

Self-Directed Certification Exam Review of GCP for Clinical Research Coordinators, Clinical Research Associates (Monitors) and Clinical Investigators

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Introduction

GCP Knowledge for Drug and Biologic Development

Clinical research professionals who are preparing for a national or international certification examination must have a comprehensive knowledge of Good Clinical Practice (GCP) regulations and guidelines. The learning objectives in this review cover the GCP requirements for investigational drugs and biologics. When the term pharmaceutical is used in the learning objectives, it refers to both drugs and biologics.

GCP Knowledge for Medical Device Development

Some exams also require candidates to be knowledgeable of GCP requirements for medical devices. If you are taking an exam that covers medical device knowledge, I encourage you to use the US Food and Drug Administration's free resources via the Internet. Use this link: [FDA's Device Advice](#)

What You Need to Know About GCP for Certification Exams

To successfully pass any certification exam, the most critical element of GCP knowledge is that you know when and where the federal or international GCP requirement begins and ends. It is critical that you understand the differences between local requirements that may be very much a part of your experience, and the actual content and requirements of the GCP regulations and guidelines.

For example, suppose you encounter a scenario-based question on the certification exam that requires you to know the GCP requirement for submission of an investigator's credential to an IRB or IEC prior to approval of a study. Test yourself with this question:

For studies conducted under a US IND, investigators are required to submit Form FDA 1572 (Statement of Investigator) to the reviewing IRB. True or False?

The correct answer is False. Although you may have experience with a local or regional IRB that includes in its policies the requirement to submit Form FDA 1572, none of the US FDA's regulations specifically require submission of the form. GCP requires that the investigator's qualifications and credentials be submitted to the IRB. However, GCP allows IRBs to define specific requirements. A simple way to look at this is that GCP defines "what" must be done, but often leaves how it is to be done at the discretion of the persons or entities responsible for compliance.

Learning Objectives and GCP Resources for Study

Mastery of the following learning objectives will help you be successful on your certification examination.

LEARNING OBJECTIVE	REFERENCES & RESOURCES
General learning objectives applicable to all clinical studies	
Define the term "GCP compliance" in clinical research and explain how it differs from the concept of GCP compliance in daily medical practice.	21 CFR 312 IND Regulations
State the regulatory definition of investigator, sponsor and sponsor-investigator.	21 CFR 312.3, 21 CFR 50.3, 21 CFR 56.102, 21 CFR 54.2
State the international principles of GCP and give an example of the practical application of each.	ICH GCP Guideline part 2, 21 CFR 312.120
Define terms included in the ICH GCP glossary.	ICH GCP Guideline, part 1
State the GCP-required qualifications of a clinical investigator.	21 CFR 312
Describe the general GCP principles of human subject protection including autonomy, beneficence and justice and discuss how the investigator applies each of these principles in a clinical study.	The Belmont Report
Describe how conflict of interest may impact a clinical study and the GCP processes established to prevent it. Discuss the GCP criteria for financial disclosure by clinical investigators.	21 CFR 54, and funding agency guidelines
State the documents that GCP requires to be submitted to and approved by an IRB or IEC prior to commencing clinical research.	21 CFR 56, ICH GCP Guideline, part 3
State the investigator's reporting responsibilities to the IRB or IEC.	21 CFR 56, 21 CFR 312, ICH GCP Guideline, parts 3 and 4
Explain the requirements for obtaining legal informed consent for a clinical study from a legally competent adult, a mentally competent, yet illiterate, English-speaking adult, a mentally competent adult who is not able to speak, an incompetent adult subject, and a child or ward.	21 CFR 50, 45 CFR 46 and The FDA Information Sheets.
Explain the GCP-defined role of a witness, legally authorized representative, subject advocate, study subject, person who obtains informed consent and the investigator during the informed consent process.	21 CFR 50, ICH GCP Guideline, parts 3 and 4.
State the GCP requirements for documentation of informed consent, including consent when a witness, subject advocate or legally authorized representative is required, including the investigator's responsibility to provide copies of informed consent documentation.	21 CFR 50, 45 CFR 46, ICH GCP Guideline, parts 3 and 4, FDA Information Sheets, Guide to Informed Consent.
Discuss the activities in the informed consent process beginning with the first communication to a subject through the closure of the study.	21 CFR 50, 45 CFR 45, ICH GCP Guideline, parts 3 and 4, FDA Information Sheets, Guide to Informed Consent.
Describe the documentation investigators should have on file prior to the start of a study.	21 CFR 312, 21 CFR 812, ICH GCP Guideline, parts 4 and 8.

