

# Association of Clinical Research Professionals (ACRP) Certified Professional Practice Exam (Sample)

## Study Guide



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

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# 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

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- 1. According to GCP requirements, who should make the decision about the suitability of subjects participating in a trial?**
  - A. The sponsor**
  - B. The investigator**
  - C. The regulatory authority**
  - D. The ethics committee**
  
- 2. What is the important factor to determine when an adverse event is classified as serious?**
  - A. The severity and duration of the event**
  - B. Whether it results in hospitalization or prolongation of existing hospitalization**
  - C. The subjective feelings of the investigator**
  - D. The overall outcome for the subject**
  
- 3. When initiating a study for a new combination of drugs, what committee is typically established for oversight?**
  - A. Research Ethics Committee**
  - B. Independent Data Monitoring Committee**
  - C. Institutional Review Board**
  - D. Safety Monitoring Board**
  
- 4. Who is responsible for sending Annual Progress Reports to the IRB/IEC?**
  - A. The Sponsor**
  - B. The Investigator**
  - C. The Clinical Research Coordinator**
  - D. The Principal Investigator**
  
- 5. What are expected adverse events (AEs) in clinical trials?**
  - A. Unpredictable and severe side effects**
  - B. Events inconsistent with patient histories**
  - C. Events consistent with prior trials**
  - D. Minor and temporary side effects**

- 6. In the context of RCTs, what does a dose response study aim to assess?**
- A. The safety of a new treatment**
  - B. The patients' reaction to varying doses**
  - C. The effectiveness across different treatments**
  - D. The duration of treatment effect**
- 7. In clinical trials, what is a critical aspect of study design for pediatric trials?**
- A. Include adult dosages only**
  - B. Develop a specific program for children's use**
  - C. Use available adult data exclusively**
  - D. Ensure only healthy participants are selected**
- 8. In a study looking at mild cognitive impairment, who can administer a psychometric test to potential subjects?**
- A. The principal investigator only**
  - B. A research nurse with relevant experience**
  - C. A research assistant who is certified to administer the psychometric test**
  - D. Any medical student participating in the research**
- 9. Which report outlines ethical principles including respect for persons, beneficence, and justice?**
- A. The Declaration of Helsinki**
  - B. The Belmont Report**
  - C. The Nuremberg Code**
  - D. The National Research Act**
- 10. Which document should detail the findings from monitoring a closed clinical trial?**
- A. The Final Report**
  - B. The Close-out Report**
  - C. The Monitoring Report**
  - D. The Study Protocol**

## Answers

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

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## **Explanations**

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**1. According to GCP requirements, who should make the decision about the suitability of subjects participating in a trial?**

- A. The sponsor
- B. The investigator**
- C. The regulatory authority
- D. The ethics committee

The investigator plays a crucial role in determining the suitability of subjects participating in a clinical trial, in accordance with Good Clinical Practice (GCP) requirements. This responsibility is grounded in the investigator's comprehensive understanding of the study protocol, the specific inclusion and exclusion criteria set forth, and the ethical considerations involved in patient recruitment. The investigator is directly involved in assessing potential participants' medical histories, current health status, and other important factors that may impact their eligibility for the trial. This ensures that the rights, safety, and well-being of the subjects are prioritized, as the investigator is responsible for obtaining informed consent and monitoring the safety of participants throughout the study. While the sponsor may provide overall guidance and the regulatory authority may set the framework for compliance and safety, it is ultimately the investigator who has the direct interaction and relationship with trial subjects and is best positioned to make this individualized assessment. The ethics committee also plays a role in the approval of protocols and oversight but does not make individual subject suitability decisions.

**2. What is the important factor to determine when an adverse event is classified as serious?**

- A. The severity and duration of the event
- B. Whether it results in hospitalization or prolongation of existing hospitalization**
- C. The subjective feelings of the investigator
- D. The overall outcome for the subject

When determining whether an adverse event is classified as serious, the most significant factor is whether it results in hospitalization or prolongation of an existing hospitalization. This criterion is outlined in regulatory definitions and guidelines, such as those provided by the FDA and ICH/GCP. A serious adverse event is typically characterized not only by the medical conditions that arise but specifically includes outcomes that necessitate medical intervention, such as hospitalization, which indicates a severe level of impact on patient health. Hospitalization serves as an objective measure of the event's seriousness, reflecting that it either required or extended a patient's need for inpatient care. This consideration is crucial as it directly influences the monitoring and reporting requirements for clinical trials. By focusing on the nature of the hospitalization, researchers can better assess the safety profile of investigational drugs or interventions and ensure appropriate responses to protect study subjects. While the severity and duration of the event, the subjective feelings of the investigator, and the overall outcome for the subject may contribute to understanding the context of an adverse event, they do not hold the same regulatory weight in categorizing an event as serious as the requirement for hospitalization does. Therefore, the classification of an adverse event hinges primarily on whether it leads to hospitalization or prolongation of hospital stay.

