

CITI HUMAN SUBJECTS RESEARCH CERTIFICATION PRACTICE TEST (SAMPLE) STUDY GUIDE



SAMPLE STUDY GUIDE WITH LIMITED QUESTIONS

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THE FULL VERSION STUDY GUIDE**

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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. When adding an adolescent population to a study initially involving adults, which statement is correct regarding the protocol review?**
 - A. Only expedited review is possible if adolescents understand adult consent forms
 - B. Full review by a convened IRB would be necessary
 - C. Only expedited review if adolescents are emancipated minors
 - D. Expedited review is possible unless risk levels are elevated for adolescents

- 2. Which situation is an example of an institutional conflict of interest?**
 - A. The organization's president is a board member for a non-profit not sponsoring research
 - B. The organization gives scholarships to some post-doctoral researchers
 - C. One of the organization's deans is the vice-chair of the IRB
 - D. An industry sponsor funds construction of a new research laboratory at the organization

- 3. Which action would constitute both a breach of confidentiality and a violation of subjects' privacy?**
 - A. A faculty member disclosing identifiable sexual behavior data
 - B. A researcher observing without informing participants
 - C. A researcher soliciting names of other cocaine users
 - D. A researcher recording conversations at dinner parties without consent

- 4. What is a medical record classified as?**
 - A. Public behavior
 - B. Private behavior
 - C. Public information
 - D. Private information

- 5. What is defined as an adverse event in clinical research?**
 - A. A participant's withdrawal from a study
 - B. An unexpected reaction to a placebo
 - C. An undesirable experience related to a medical product
 - D. A breach of confidentiality in a study

- 6. What is a recommended confidentiality procedure in a longitudinal study collecting information about illegal activities?**
- A. Using data encryption for stored files
 - B. Securing a Certificate of Confidentiality
 - C. Using pseudonyms in research reports
 - D. Waiving documentation of consent
- 7. Which ethical principle relates to treating individuals with respect and allowing them to make informed choices?**
- A. Justice
 - B. Integrity
 - C. Beneficence
 - D. Respect for persons
- 8. In studies involving children, what aspect must always be prioritized in the consent process?**
- A. Parents must be notified of all potential study risks.
 - B. Children's cognitive ability to understand their role in the research.
 - C. Affluent families should not receive preferential treatment.
 - D. Special attention must be given to subjects from multiple backgrounds.
- 9. How can researchers enhance participant recruitment in studies?**
- A. By advertising heavily on social media
 - B. By fostering trust and understanding within diverse communities
 - C. By ensuring that all studies are paid
 - D. By minimizing communication with participants
- 10. What is the primary purpose of the Belmont Report?**
- A. To provide legal regulations for research
 - B. To outline ethical principles and guidelines for research involving human subjects
 - C. To promote financial transparency in research projects
 - D. To establish unique identification for human research participants

Answers

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

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Explanations

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1. When adding an adolescent population to a study initially involving adults, which statement is correct regarding the protocol review?

- A. Only expedited review is possible if adolescents understand adult consent forms
- B. Full review by a convened IRB would be necessary
- C. Only expedited review if adolescents are emancipated minors

D. Expedited review is possible unless risk levels are elevated for adolescents

The correct statement regarding the protocol review when adding an adolescent population to a study initially involving adults is that expedited review is possible unless risk levels are elevated for adolescents. In the context of human subjects research, when a study is modified to include a more vulnerable population, such as adolescents, the risk level associated with that population is a critical factor in determining the type of IRB review required. If the research poses minimal risk to the adolescents and complies with the guidelines outlined for expedited review by the Institutional Review Board (IRB), then researchers may proceed with an expedited review. Expedited review is designed to facilitate faster approval for studies that involve minimal risk, making it a suitable option in many cases involving adolescents, as long as the level of risk does not exceed what is deemed acceptable. In contrast, if the research presents elevated risks or if the protocols for obtaining consent or assent do not adequately protect the adolescents' rights and welfare, then a full review by a convened IRB would be mandated to ensure comprehensive oversight and ethical integrity in research. This review process further guarantees that the research meets the necessary ethical standards for protecting vulnerable populations.

