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Part 1: Introduction to Good Clinical Practice (GCP)

What is Good Clinical Practice?

Good Clinical Practice (GCP) is an international ethical and scientific standard for conducting biomedical and behavioral research involving human participants. The objective of this guideline is to provide a unified standard across the European Union (EU), Japan, the United States, Canada, and Switzerland to facilitate the mutual acceptance of data from clinical trials by Regulatory Authorities.

The current system of Good Clinical Practice has evolved, in part, in response to revelations of past episodes in which research participants were grossly abused. Exposure of these incidents provided much of the momentum for the development of regulations and ethical guidelines on the protection of human research participants.



Why is GCP training necessary?

This training is important for all staff involved in Clinical Research and ensures an understanding of the principles adopted in research.

- GCP is widely accepted and expected in all research involving human participants.
- GCP is not specific to a protocol, but rather is general and applicable to all protocols.

Anyone directly involved in the design or conduct, oversight, or management of research involving human participants, including research site staff, back-up staff, contractors, subcontractors, and consultants who perform key study functions, should complete the GCP training. Non-study staff at the research site who provide standard care or other non-study related services should be encouraged to complete the GCP training, but they are not required to do so.

The course is self-paced and takes approximately 4-6 hours to complete. Completion

of the course is required every three years for NIH-affiliated staff to ensure that all researchers stay informed of developments regarding GCP, such as changes in federal regulations concerning the protection of vulnerable research participants, electronic data, or privacy protections. Others are encouraged to consult and comply with their institutional, regulatory, and other oversight committee guidelines for renewal requirements.

Part 2: The Good Clinical Practice Guidelines

What are the Good Clinical Practice guidelines?

The Good Clinical Practice (GCP) guidelines were prepared in association with the [International Council for Harmonization](#) (ICH). Consolidating many of the same principles set out in earlier codes of medical ethics, the GCP guidelines provide a framework for the fair, scientifically sound conduct of research studies involving human participants. The ICH GCP (R1) guidelines, dated June 10, 1996, were published in the U.S. Federal Register in 1997 and revised to version R2 on November 9, 2016. These guidelines apply to all research involving human research participants.

The purpose of the ICH GCP guidelines is twofold:

- To ensure that the rights, safety, and confidentiality of participants in clinical trials are protected.
- To ensure that the data collected in clinical trials, as well as the reported results of clinical trials, are accurate and credible.

The principles in this guideline may be applied to all clinical investigations involving human participants, such as those involving an investigational product, a marketed drug, a medical device, or a behavioral intervention.

[Click Here](#) to read the ICH GCP Principles.

[Click Here](#) to read and download the ICH Guideline E6 Good Clinical Practice documentation.

Part 2: The Good Clinical Practice Guidelines

What is the Code of Federal Regulations?

The Code of Federal Regulations (CFR) is the codification (systematic arrangement) of rules published in the Federal Register by the executive departments and agencies of the U.S. Government. The principles of Good Clinical Practice (GCP) are codified in several sections, or titles, of the CFR. Noncompliance with these regulations may result in suspension of a research study as well as fines and penalties.

Which parts of the CFR must researchers be familiar with?

Researchers and clinicians participating in clinical trials need to be familiar, at a minimum, with the following sections of the CFR, which are directly relevant to research involving human participants:

(Text below expands when clicked on.)

[21 CFR 11](#)

This section regulates the handling of electronic data and electronic signatures when an Electronic Data Capture system is used. It is enforced by the U.S. Food and Drug Administration (FDA). For more information on 21 CFR 11, click [here](#).

[21 CFR 50](#)

This section, enforced by the FDA, regulates the informed consent process, setting out the elements of informed consent, exceptions from the general requirements, and other related information. (See related material from the [Informed Consent module](#).) For more information on 21 CFR 50, click [here](#).

[21 CFR 54](#)

This section, enforced by the FDA, regulates investigator conflicts of interest. For more information on 21 CFR 54, click [here](#).

[21 CFR 56](#)

This section, enforced by the FDA, regulates the membership, responsibilities, and operations of Institutional Review Boards (IRBs). (See related material from the [Institutional Review Boards module](#).) For more information on 21 CFR 56, click [here](#).

[21 CFR 312](#)

This section, enforced by the FDA, regulates the conduct of studies involving the use of Investigational New Drugs. (See related material from the [Investigational New Drugs module](#).) For more information on 21 CFR 312, click [here](#).

