ACRP GCP AND CLINICAL TRIAL PRINCIPLES PRACTICE TEST (SAMPLE)

STUDY GUIDE

SAMPLE STUDY GUIDE WITH LIMITED QUESTIONS

VISIT US ONLINE FOR THE FULL VERSION STUDY GUIDE

https://acrpgcpclinicaltrialprinciples.examzify.com

Table of Contents

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

1. What is a key aspect of recruitment that protects participants?

A. Aggressive recruitment strategies with monetary incentives.

B. Recruitment limited to hospital staff.

C. Recruitment primarily via social media without oversight.

D. Ethical recruitment practices and ensuring informed consent.

2. Which principle requires fair and equitable subject selection?

A. Respect for persons.

B. Beneficence.

C. Justice.

D. Non-maleficence.

3. Which version of ICH E6 is referenced for 2025 exams?

A. E6 (R2) with principles aligned to E6 (R3).

B. E6 (R1).

C. E6 (R3).

D. E6 (R2) and E6 (R3) combined.

4. 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

5. What is a primary endpoint?

A. Time to trial completion.

B. Main outcome used to evaluate treatment effect.

C. Total sample size.

D. Any observed adverse event.

6. Which entity is responsible for approving the consent process in a trial?

A. Sponsor

B. Investigators

C. CRO

D. IRB/IEC

7. Who has overall responsibility for trial conduct at the site?

A. Sponsor

B. Principal Investigator (PI)

C. Clinical Research Coordinator (CRC)

D. IRB

8. Who supervises the research team?

A. Principal Investigator (PI)

B. Clinical Research Coordinator (CRC)

C. Sponsor's monitor

D. IRB member

9. What must be included in an informed consent form to comply with GCP?

A. Purpose of the research, risks/benefits, voluntary participation, alternatives, confidentiality, contact details, and right to withdraw.

B. Potential compensation and trial duration only

C. Personal preferences of the investigator

D. Government sponsorship details

10. In a trial, what is the purpose of screening?

A. To determine eligibility of potential participants before enrollment.

B. To assign participants to treatment groups.

C. To monitor adverse events during follow-up.

D. To obtain consent from participants.

Answers

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

Explanations

1. What is a key aspect of recruitment that protects participants?

A. Aggressive recruitment strategies with monetary incentives.

B. Recruitment limited to hospital staff.

C. Recruitment primarily via social media without oversight.

D. Ethical recruitment practices and ensuring informed consent.

Protecting participants in recruitment comes from ethical recruitment practices and obtaining informed consent. Informed consent means presenting all relevant information in clear, understandable language, verifying the person has the capacity to decide, giving time to consider the decision, and ensuring they know they can decline or withdraw at any time without penalty. This process, often overseen by an ethics board, safeguards privacy, explains risks and benefits, and outlines alternatives and confidentiality. Aggressive monetary incentives can unduly influence decisions, recruitment limited to hospital staff can introduce coercion or bias, and recruiting via social media without proper oversight risks miscommunication and lack of proper consent. These approaches undermine protection, whereas ethical recruitment with informed consent directly upholds participants' rights and welfare.

2. Which principle requires fair and equitable subject selection?

A. Respect for persons.

B. Beneficence.

C. Justice.

D. Non-maleficence.

Distributive justice in research ethics requires fair and equitable subject selection. It means the burdens and benefits of the study should be distributed fairly across populations, avoiding the exploitation of vulnerable groups or selecting participants simply because they are convenient, and ensuring inclusion supports the study's scientific aims. While the other principles address autonomy (respect for persons), avoidance of harm (non-maleficence), and maximizing overall benefit (beneficence), justice specifically governs who bears risks and who benefits from research. This is why fair subject selection is central to the justice principle.

3. Which version of ICH E6 is referenced for 2025 exams?

A. E6 (R2) with principles aligned to E6 (R3).

B. E6 (R1).

C. E6 (R3).

D. E6 (R2) and E6 (R3) combined.

The question tests your understanding of how the ICH E6 guidelines are used for exams during a transition period. For 2025 exams, the referenced standard is E6 in its R2 revision, but the exam content is aligned to the principles of E6(R3). This means you're measured against the established requirements of R2 while also incorporating the newer ideas and expectations from R3—such as stronger emphasis on risk-based quality management and data integrity—without fully switching to R3 as the sole baseline. E6(R1) is outdated and not the reference used, and treating both R2 and R3 as completely separate standards isn't how the exam is structured; it uses R2 as the base with alignment to R3.

4. 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.