LEARNING OBJECTIVE	REFERENCES & RESOURCES
Discuss the documentation associated with a study initiation meeting and the role of the investigator.	21 CFR 312, ICH GCP Guideline, parts 4, 5 and 8.
State the investigator's responsibilities for compliance with the study protocol and how changes to the protocol may be made.	21 CFR 56, 21 CFR 312, Form FDA 1572 , ICH GCP Guideline, parts 3, 4 and 5.
Discuss the role of the study monitor in a clinical study and the investigator's responsibility for interaction with the sponsor's monitor.	21 CFR 312, ICH GCP Guideline parts 4, 5 and 8.
Describe the investigator's reporting responsibilities in the event that a clinical study is terminated prematurely by the IRB or the IEC, regulatory authority, sponsor or investigator.	21 CFR 56, 21 CFR 312, ICH GCP Guideline, part 4
Describe the investigator's responsibilities with study records related to preparation, maintenance, providing access to authorized persons, security, and long-term retention.	21 CFR 11, 21 CFR 50, 21 CFR 54, 21 CFR 56, 21 CFR 312, ICH GCP Guideline, parts 4 and 8.
Describe the purpose of each GCP-required essential document for a clinical study when given a list of documents.	ICH GCP Guideline, part 8
Describe the investigator's responsibilities with case report forms and source documentation in the clinical study.	21 CFR 312, ICH GCP Guideline, parts 4, 5 and 8.
Discuss the roles of the clinical investigator, clinical research coordinator, sponsor, IRB, study subject, regulatory authorities, data safety monitoring board and contract research organization in GCP-compliant research.	21 CFR 50, 56, 312. The Ultimate Step-by-Step Guide to Conducting Pharmaceutical Clinical Trials in the USA, plus other clinical research guides.
Describe the agreements made by clinical investigators with regulatory authorities, such as the FDA, the sponsor, a contract research organization, the institution in which the research is conducted, or by whom the investigator is employed, the IRB or IEC, and study subjects.	21 CFR 312.60-70, ICH GCP Guideline, part 4.
Describe how to prepare and submit research to an IRB or IEC for review and the role of the investigator in attending a meeting and addressing modifications required by the IRB or IEC.	21 CFR 56, 21 CFR 312, ICH GCP Guideline, parts 3 and 4
Discuss the inspections of investigator's records that are permitted by GCP as well as the audit process by regulatory authorities.	21 CFR 312, ICH GCP Guideline parts 4, 5 and 8.
Learning objectives applicable to drug and biologic studies	
Discuss the phases of pharmaceutical clinical studies as defined in GCP.	21 CFR 312
Describe the essential resources required of investigators in pharmaceutical studies.	21 CFR 312.60-70, ICH GCP Guideline, part 4.
Discuss the GCP requirements for the investigator's receipt of investigational supplies.	21 CFR 312, ICH GCP Guideline, parts 4, 5 and 8.

LEARNING OBJECTIVE	REFERENCES & RESOURCES
State the GCP requirements for documentation of investigational pharmaceutical products.	21 CFR 312, ICH GCP Guideline, parts 4, 5 and 8
Discuss the GCP requirements for destruction or disposal of investigational drugs.	21 CFR 312, ICH GCP Guideline, parts 4, 5 and 8
Discuss the GCP criteria for storage of investigational drugs.	21 CFR 312, ICH GCP Guideline, parts 4, 5 and 8
Describe the investigator's responsibilities with the identification, documentation, reporting and follow-up of adverse experiences.	21 CFR 56, 21 CFR 312, Form FDA 1572, ICH GCP Guideline, parts 3, 4, 5 and 8.
Describe the responsibility of the sponsor for monitoring clinical studies.	21 CFR 312.56, ICH GCP 5.18
State the qualifications for clinical study monitors.	21 CFR 312.53, ICH GCP 5.18.2
State the monitor's requirements related to the verification of proper management and documentation of investigational products by investigators.	21 CFR 312.57, 21 CFR 312.59, 21 CFR 312.61, 21 CFR 312.62, 21 CFR 312. 69, ICH GCP 5.18.5
Describe the GCP requirements for the verification of data reported by clinical investigators with source documents.	21 CFR 312.56, ICH GCP 5.18.4
Discuss the monitor's responsibilities with verifying protocol compliance and subject enrollment.	21 CFR 312.50, 21 FR 312.60, ICH GCP 5.18.4
Describe the monitor's responsibilities with adverse events and safety reporting by investigators.	21 CFR 312.32, ICH GCP 5.18.4
Describe the IRB-related documentation requirements that should be reviewed by clinical monitors	21 CFR 56, 21 CFR 312.50, 21 CFR 312.66, ICH GCP 3, 5.18.4
State the documentation that should be reviewed during monitoring visits related to informed consent.	21 CFR 312.50, ICH GCP 5.18.4
Name the GCP-required elements in a monitoring visit report.	FDA Guideline for the Monitoring of Clinical Investigations, ICH GCP 5.18.6

Resources

The following resource links are provided to assist you with your GCP review.

1. [The ICH GCP Guideline](#).
2. Code of Federal Regulations
 - [21 CFR 11](#) Electronic Records; Electronic Signatures
 - [21 CFR 50](#) Protection of Human Subjects
 - [21 CFR 54](#) Financial Disclosure by Clinical Investigators
 - [21 CFR 56](#) Institutional Review Boards
 - [21 CFR 312](#) Investigational New Drug Application
 - [21 CFR 812](#) Investigational Device Exemptions
 - [45 CFR 46](#) Protection of Human Subjects
3. [Guideline for the Monitoring of Clinical Investigations](#)

Note: We have color-coded flash cards covering all of the above regulations and guidelines to facilitate your study. The materials you use to study are at your discretion. What is most important is that you master the material, either by comprehensive reading and study of the regulations and guidelines, or by some other method.

4. [Clinical Research and the HIPAA Privacy Rule](#) – This is an excellent resource for all sponsor and investigative site personnel that clearly defines the proper implementation of the HIPAA requirements within the context of clinical studies in the US.

Additional GCP Training Resources available from The RAN Institute

- ❑ *GCPs Made Easy*® Flash Cards in USA Drug and ICH editions. These have been used by thousands of certified research professionals since 1996. Our experiences is that most certification exam candidates study with the All Flash Card Pack.
- ❑ GCP Practice Test. Includes 100 questions and answers with feedback on every response. Includes unlimited access to test and re-test yourself. (Item 5102 in our product catalog. This practice test is also available at a discounted rate within our certification preparation packages).
- ❑ The Ultimate Step By Step Guide to Conducting Pharmaceutical Clinical Trials in the USA
- ❑ On-line GCP training courses available with or without continuing education credit are an excellent way to complete a comprehensive review of GCP in preparation for certification.
- ❑ [Click here](#) for the on-line product catalog for these resources.

Please contact us to learn how you can use our on-line training resources and receive CE or CME credit following your certification.

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