**3. When initiating a study for a new combination of drugs, what committee is typically established for oversight?**

- A. Research Ethics Committee**
- B. Independent Data Monitoring Committee**
- C. Institutional Review Board**
- D. Safety Monitoring Board**

The establishment of an Independent Data Monitoring Committee (IDMC) is essential in overseeing studies involving new combinations of drugs, particularly when safety and efficacy concerns arise during clinical trials. The primary role of the IDMC is to assess accumulating data and ensure the trial is conducted ethically and safely. They monitor interim results to make decisions about the continuation, modification, or termination of the trial based on safety and efficacy. This oversight becomes vital when handling new drug combinations, as the safety profile can be unpredictable, and the committee has the authority to safeguard participant welfare and ensure the integrity of the study. While other committees like the Institutional Review Board (IRB) and Research Ethics Committee are important for ethical oversight and approving study protocols, the IDMC is specifically focused on real-time data analysis throughout the trial, which is crucial for drug combination studies where adverse effects or unexpected outcomes may be more pronounced. The Safety Monitoring Board operates similarly to an IDMC, but the specific distinction here leans towards the independent oversight role of the IDMC in the context of drug combination studies.

**4. Who is responsible for sending Annual Progress Reports to the IRB/IEC?**

- A. The Sponsor**
- B. The Investigator**
- C. The Clinical Research Coordinator**
- D. The Principal Investigator**

The responsibility for sending Annual Progress Reports to the Institutional Review Board (IRB) or Independent Ethics Committee (IEC) primarily lies with the Investigator. This can often be the Principal Investigator, who leads the clinical trial, but it is typically framed within the broader role of the Investigator in the context of regulatory compliance and ethical oversight. The Annual Progress Report is an essential component of the ongoing communication between the study site and the IRB/IEC, helping to ensure that the study continues to align with ethical standards and regulatory requirements. This report provides important updates on the trial's status, enrollment figures, any adverse events that may have occurred, and updates on protocol deviations. The Investigator, having the most direct interactions with the trial's operations, is ideally positioned to provide accurate and comprehensive updates. While the Sponsor, Clinical Research Coordinator, and Principal Investigator have significant roles within the study, the responsibility for communication regarding the ongoing status and ethical conduct of the study primarily rests with the Investigator.

## 5. What are expected adverse events (AEs) in clinical trials?

- A. Unpredictable and severe side effects
- B. Events inconsistent with patient histories
- C. Events consistent with prior trials**
- D. Minor and temporary side effects

Expected adverse events (AEs) in clinical trials refer to events that have been previously observed and documented in prior studies or research related to a specific treatment or intervention. These events are anticipated based on existing data about the drug or device being tested, which helps researchers prepare for monitoring and managing these events during the trial. Identifying AEs that have been encountered in prior studies allows clinical trial teams to inform participants about possible risks and to develop strategies for monitoring patient safety effectively. Furthermore, expected AEs play a crucial role in risk assessment and benefit analysis during the design of the clinical trial, helping ensure that the potential harms are weighed against the anticipated benefits of the intervention. In contrast, unpredictable and severe side effects or events inconsistent with patient histories would not be classified as expected adverse events, as they deviate from what has been previously documented. Minor and temporary side effects may not always qualify as adverse events depending on their severity and impact on the patients' well-being. Hence, only those AEs that are consistent with prior trials provide a reliable framework for understanding possible outcomes during ongoing research.

## 6. In the context of RCTs, what does a dose response study aim to assess?

- A. The safety of a new treatment
- B. The patients' reaction to varying doses**
- C. The effectiveness across different treatments
- D. The duration of treatment effect

A dose response study in the context of Randomized Controlled Trials (RCTs) aims to assess how patients respond to varying doses of a treatment. This type of study is critical for understanding the relationship between the dose of a drug or intervention and the resulting effect on the patients. By examining different doses, researchers can identify the optimal dose that yields the best therapeutic response while minimizing side effects. Such studies are vital for determining not only the efficacy of a treatment but also its safety profile at different dosages. The findings aid in establishing guidelines for appropriate dosing that ensure patients receive the maximum benefit from a treatment. They can also reveal whether increased doses lead to increased effects, whether there is a plateau effect, or if there are enhanced side effects at higher dosages. In contrast, the other choices focus on different aspects of treatment research. Safety studies specifically evaluate adverse effects, while effectiveness assessments compare the results of various treatments rather than their dosing. Duration studies focus on how long the effects of a treatment last, which is separate from the immediate patient responses to varying doses. Thus, the primary focus of a dose response study is indeed on how patients react to different amounts of a treatment.