[21 CFR 314](#)

This section, enforced by the FDA, regulates the application procedure for approval of new drugs. For more information on 21 CFR 314, click [here](#).

[42 CFR 2 and 42 CFR 2a](#)

These are the confidentiality regulations, which fall under the jurisdiction of the Department of Health and Human Services (DHHS). Section 2 deals with the confidentiality of alcohol and drug abuse patient records. Section 2a deals with the protection of research participants' identity. (See related material from the [Confidentiality and Privacy module](#).) For more information on 42 CFR 2 and 42 CFR 2a, click [here](#).

[45 CFR 46](#)

This regulation also governs Institutional Review Board (IRB) membership, functions, and operations. In addition, it includes the general requirements for informed consent and codifies additional protections for vulnerable participants. Subpart A of this regulation is also known as the [Common Rule](#), which has recently undergone revision and will be effective in 2018. Subparts B, C, and D include provisions for pregnant women, children, and prisoners in research studies. It is enforced by the DHHS [Office for Human Research Protections](#). For more information on 45 CFR 46, click [here](#).

[45 CFR 160 and 45 CFR 164](#)

These are the Health Insurance Portability and Accountability Act (HIPAA) privacy rules, which are enforced by the DHHS [Office of Civil Rights](#).

Part 3: Other Federal Regulations

What other federal regulations must researchers be familiar with?

Research that involves the use of controlled substances must comply with U.S. Drug Enforcement Administration regulations ([21 CFR 1300](#)).

In addition to the Office of the Commissioner, the Food and Drug Administration (FDA) oversees scientific activities in four areas. These areas include Medical Products and Tobacco, Foods and Veterinary Medicine, Global Regulatory Operations and Policy, and Operations. Scientific investigations involving drugs are subject to FDA regulations. In addition to regulating the use of investigational new drugs ([21 CFR 312](#)) and marketing of drug ([21 CFR 314](#)) mentioned in Part 3 of this module, FDA regulations apply to Good Manufacturing Practice (GMP), such as:

- [21 CFR 210](#) — Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; and
- [21 CFR 211](#) — Current Good Manufacturing Practice for Finished Pharmaceuticals.

Another Federal law is the [Health Insurance Portability and Accountability Act \(HIPAA\) Privacy Rule](#) and HIPAA Security Rule, which protects the privacy of research participants and their personal health information. (HIPAA is discussed in more detail in the Confidentiality & Privacy module, Part 8).

NIH policies regulate grant management. For more information on the NIH Grants Policy, reference the website [here](#).

What additional regulations affect clinical research?

Countries, states, cities, and institutions may implement additional policies for the protection of human participants. These policies may impose requirements more stringent than those set down in federal regulations. Where more stringent local policies on human participant protection have been enacted, researchers must ensure at all times that their studies are designed and conducted in a manner that complies with both local and federal requirements.

Part 4: Summary of Key Points

- Good Clinical Practice (GCP) is an international ethical and scientific standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. This standard provides assurance that:
 - The rights, safety, well-being, and confidentiality of trial participants are protected.
 - The data collected in clinical trials as well as the reported results of clinical trials are credible and accurate.
- The current system of Good Clinical Practice has evolved, in part, in response to revelations of past episodes in which research participants were grossly abused.
- The Good Clinical Practice guidelines provide a framework for the fair, scientifically sound conduct of research studies involving human participants. Therefore, all trials should be conducted according to Good Clinical Practice (GCP) and all research staff should be trained and remain current in GCP.
- All key personnel who submit applications to the National Institutes of Health for competing or noncompeting projects that involve human research participants must receive training in the protection of human research participants.
- The Code of Federal Regulations (CFR) is the codification (systematic arrangement) of rules published in the Federal Register by the executive departments and agencies of the U.S. Government. The principles of Good Clinical Practice are codified in several sections, or titles, of the CFR. Noncompliance with these regulations may result in suspension of a research study as well as fines and penalties.
- Countries, states, cities, and institutions may implement additional policies for the protection of human participants. These policies may impose requirements more stringent than those set down in federal regulations. Where more stringent local policies on human participant protection have been enacted, researchers must ensure at all times that their studies are designed and conducted in a manner that complies with both local and federal requirements.