Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials

Notice Number: NOT-OD-16-148

Key Dates
Release Date: September 16, 2016

Related Announcements
None

Issued by
National Institutes of Health (NIH)

Purpose

Policy Statement

This policy establishes the expectation that all NIH-funded investigators and 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 on Harmonisation (ICH) E6 (R2).[1]

The principles of GCP help assure the safety, integrity, and quality of clinical trials. GCP provides a standard for ensuring clinical trial compliance, implementation, data collection, monitoring, and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data), and outline the responsibilities of Institutional Review Boards (IRBs), investigators, sponsors and monitors. GCP addresses elements related to the design, conduct and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data) of clinical trials.

Background

GCP principles constitute an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. The principles were developed in 1996 by the ICH in collaboration with representatives from the European Union, Japan, and the United States. The U.S. Food and Drug Administration (FDA) requires GCP compliance for studies conducted under an investigational new drug application or investigational device exemption.

GCP describes the responsibilities of investigators, sponsors, monitors and IRBs in the conduct of clinical trials. Compliance with GCP provides assurance that the rights, safety and well-being of human subjects are protected, that clinical trials are conducted in accordance with approved plans with rigor and integrity, and that data derived from clinical trials are reliable.

GCP training complements other required training on protections for human research participants. Since June 2000, the NIH Extramural Research Program has required training on protections for

human research participants for all NIH-funded investigators and individuals responsible for the design or conduct of a research involving human subjects.[2]

Scope and Applicability

This Policy applies to NIH-funded investigators and clinical trial site staff who are responsible for the conduct, management and oversight of NIH-funded clinical trials.[3] GCP training includes the Principles of ICH GCP found in Section 2 of ICH E6.[4] GCP training may be achieved through a class or course, academic training

program, or certification from a recognized clinical research professional organization. Completion of GCP training will demonstrate that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants. GCP training should be refreshed at least every three years in order remain current with regulations, standards and guidelines. Recipients of GCP training are expected to retain documentation of their training.

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.

Effective Date

This policy is effective as of January 1, 2017

Inquiries

Contact the program official at the funding NIH IC

Or

Clinical Trials Program
Office of the Director (OD)
Office of Extramural Programs (OEP)
Office of Extramural Research (OER)
National Institutes of Health (NIH)
Email: oepmailbox@od.nih.gov

---

[1] International Conference on Harmonisation (ICH) E6
http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073122.pdf

[2] Required Education in the Protection of Human Research Participants, see
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

[3] 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. See https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html.

[4] Acceptable GCP courses include the NIAID GCP Learning Center website (http://gcplearningcenter.niaid.nih.gov) and National Drug Abuse Treatment Clinical Trials Network (https://gcp.nihtraining.com/).

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

35 **13**

NIH... Turning Discovery Into Health®

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.