training for the following individuals involved with a *clinical trial*:

> **Investigator**: *The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.*
>
> **Clinical trial staff**: *Individuals, identified by the 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.*[3]

[1] http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073122.pdf
[2] http://osp.od.nih.gov/sites/default/files/NIH%20Definition%20of%20Clinical%20Trial%2010-23-2014-UPDATED_0.pdf
[3] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html

Meeting Training Requirements

Completion of GCP training is intended to ensure that individuals have obtained the knowledge of standards for conducting, recording, and reporting clinical trials that involve human participants. Training must be refreshed every three years.

To meet the requirements, ISU has adopted the following course offered through the CITI Program:

For first-time GCP training

GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)

For a refresher (every three years)

GCP FDA Refresher

Recipients of the training are expected to retain documentation of their training. It is strongly recommended that principal investigators retain records of GCP training for their clinical trial staff.

Recipients can log into the CITI Program at any time to obtain training records. Documentation of GCP training will be automatically registered in Learn@ISU for individuals who are affiliated with ISU and who use their ISU email address to register with the CITI Program.

References:

NIH Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials, NOT-OD-16-148

Guidance for Industry: E6 Good Clinical Practice: Consolidated Guidance, U.S. Department of Health and Human Services, Food and Drug Administration, April 1996

NIH Definition of Clinical Trial, October 23, 2014

NIH Frequently Asked Questions on Good Clinical Practice Training Policy, December 20, 2016