

# ACRP GCP and Clinical Trial Principles Practice Test (Sample)

## Study Guide



**Everything you need from our exam experts!**

**Copyright © 2026 by Examzify - A Kaluba Technologies Inc. product.**

**ALL RIGHTS RESERVED.**

**No part of this book may be reproduced or transferred in any form or by any means, graphic, electronic, or mechanical, including photocopying, recording, web distribution, taping, or by any information storage retrieval system, without the written permission of the author.**

**Notice: Examzify makes every reasonable effort to obtain accurate, complete, and timely information about this product from reliable sources.**

**SAMPLE**

# Table of Contents

<b>Copyright</b> .....	<b>1</b>
<b>Table of Contents</b> .....	<b>2</b>
<b>Introduction</b> .....	<b>3</b>
<b>How to Use This Guide</b> .....	<b>4</b>
<b>Questions</b> .....	<b>5</b>
<b>Answers</b> .....	<b>8</b>
<b>Explanations</b> .....	<b>10</b>
<b>Next Steps</b> .....	<b>16</b>

SAMPLE

# Introduction

Preparing for a certification exam can feel overwhelming, but with the right tools, it becomes an opportunity to build confidence, sharpen your skills, and move one step closer to your goals. At Examzify, we believe that effective exam preparation isn't just about memorization, it's about understanding the material, identifying knowledge gaps, and building the test-taking strategies that lead to success.

This guide was designed to help you do exactly that.

Whether you're preparing for a licensing exam, professional certification, or entry-level qualification, this book offers structured practice to reinforce key concepts. You'll find a wide range of multiple-choice questions, each followed by clear explanations to help you understand not just the right answer, but why it's correct.

The content in this guide is based on real-world exam objectives and aligned with the types of questions and topics commonly found on official tests. It's ideal for learners who want to:

- Practice answering questions under realistic conditions,
- Improve accuracy and speed,
- Review explanations to strengthen weak areas, and
- Approach the exam with greater confidence.

We recommend using this book not as a stand-alone study tool, but alongside other resources like flashcards, textbooks, or hands-on training. For best results, we recommend working through each question, reflecting on the explanation provided, and revisiting the topics that challenge you most.

**Remember:** successful test preparation isn't about getting every question right the first time, it's about learning from your mistakes and improving over time. Stay focused, trust the process, and know that every page you turn brings you closer to success.

Let's begin.

# How to Use This Guide

**This guide is designed to help you study more effectively and approach your exam with confidence. Whether you're reviewing for the first time or doing a final refresh, here's how to get the most out of your Examzify study guide:**

## **1. Start with a Diagnostic Review**

**Skim through the questions to get a sense of what you know and what you need to focus on. Your goal is to identify knowledge gaps early.**

## **2. Study in Short, Focused Sessions**

**Break your study time into manageable blocks (e.g. 30 - 45 minutes). Review a handful of questions, reflect on the explanations.**

## **3. Learn from the Explanations**

**After answering a question, always read the explanation, even if you got it right. It reinforces key points, corrects misunderstandings, and teaches subtle distinctions between similar answers.**

## **4. Track Your Progress**

**Use bookmarks or notes (if reading digitally) to mark difficult questions. Revisit these regularly and track improvements over time.**

## **5. Simulate the Real Exam**

**Once you're comfortable, try taking a full set of questions without pausing. Set a timer and simulate test-day conditions to build confidence and time management skills.**

## **6. Repeat and Review**

**Don't just study once, repetition builds retention. Re-attempt questions after a few days and revisit explanations to reinforce learning. Pair this guide with other Examzify tools like flashcards, and digital practice tests to strengthen your preparation across formats.**

**There's no single right way to study, but consistent, thoughtful effort always wins. Use this guide flexibly, adapt the tips above to fit your pace and learning style. You've got this!**

## Questions

SAMPLE

- 1. Which statement best defines ALCOA?**
  - A. ALCOA stands for Attributable, Legible, Contemporaneous, Original, Accurate.**
  - B. ALCOA is only about data integrity.**
  - C. ALCOA+ means data must be accessible within 24 hours.**
  - D. ALCOA prohibits any changes after data entry.**
  
- 2. How are ACRP exam questions structured?**
  - A. True/false statements**
  - B. Scenario-based**
  - C. Short answer**
  - D. Fill-in-the-blank**
  
- 3. What is source data in clinical trials?**
  - A. Original records or certified copies containing the data that support trial findings**
  - B. The study protocol**
  - C. The trial budget**
  - D. The final publication**
  
- 4. What is an Investigational Product (IP)?**
  - A. Approved product used in standard care.**
  - B. Drug, device, or biologic under investigation.**
  - C. Only a device.**
  - D. Only a drug.**
  
- 5. Informed consent is best described as which of the following?**
  - A. A continuous process throughout the study**
  - B. A one-time event**
  - C. Optional if risks are low**
  - D. Only required for high-risk studies**