5. What is a primary endpoint?

A. Time to trial completion.

B. Main outcome used to evaluate treatment effect.

C. Total sample size.

D. Any observed adverse event.

The primary endpoint is the main outcome the study is designed to assess to determine whether the treatment has a meaningful effect. It is the central result used to judge efficacy and is specified before data collection so the study can be properly powered to detect a difference. This outcome drives the statistical analysis and is the primary basis for concluding whether the treatment works. Time to trial completion is about logistics and duration, not the treatment's effect. Total sample size is a planning/design parameter, not an outcome measured to judge efficacy. An observed adverse event is a safety observation and, while important, is typically considered a secondary endpoint or part of safety analyses rather than the primary measure of treatment effect. For example, in a cancer trial the primary endpoint might be progression-free survival, while adverse events would be analyzed separately for safety.

6. Which entity is responsible for approving the consent process in a trial?

A. Sponsor

B. Investigators

C. CRO

D. IRB/IEC

Approval of the informed consent process is handled by an IRB or IEC. They review and approve the consent document and the way consent is obtained to ensure that information is clear, complete, and presented in a way that supports voluntary, informed participation, including disclosure of risks, benefits, and alternatives. This approval must be in place before the trial starts and whenever the consent form or process is updated. The investigator is responsible for obtaining consent according to the IRB/IEC-approved plan, but does not grant the approval themselves. Sponsors and CROs may prepare and manage the consent materials and trial procedures, but the ethical and regulatory endorsement comes from the IRB/IEC.

7. Who has overall responsibility for trial conduct at the site?

A. Sponsor

B. Principal Investigator (PI)

C. Clinical Research Coordinator (CRC)

D. IRB

The main idea is that the Principal Investigator has the ultimate responsibility for how the trial is conducted at the site. Under GCP, the PI is accountable for the proper conduct of the study at their site, including protocol adherence, protecting participant rights and safety, ensuring informed consent is properly obtained, and keeping accurate, verifiable data. Delegation is allowed to qualified staff like a Clinical Research Coordinator, but the PI remains responsible for those tasks and for overall compliance with the protocol and regulations. The sponsor oversees the trial at a broader level—design, funding, and sponsor-level monitoring—but is not responsible for day-to-day site conduct. The IRB/IEC focuses on participant protection and protocol approval/oversight, not running the site. So, the person with overall responsibility for trial conduct at the site is the Principal Investigator.

8. Who supervises the research team?

A. Principal Investigator (PI)

B. Clinical Research Coordinator (CRC)

C. Sponsor's monitor

D. IRB member

The principal investigator is the person responsible for the overall conduct of the study at the site and for the safety and rights of participants. They ensure protocol adherence, regulatory compliance, informed consent, adverse event reporting, and data integrity, and they supervise the research team to ensure those standards are met. The clinical research coordinator assists with day-to-day tasks under the PI's direction but does not supervise the entire team. The sponsor's monitor provides independent oversight and checks on compliance and data quality during visits, not ongoing supervision of site staff. An IRB member reviews and approves the protocol from an ethics standpoint, but they do not manage trial operations.

9. What must be included in an informed consent form to comply with GCP?

A. Purpose of the research, risks/benefits, voluntary participation, alternatives, confidentiality, contact details, and right to withdraw.

B. Potential compensation and trial duration only

C. Personal preferences of the investigator

D. Government sponsorship details

Informed consent forms are designed so participants can make a voluntary, well-informed decision about joining a study. Under GCP, the form must present the essential elements that allow that decision: the purpose of the research, the expected duration, the procedures involved, the reasonably foreseeable risks and benefits, the alternatives to participation, how confidentiality will be protected, whom to contact with questions, and the participant's right to withdraw at any time without penalty. This combination ensures transparency, respects participant autonomy, and provides clear pathways for questions or concerns. The other options miss critical pieces (for example, focusing only on compensation or duration, or including investigator preferences or sponsorship details), so they do not satisfy the required content for informed consent.

10. In a trial, what is the purpose of screening?

A. To determine eligibility of potential participants before enrollment.

B. To assign participants to treatment groups.

C. To monitor adverse events during follow-up.

D. To obtain consent from participants.

Screening determines whether a potential participant meets the trial's inclusion and exclusion criteria before enrollment. This step is essential to ensure the study population is appropriate for answering the research question and to protect participant safety, as it filters out individuals who could be harmed or for whom the trial isn't suitable. Screening may involve medical history, physical exams, and necessary tests to confirm eligibility. It's separate from obtaining consent (which happens to authorize participation) and from the processes that come after enrollment, such as randomization to treatment groups or monitoring adverse events during follow-up.

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.

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

https://acrpgcpclinicaltrialprinciples.examzify.com

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