SOCRA CCRP PRACTICE EXAM (SAMPLE)

STUDY GUIDE



SAMPLE STUDY GUIDE WITH LIMITED QUESTIONS

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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.

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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!

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Questions

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1. **Within how many days does an IRB have to report a change in registration information due to a change in chairperson or contact?**

   A. 30 days

   B. 60 days

   C. 90 days

   D. 120 days

2. **What requirements must be met to conduct research with pregnant women/fetuses?**

   A. Risk is least possible, Consent obtained, No inducements offered to terminate pregnancy

   B. Participants must be over 18 years of age, Consent from a legal guardian, Participants must have a high school diploma

   C. Research must be conducted by licensed physicians only, Participants must receive financial compensation, Research must not last longer than 3 months

   D. Only non-invasive procedures are permitted, Participants must be screened for allergies, All participants must reside in the same geographic location

3. **Who must sign the short form consent and summary?**

   A. Just the subject/LAR

   B. Both the subject/LAR and witness

   C. Only the witness

   D. Only the investigator

4. **How many days does an IRB have to inform the FDA that it is reviewing different types of FDA-regulated products?**

   A. 15 days

   B. 30 days

   C. 45 days

   D. 60 days

5. **What additional controls are Class II devices subject to beyond those for Class I?**

   A. Premarket approval

   B. Special controls

   C. Clinical trials

   D. Advanced performance standards

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6. Who ultimately approves an ICF?

A. FDA

B. Sponsor

C. IRB

D. Principal Investigator

7. What does Source Data Verification aim to confirm?

A. Patient satisfaction

B. Data accuracy by comparing CRF or other instruments to original source

C. The effectiveness of the consent process

D. That all patients have been debriefed

8. What action should the person obtaining consent do in the short form consent process?

A. Sign the long form consent

B. Give a verbal summary only

C. Sign the summary

D. Recite the IRB guidelines

9. What are an investigator's responsibilities regarding safety reports for drug studies?

A. Report SAEs immediately, Record and report non-serious AEs, Report SAEs to IRB

B. Ensure IRB compliance, Develop ICFs, Submit protocol changes

C. Conduct study per investigational plan, Protect subjects, Obtain informed consent

D. Conduct according to current protocol, Train staff, Maintain adequate records

10. Whose responsibility is it to ensure investigators and staff are trained?

A. Sponsors

B. Principal Investigator

C. CTM or CRA

D. FDA

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Answers

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

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Explanations

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1. Within how many days does an IRB have to report a change in registration information due to a change in chairperson or contact?

A. 30 days

B. 60 days

C. 90 days

D. 120 days

An Institutional Review Board (IRB) must report any changes in registration information due to a change in chairperson or contact within 90 days. Options A, B, and D are incorrect because they provide shorter or longer time frames, which would not allow the IRB enough time to properly report the change. Option A (30 days) is too short of a time frame, and options B (60 days) and D (120 days) are too long. Therefore, the correct answer is C (90 days).

2. What requirements must be met to conduct research with pregnant women/fetuses?

A. Risk is least possible, Consent obtained, No inducements offered to terminate pregnancy

B. Participants must be over 18 years of age, Consent from a legal guardian, Participants must have a high school diploma

C. Research must be conducted by licensed physicians only, Participants must receive financial compensation, Research must not last longer than 3 months

D. Only non-invasive procedures are permitted, Participants must be screened for allergies, All participants must reside in the same geographic location

To conduct research with pregnant women/fetuses, it is important to meet certain requirements to ensure the safety and well-being of these vulnerable populations. Option A is the correct answer because it outlines three key requirements that must be met. First, the research must pose the least possible risk to the pregnant woman and the fetus. This means that steps must be taken to minimize any potential harm that could come from participating in the research study. Second, researchers must obtain consent from the pregnant woman before she can participate in the study. This is to ensure that she fully understands the potential risks and benefits and voluntarily agrees to participate. Third, researchers must not offer any inducements to the pregnant woman to terminate her pregnancy. This is to ensure that there is no pressure or coercion for the woman to end her pregnancy in order to participate in the study. Options B, C, and D are incorrect because

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3. Who must sign the short form consent and summary?

A. Just the subject/LAR

B. Both the subject/LAR and witness

C. Only the witness

D. Only the investigator

The requirement for both the subject or legally authorized representative (LAR) and a witness to sign the short form consent and summary is rooted in the ethical principles and regulatory guidelines governing informed consent in clinical research. Informed consent is a cornerstone of ethical research practices, ensuring that participants are adequately informed about the study and provide voluntary consent. The presence of both signatures serves several important purposes. Firstly, it verifies that the subject or LAR has received and understood the information conveyed in the short form, which summarizes the key elements of the study in a clear and concise manner. This is crucial for ensuring that subjects are fully informed about what their participation entails. Secondly, having a witness sign the document attests to the fact that the consent process was conducted properly and ethically. The witness can confirm that the subject or LAR had the opportunity to ask questions and that their consent was given freely without coercion. This two-signature requirement enhances the integrity of the informed consent process and helps to protect the rights of participants, ensuring they are not only informed but also that their consent is appropriately documented and acknowledged within the study.