- 6. SUSAR differs from a general SAE because it is**
- A. Not related to IP**
  - B. Not serious**
  - C. Suspected to be related to IP and is unexpected**
  - D. Always fatal**
- 7. What document provides clinically relevant information about the investigational product to investigators and assessors?**
- A. The Investigator's Brochure**
  - B. The Protocol**
  - C. The Safety Data Sheet**
  - D. The Clinical Study Report**
- 8. How do you distinguish a deviation from a violation?**
- A. Deviation is typically a minor, non-safety-impacting departure; a violation breaches the protocol and may affect safety or data integrity.**
  - B. Deviation is more serious than a violation.**
  - C. Violation is a minor symptom of noncompliance.**
  - D. Deviation always requires immediate termination of the study.**
- 9. What is the CRC's role in AE/SAE reporting?**
- A. Document, report per protocol, follow up until resolution.**
  - B. Only escalate to IRB if death.**
  - C. Record events in local log only.**
  - D. Classify all events as SAE automatically.**
- 10. Which elements are typically included in informed consent to help the subject decide whether to participate?**
- A. Only the risks and benefits**
  - B. The purpose and design only**
  - C. Purpose, procedures, risks, benefits, alternatives, confidentiality, and voluntary nature**
  - D. A summary of the sponsor's marketing goals**

## Answers

SAMPLE

1. A
2. B
3. A
4. B
5. A
6. C
7. A
8. D
9. A
10. C

SAMPLE

## **Explanations**

SAMPLE

## 1. Which statement best defines ALCOA?

- A. ALCOA stands for Attributable, Legible, Contemporaneous, Original, Accurate.**
- B. ALCOA is only about data integrity.**
- C. ALCOA+ means data must be accessible within 24 hours.**
- D. ALCOA prohibits any changes after data entry.**

ALCOA is a set of data quality attributes used to ensure data in clinical trials are trustworthy. The statement that ALCOA stands for Attributable, Legible, Contemporaneous, Original, Accurate is the best because it precisely defines each element: Attributable means the data can be traced to the person who recorded it; Legible means it is readable and unambiguous; Contemporaneous means it is recorded at the time of the event or as close to it as possible; Original means the data element is the original record or a verified copy; Accurate means the data correctly reflect the observation or event. ALCOA+ extends with Complete, Consistent, Enduring, Available, but the core five are captured by that definition. The other options misstate the scope or requirements: data integrity is broader than ALCOA and doesn't specify accountability for who entered the data; ALCOA+ is not a 24-hour accessibility requirement; changes are allowed in a controlled, auditable way rather than prohibited.

## 2. How are ACRP exam questions structured?

- A. True/false statements**
- B. Scenario-based**
- C. Short answer**
- D. Fill-in-the-blank**

Questions are built around realistic clinical trial scenarios that require you to determine the best action, decision, or interpretation given regulatory and ethical requirements. This structure tests your ability to apply guidelines to a concrete situation, mirroring the decisions a study team faces in daily practice. The scenario format aligns with the exam's goal of assessing applied knowledge of GCP, trial conduct, and participant safety, rather than simple memorization. Formats like true/false, short answer, or fill-in-the-blank don't provide the same depth of applied judgment. True/false is limited to binary choices and can encourage guessing; short answer and fill-in-the-blank emphasize recall and free-form response rather than selecting the best option in a defined scenario. With scenario-based questions, you evaluate factors such as consent validity, safety reporting timelines, protocol adherence, data integrity, and regulatory obligations within the context presented.

### 3. What is source data in clinical trials?

- A. Original records or certified copies containing the data that support trial findings**
- B. The study protocol**
- C. The trial budget**
- D. The final publication**

Source data are the original records or certified copies that contain the data used to support the trial findings. They are the first place where information about a participant is recorded—such as patient charts, hospital records, lab worksheets, or electronic files that originate from the source document—before it's entered into the case report forms. Regulators require that data in the study be traceable back to these source documents, and you verify this by comparing the CRF data to the source data to ensure accuracy and integrity. The study protocol describes how the trial is run, the budget covers finances, and the final publication presents the results, not the raw data used to derive them.

### 4. What is an Investigational Product (IP)?

- A. Approved product used in standard care.**
- B. Drug, device, or biologic under investigation.**
- C. Only a device.**
- D. Only a drug.**

An Investigational Product is anything used or studied in a clinical trial that has not yet been approved for marketing in the country where the trial takes place. It can be a drug, a device, or a biologic, and it may include combination products or treatments being evaluated for safety and efficacy. That breadth is why describing an IP as a drug, device, or biologic under investigation best fits, because it covers all possible product types and emphasizes that the product is still under study rather than approved for standard care. An approved product used in standard care isn't an IP, and limiting IP to only a device or only a drug misses the full range of possibilities.

### 5. Informed consent is best described as which of the following?

- A. A continuous process throughout the study**
- B. A one-time event**
- C. Optional if risks are low**
- D. Only required for high-risk studies**

Informed consent is an ongoing commitment to respecting a participant's autonomy throughout the research, not a one-time form signing. It starts with clear disclosure about purpose, procedures, risks, benefits, and alternatives, and must be understood and voluntarily given. But the process doesn't end at enrollment; as the study progresses, new information may arise, procedures may change, or burdens may shift, so participants should be re-informed and asked to reaffirm their willingness to continue. The participant must always have the option to withdraw at any time without penalty, and consent is required regardless of the level of risk, with rare emergency situations as exceptions rather than the rule. This continuous approach protects participants' rights and ensures ongoing agreement to what happens during the study.