2. Which situation is an example of an institutional conflict of interest?

- A. The organization's president is a board member for a non-profit not sponsoring research
- B. The organization gives scholarships to some post-doctoral researchers
- C. One of the organization's deans is the vice-chair of the IRB

D. An industry sponsor funds construction of a new research laboratory at the organization

An institutional conflict of interest arises when an organization has financial or other interests that might compromise the integrity of its research or the welfare of its research subjects. In this case, when an industry sponsor provides funding for the construction of a new research laboratory, it can create an obligation or bias that may influence the research agenda, priorities, or the results obtained within that laboratory. Such a situation raises concerns about whether the organization might favor the sponsor's interests over the scientific integrity or ethical considerations of research involving human subjects. This could affect the impartiality of research outcomes or lead to decisions that prioritize the sponsor's needs rather than the welfare of participants or the quality of the research being conducted. By contrast, the other options do not present clear institutional conflicts of interest. For instance, a president serving on a board of a non-profit not sponsoring research would not inherently cause a conflict related to the organization's research activities. Scholarships given to post-doctoral researchers may support academic growth without compromising research integrity, and having a dean serve as vice-chair of the Institutional Review Board (IRB) could actually support oversight rather than conflict.

3. Which action would constitute both a breach of confidentiality and a violation of subjects' privacy?

- A. A faculty member disclosing identifiable sexual behavior data**
- B. A researcher observing without informing participants
- C. A researcher soliciting names of other cocaine users
- D. A researcher recording conversations at dinner parties without consent

The action that constitutes both a breach of confidentiality and a violation of subjects' privacy is disclosing identifiable sexual behavior data. Confidentiality refers to the obligation of researchers to protect the information provided by research participants, ensuring that their identities and information are kept secure. In the case of disclosing identifiable sexual behavior data, the researcher is revealing specific and sensitive information that can directly link back to an individual, thereby violating the promise of confidentiality and exposing that individual's private life. In addition to breaching confidentiality, this action also violates privacy because individuals have a reasonable expectation that sensitive information regarding their sexual behavior will not be shared without their explicit consent. Respecting this expectation is crucial in maintaining the trust between researchers and participants, which is a foundational element of ethical research practices. While other actions may involve ethical concerns, they do not necessarily encompass both breaches of confidentiality and violations of privacy to the same extent. For example, simply observing without informing participants may raise ethical issues regarding informed consent, but it does not directly involve disclosing sensitive information. Similarly, soliciting names or recording conversations without consent also has ethical implications, but the level of sensitivity and direct impact on privacy and confidentiality is more pronounced in the disclosure of identifiable sexual behavior data.

4. What is a medical record classified as?

- A. Public behavior
- B. Private behavior
- C. Public information
- D. Private information**

A medical record is classified as private information because it contains sensitive and personal health data about an individual. This information is protected by laws and regulations, like the Health Insurance Portability and Accountability Act (HIPAA) in the United States, which establishes standards for the privacy and security of health information. Medical records include details such as medical history, diagnoses, treatment plans, and other confidential health-related information that must be kept private to respect patient confidentiality and autonomy. The classification as private information emphasizes the need for proper consent and ethical considerations when handling such records in research or other contexts. This ensures that the rights of individuals to control their personal information are upheld and that their privacy is maintained, particularly in research settings where data may be shared or analyzed.

5. What is defined as an adverse event in clinical research?

- A. A participant's withdrawal from a study
- B. An unexpected reaction to a placebo
- C. An undesirable experience related to a medical product**
- D. A breach of confidentiality in a study

An adverse event in clinical research refers to any undesirable experience that a participant may have during the course of a study that is related to a medical product, such as a drug or device. This definition encompasses a wide range of negative outcomes, from mild side effects to severe reactions, and helps researchers assess the safety and efficacy of the investigational product. In the context of clinical trials, it is crucial to monitor and report these events to ensure participant safety and regulatory compliance. By identifying and documenting adverse events, researchers can better understand the risks associated with the intervention being studied and take necessary actions to protect participants. The other options represent different concepts: a participant's withdrawal from a study pertains to their decision to leave the trial, which may occur for various reasons but is not classified as an adverse event. An unexpected reaction to a placebo is noteworthy, but it doesn't involve the experimental drug or intervention itself and doesn't generally qualify as an adverse event in the context of the primary treatment being studied. A breach of confidentiality is a serious matter concerning data privacy and participant rights, but it does not relate to the clinical effects or experiences associated with the medical product in question.

6. What is a recommended confidentiality procedure in a longitudinal study collecting information about illegal activities?

- A. Using data encryption for stored files
- B. Securing a Certificate of Confidentiality**
- C. Using pseudonyms in research reports
- D. Waiving documentation of consent

In the context of a longitudinal study that involves collecting sensitive information about illegal activities, securing a Certificate of Confidentiality is particularly crucial. This certificate provides legal protection to researchers regarding the confidentiality of sensitive data, ensuring that the information cannot be disclosed in legal proceedings or to unauthorized parties. This protection is especially necessary when dealing with illegal activities, as participants may be more willing to provide honest information if they believe their identities and disclosures will remain confidential under legal standards. The other options, while they may enhance data security or confidentiality in other types of research, do not provide the same level of legal protection offered by a Certificate of Confidentiality. Data encryption is useful for protecting stored files from unauthorized access, but it does not prevent compelled disclosure in legal contexts. Using pseudonyms can help protect identities in reports but does not offer the same legal backing against compelled disclosure. Waiving documentation of consent is not a confidentiality measure; it relates to the ethical consideration of informed consent and does not address the confidentiality of the sensitive information being collected. Thus, securing a Certificate of Confidentiality is the most recommended procedure to safeguard the privacy of participants in this specific research scenario.