**7. In clinical trials, what is a critical aspect of study design for pediatric trials?**

- A. Include adult dosages only**
- B. Develop a specific program for children's use**
- C. Use available adult data exclusively**
- D. Ensure only healthy participants are selected**

Developing a specific program for children's use is critical in pediatric trials because the physiological and metabolic differences between children and adults significantly impact drug absorption, distribution, metabolism, and excretion. Pediatric populations are not simply smaller adults; they can exhibit different sensitivities to medications, varying responses to treatment, and distinct side effects. Therefore, creating tailored study designs that consider the unique needs of pediatric participants—such as appropriate dosage forms, routes of administration, and safety monitoring—is essential for obtaining relevant and safe data. By focusing on a specific program for children's use, researchers ensure that the study addresses the correct age groups, includes appropriate endpoints, and collects data that can inform safe and effective treatment options for this vulnerable population. This approach also fosters ethical considerations, making sure that the trial design is in the best interest of the pediatric subjects involved.

**8. In a study looking at mild cognitive impairment, who can administer a psychometric test to potential subjects?**

- A. The principal investigator only**
- B. A research nurse with relevant experience**
- C. A research assistant who is certified to administer the psychometric test**
- D. Any medical student participating in the research**

The correct choice indicates that a research assistant who is certified to administer the psychometric test can conduct the assessment on potential subjects. Certification is crucial in administering psychometric tests, as it ensures that the individual has the necessary training and understanding of the specific protocols and procedures required for accurate and reliable test execution. Psychometric tests often involve nuances in administration, scoring, and interpretation, which can significantly affect the results. A certified research assistant possesses the knowledge and skills to properly administer these tests, ensuring the integrity of the data collected in the study. Certification also often includes training in ethical considerations, informed consent, and confidentiality, which are critical when working with vulnerable populations, such as individuals with mild cognitive impairment. Therefore, having a certified individual administer the test not only enhances the reliability of the study's findings but also upholds the ethical standards required in research involving human subjects. While a principal investigator and experienced research nurses may have the necessary knowledge and training, the explicit requirement of certification for administering psychometric tests makes the certified research assistant the most appropriate choice. Participation by a medical student, without further qualifications or certification, does not inherently guarantee the necessary expertise to administer psychometric assessments competently.

**9. Which report outlines ethical principles including respect for persons, beneficence, and justice?**

- A. The Declaration of Helsinki**
- B. The Belmont Report**
- C. The Nuremberg Code**
- D. The National Research Act**

The Belmont Report is the key document that outlines fundamental ethical principles for conducting research involving human subjects, focusing specifically on respect for persons, beneficence, and justice. Respect for persons emphasizes the importance of recognizing individual autonomy and the requirement for informed consent, ensuring that participants are adequately informed about the study and can make voluntary decisions regarding their participation. Beneficence involves an obligation to minimize harm and maximize benefits, guiding researchers to prioritize the well-being of participants throughout the research process. Justice relates to fairness in the distribution of research benefits and burdens, ensuring that no particular group is unfairly burdened by research interventions while others benefit. These principles collectively serve as a foundation for ethical research practices in the United States and have influenced many regulatory frameworks in research involving human subjects, making the Belmont Report a critical resource in the field of research ethics.

**10. Which document should detail the findings from monitoring a closed clinical trial?**

- A. The Final Report**
- B. The Close-out Report**
- C. The Monitoring Report**
- D. The Study Protocol**

The document that should detail the findings from monitoring a closed clinical trial is the Close-out Report. This report is specifically designed to summarize the overall outcomes of the trial, including insights drawn from monitoring activities. It includes information about the trial's conduct, any deviations from the protocol, data management practices, and final outcome measures. The Close-out Report serves as a comprehensive account that reflects the status of the investigation at the time of closing. It provides essential information that researchers and stakeholders can review to understand how the study was managed and any relevant observations that emerged during monitoring. This is particularly important for ensuring transparency and accountability in clinical research, as it allows for evaluation of the study's integrity and compliance with regulatory expectations. In contrast, while the other documents may play various roles in the clinical trial process, they do not specifically encapsulate the monitoring findings of a closed trial. The Final Report typically summarizes the overall results and conclusions of the study rather than the monitoring aspects. The Monitoring Report generally outlines ongoing monitoring activities and findings during the study, so it would not reflect the overall insights after closure. Meanwhile, the Study Protocol lays out the plan for the study prior to initiation, including objectives, design, and methodology, but does not encompass the findings from the monitoring conducted

## 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://acrp-cp.examzify.com>**

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

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