**6. SUSAR differs from a general SAE because it is**

- A. Not related to IP**
- B. Not serious**
- C. Suspected to be related to IP and is unexpected**
- D. Always fatal**

SUSARs are defined by a combination of three ideas: the event is serious, it is suspected to be related to the investigational product, and it is unexpected based on what is already known about the product. This means the reaction is not only severe, but also potentially caused by the IP and not described in the current safety information (like the Investigator's Brochure). If an event is clearly unrelated to the IP or is an already-described, anticipated reaction, it would not be a SUSAR—even if it's serious. So the best description is that it's suspected to be related to the IP and is unexpected.

**7. What document provides clinically relevant information about the investigational product to investigators and assessors?**

- A. The Investigator's Brochure**
- B. The Protocol**
- C. The Safety Data Sheet**
- D. The Clinical Study Report**

The Investigator's Brochure is the primary source of clinically relevant information about the investigational product for investigators and assessors. It compiles nonclinical and clinical data on the product, including pharmacology, safety, dosing guidance, routes of administration, potential risks, adverse events, interactions, and monitoring and handling recommendations. It is provided before a trial begins and updated as new information becomes available, so investigators can assess risks, inform their monitoring plans, and communicate appropriately with participants. The protocol describes how the trial is conducted rather than detailing the product's clinical profile. The Safety Data Sheet covers hazard and handling information for workplace safety, not clinical use in trials. The Clinical Study Report summarizes study results after completion, not the ongoing information provided to investigators during the trial.

## 8. How do you distinguish a deviation from a violation?

- A. Deviation is typically a minor, non-safety-impacting departure; a violation breaches the protocol and may affect safety or data integrity.
- B. Deviation is more serious than a violation.
- C. Violation is a minor symptom of noncompliance.
- D. Deviation always requires immediate termination of the study.**

Distinguishing factor: safety and data impact plus regulatory significance. A deviation is a minor departure from the protocol that does not affect participant safety or data integrity; it is typically documented, monitored, and corrected without altering the study's overall conduct. A protocol violation is a more serious breach that may compromise safety, rights, welfare, or data integrity, and it requires escalated investigation, reporting, and potentially regulatory action or corrective measures. In practice, you'd see a deviation for something like a missed visit window or a minor data-entry error that doesn't change outcomes. A violation would involve a significant breach, such as enrolling an ineligible participant or performing a procedure outside the approved protocol. That's why the best description is that deviations are minor departures, while violations breach the protocol and may affect safety or data integrity. The idea that deviations always require immediate termination is not correct.

## 9. What is the CRC's role in AE/SAE reporting?

- A. Document, report per protocol, follow up until resolution.**
- B. Only escalate to IRB if death.
- C. Record events in local log only.
- D. Classify all events as SAE automatically.

This item centers on how a CRC handles adverse event reporting in a trial. The correct approach is for the CRC to document each event clearly in the source records, report it to the sponsor and the study team per the protocol's defined timelines, and pursue follow-up information until the event is resolved or its outcome is known. This ensures safety data are captured accurately, regulatory requirements are met, and all necessary parties stay informed as the situation evolves. The other options miss key elements: reporting only in limited circumstances or logging locally without required dissemination, and automatically classifying every event as an SAE.

**10. Which elements are typically included in informed consent to help the subject decide whether to participate?**

**A. Only the risks and benefits**

**B. The purpose and design only**

**C. Purpose, procedures, risks, benefits, alternatives, confidentiality, and voluntary nature**

**D. A summary of the sponsor's marketing goals**

Understanding informed consent means providing information that supports a truly voluntary and informed decision. The elements that fit best are the study's purpose, what will be done (procedures), potential risks and anticipated benefits, available alternatives to participation, how private information will be kept confidential, and the fact that participation is voluntary and can be withdrawn at any time without penalty. Including these pieces helps the person weigh what involvement would mean, what they might experience, and what other options exist, so they can decide in an autonomous, well-informed way. Options that omit any of these core elements, or introduce unrelated goals like marketing aims, don't provide the complete, unbiased basis for making an informed choice.

SAMPLE

## Next Steps

**Congratulations on reaching the final section of this guide. You've taken a meaningful step toward passing your certification exam and advancing your career.**

**As you continue preparing, remember that consistent practice, review, and self-reflection are key to success. Make time to revisit difficult topics, simulate exam conditions, and track your progress along the way.**

**If you need help, have suggestions, or want to share feedback, we'd love to hear from you. Reach out to our team at [hello@examzify.com](mailto:hello@examzify.com).**

**Or visit your dedicated course page for more study tools and resources:**

**<https://acrpgcpcclinicaltrialprinciples.examzify.com>**

**We wish you the very best on your exam journey. You've got this!**

SAMPLE