4. How many days does an IRB have to inform the FDA that it is reviewing different types of FDA-regulated products?

A. 15 days

B. 30 days

C. 45 days

D. 60 days

An IRB (Institutional Review Board) is a committee that is responsible for reviewing and approving research involving human subjects. In this case, the question is asking how many days an IRB has to inform the FDA (Food and Drug Administration) when they are reviewing different types of FDA-regulated products. The answer is 30 days. This is the required timeframe according to the federal regulations for IRBs (45 CFR 56.108) which state that IRBs must notify the FDA within 30 days of reviewing a product for the first time. Option A (15 days) is incorrect because it does not align with the federal regulations. Option C and D (45 and 60 days) are also incorrect as they are outside of the required 30 day timeframe.

5. What additional controls are Class II devices subject to beyond those for Class I?

A. Premarket approval

B. Special controls

C. Clinical trials

D. Advanced performance standards

Class II devices are defined as medium-risk devices that require special controls in addition to the general controls required for Class I devices. These special controls may include performance standards, post-market surveillance, patient registries, and other measures to ensure the safety and effectiveness of the device. Therefore, options A, C, and D would not be additional controls for Class II devices as they may already fall under the category of general controls for Class I devices. In contrast, special controls are specifically required for Class II devices to ensure their safety and efficacy.

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6. Who ultimately approves an ICF?

A. FDA

B. Sponsor

C. IRB

D. Principal Investigator

An ICF, or Informed Consent Form, is an important document used in the clinical trial process. It outlines the important information that a participant needs to know before deciding to participate in a clinical trial, including potential risks and benefits. Ultimately, the party responsible for approving the ICF is the IRB, or Institutional Review Board. The FDA, or Food and Drug Administration, oversees the entire clinical trial process, but they do not have direct involvement in approving the ICF. The sponsor of the clinical trial may also be involved in reviewing and approving the ICF, but their role is primarily to provide the necessary resources and funding for the trial. The principal investigator is responsible for conducting the trial and obtaining informed consent from participants, but they are not the ultimate authority for approving the ICF. Therefore, the correct answer is C IRB.

7. What does Source Data Verification aim to confirm?

A. Patient satisfaction

B. Data accuracy by comparing CRF or other instruments to original source

C. The effectiveness of the consent process

D. That all patients have been debriefed

Source Data Verification (SDV) is an important process in clinical research that aims to confirm the accuracy of data collected in the clinical study. By comparing the data collected in Consecutive Review Forms (CRFs) or other instruments to the original source, this verification process ensures that there are no discrepancies or errors in the data. This is crucial for maintaining the integrity and validity of the study results. Option A is incorrect because patient satisfaction is not the main focus of SDV. Similarly, option C and D are incorrect because they do not pertain to the verification of data accuracy.

8. What action should the person obtaining consent do in the short form consent process?

A. Sign the long form consent

B. Give a verbal summary only

C. Sign the summary

D. Recite the IRB guidelines

In the short form consent process, the written record that documents consent is the summary itself. When a participant does not speak English, an IRB-approved short form in the participant's language is used along with a translation of the information read aloud. The person obtaining consent must sign that short form summary to certify that the essential information was conveyed and that consent was obtained. This signature provides the written documentation of the consent event, often with a witness or translator signing as well. Signing the long form isn't required in this scenario, and a verbal summary alone wouldn't create the proper written record, while reciting IRB guidelines doesn't document consent.

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9. What are an investigator's responsibilities regarding safety reports for drug studies?

A. Report SAEs immediately, Record and report non-serious AEs, Report SAEs to IRB

B. Ensure IRB compliance, Develop ICFs, Submit protocol changes

C. Conduct study per investigational plan, Protect subjects, Obtain informed consent

D. Conduct according to current protocol, Train staff, Maintain adequate records

An investigator's responsibilities regarding safety reports for drug studies include reporting Serious Adverse Events (SAEs) immediately, recording and reporting non-serious Adverse Events (AEs), and reporting SAEs to the Institutional Review Board (IRB). Option B is incorrect because it does not mention the specific responsibilities regarding safety reports. Option C is incorrect because it focuses on the overall responsibilities of an investigator in a drug study, rather than specifically addressing safety reports. Option D is incorrect because it does not mention the reporting of SAEs to the IRB, which is a crucial responsibility. Therefore, A is the most accurate and comprehensive answer.

10. Whose responsibility is it to ensure investigators and staff are trained?

A. Sponsors

B. Principal Investigator

C. CTM or CRA

D. FDA

The responsibility for ensuring that investigators and staff are properly trained ultimately lies with the Principal Investigator (PI). The PI is accountable for the overall conduct of the clinical trial, including the adherence to protocols and regulations. Proper training is crucial for the successful execution of a study, as it ensures that all team members understand their roles, the study protocols, the ethical considerations, and regulatory requirements. The PI must ensure that all staff involved in the trial possess the necessary knowledge and skills to carry out their responsibilities, which may include training on Good Clinical Practice (GCP), study-specific protocols, and safety procedures. Therefore, the PI plays a central role in establishing a competent and well-informed team, ensuring that all aspects of the study are conducted adhering to applicable standards and regulations. While sponsors and other entities may provide resources and support for training, it is ultimately the PI's duty to verify that their team is adequately trained to ensure patient safety and data integrity throughout the study.

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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://ccrpsocraexam.examzify.com

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

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