7. Which ethical principle relates to treating individuals with respect and allowing them to make informed choices?

- A. Justice
- B. Integrity
- C. Beneficence

D. Respect for persons

The principle that relates to treating individuals with respect and allowing them to make informed choices is known as "Respect for persons." This ethical principle emphasizes the importance of recognizing the autonomy and dignity of each individual. It involves acknowledging a person's right to make decisions about their own life and participating in research voluntarily. Respect for persons also includes ensuring that individuals are provided with all the necessary information in a comprehensible manner, enabling them to make informed choices about their participation in research. This principle is foundational in research ethics, as it reinforces the significance of informed consent, where participants are not only informed about the nature of the study but also understand the potential risks and benefits involved. It establishes the expectation that researchers will engage with participants in a manner that honors their personal values, preferences, and decision-making rights.

8. In studies involving children, what aspect must always be prioritized in the consent process?

- A. Parents must be notified of all potential study risks.
- B. Children's cognitive ability to understand their role in the research.**
- C. Affluent families should not receive preferential treatment.
- D. Special attention must be given to subjects from multiple backgrounds.

In studies involving children, the consent process must prioritize the cognitive ability of the children to understand their role in the research. This is essential because informed consent is not solely about obtaining permission from a parent or guardian; it also involves ensuring that the child comprehends the nature of the study, what it will entail, and any risks involved. Children have varying levels of cognitive development, and it is crucial that their capacity to understand and make a voluntary choice regarding participation is assessed and respected. Ensuring that children can make informed decisions helps to protect their rights and welfare as research participants. The other options, while relevant to ethical considerations in research involving children, do not focus on the fundamental aspect of informed consent that directly ties to the child's involvement. Notifying parents about potential study risks is important, but it does not address the child's ability to understand the study. Similarly, notions of preferential treatment based on socioeconomic status and the need for diverse representation are significant in promoting equity in research, yet they do not capture the essence of informed consent from the child's perspective. Thus, the main focus in the consent process for children must always be on their cognitive understanding and capacity to engage in the research process.

9. How can researchers enhance participant recruitment in studies?

- A. By advertising heavily on social media
- B. By fostering trust and understanding within diverse communities**
- C. By ensuring that all studies are paid
- D. By minimizing communication with participants

Fostering trust and understanding within diverse communities is an effective strategy for enhancing participant recruitment in studies because it builds rapport and encourages engagement from potential participants. When researchers take the time to understand the unique cultural, social, and historical contexts of diverse communities, they can design recruitment strategies that resonate with those individuals. This approach also highlights the importance of respecting community values and practices, which can lead to participants feeling more valued and secure in their involvement. Establishing trust is crucial in research involving human subjects, particularly in communities that may have had negative experiences with research in the past. By demonstrating a genuine commitment to the well-being of the community and openly communicating the goals and potential benefits of the research, researchers can improve the likelihood of participants agreeing to join the study. While advertising heavily on social media may reach a broader audience, it may not necessarily connect with specific communities in the same meaningful way. Offering compensation can motivate some individuals to participate, but it does not address the key issue of trust and understanding for sustainable engagement. Finally, minimizing communication with participants can harm the recruitment effort, as it may lead to misunderstandings or feelings of neglect, further distancing the community from the research initiative.

10. What is the primary purpose of the Belmont Report?

- A. To provide legal regulations for research
- B. To outline ethical principles and guidelines for research involving human subjects**
- C. To promote financial transparency in research projects
- D. To establish unique identification for human research participants

The Belmont Report plays a crucial role in the field of research involving human subjects by outlining ethical principles and guidelines that govern such studies. Its primary purpose is to ensure the protection of human subjects by identifying fundamental ethical principles: respect for persons, beneficence, and justice. Respect for persons emphasizes the importance of informed consent and recognizing the autonomy of individuals. Beneficence focuses on maximizing benefits while minimizing harm to participants. Justice pertains to the fair distribution of the benefits and burdens of research. Together, these principles serve as the foundational ethical framework that researchers must consider when designing and conducting studies involving human subjects. The Belmont Report has significantly influenced policies and regulations surrounding ethical research practices, ensuring that the rights and welfare of participants are prioritized. This focus on ethical considerations distinguishes it from responses that pertain to legal regulations, financial transparency, or identification of participants, which are not the primary objectives of the report.

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:

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

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