The University of New Mexico Health Sciences Clinical & Translational Science Center
Zoom Good Clinical Practice (GCP) Training

This innovative hybrid course consists of nine NIH-generated pre-recorded modules fortified with four live Zoom laboratory sessions. The course is designed to promote investigator and staff compliance with the thirteen principles of Good Clinical Practice (GCP).

In order to earn a certificate, participants must attend each lab session (A, B, C, D) and complete the online modules. During this series, the participants will complete 2 to 3 hours of online content each week, prior to applying the concepts during the live Zoom laboratory sessions.

A 30-question summative assessment ends the course. Participants must answer 24 questions correctly out of 30 to receive a GCP training certificate that is valid for three years.

Enrollment Period (**extended until October 30**).

- ✓ Space is limited to eight participants per cohort.
- ✓ Learners complete registration & pre-assessment by 10/25/2019 via CTR-IN Portal.
- ✓ All training materials (syllabus and Lab A, B, C, & D course handouts) and instructions for using the HSC Moodle and Zoom connections will be downloadable at the time of registration.
- ✓ Learners will view NIH GCP Modules via UNM HSC Moodle.
- ✓ Cohort 1 begins November 1, 2019, four Fridays from 1:00 – 3:00pm MST via Zoom:
  - November 1
  - November 8
  - November 15
  - November 22
- ✓ Upon successful completion of all course requirements, certificates valid for three years will be distributed.

To enroll, go to https://ctrin.health.umt.edu/public/showcourse/51

By the end of this course, participants will be able to:

- Apply the 13 GCP principles to their work.
- Evaluate the ethical implications of research decisions.
- Identify best practices for recruitment and retention.
- Outline the Informed Consent process.
- Differentiate concepts of confidentiality and privacy.
- Employ strategies for detecting and reporting adverse events.
- Explain the importance of quality control/assurance in a clinical trial.
- Define and identify behavior that constitutes research misconduct.
- List the process by which the FDA conducts audits.
- Be familiar with the basics of Clinicaltrials.gov requirements.

Questions? Contact Rebecca Monette, CTSC Translational Workforce Training Manager.

https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm

NIH Grants & Funding, NIH Central Resource for Grants & Funding Information

Good Clinical Practice Training

All NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials can learn about the requirement to be trained in Good Clinical Practice (GCP).

Purpose

The principles of Good Clinical Practice (GCP) help assure the safety, integrity, and quality of clinical trials by addressing elements related to the design, conduct, and reporting of clinical trials. GCP training describes the responsibilities of investigators, sponsors, monitors, and IRBs in the conduct of clinical trials.

GCP training aims to ensure that:

- the rights, safety, and well-being of human subjects are protected
- clinical trials are conducted in accordance with approved plans with rigor and integrity
- data derived from clinical trials are reliable

Training Options

The policy does not require a particular GCP course or program. Training in GCP may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. NIH also offers GCP training that is free of charge, including options from NIAID, NIDA, and NCATS. Other free courses as well as fee-based courses are available.

Policy Guidelines & Implementation

Effective January 1, 2017 – NIH expects all NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP). Recipients of GCP training are expected to retain documentation of their training. GCP training should be refreshed at least every three years in order to stay up to date with regulations, standards, and guidelines.

Notices

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