SOCRA CCRP Practice Exam (Sample)

Study Guide

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Questions

1. Which of the following is an example of a Class I device?

A. Bandages

B. X-ray machines

C. Infusion pumps

D. Physiologic monitors

2. What is required in an IRB application regarding inc/exc criteria?

A. A detailed plan for data analysis

B. Documentation of IRB meetings

C. Inclusion and exclusion criteria

D. A list of potential side effects

3. What criterion must otherwise unapprovable research involving children meet to be considered by an IRB?

A. Guaranteed to provide direct benefits to participants

B. Presents an opportunity to understand significant problems affecting children's welfare

C. Must have parental consent

D. Approved by all guardians

4. What is a consideration for maintaining documentation electronically?

A. Social media integration

B. IRB records should be secure

C. Unlimited access

D. Decorative themes

5. What is a requirement for IRB approval of research in children with more than minimal risk and no prospect of direct benefit?

A. High risk, high reward

B. Risk must be a minor increase over minimal

C. Children must receive some form of compensation

D. Parental consent is enough for approval

6. Which of the following is part of the CAPA process?

- **A. Recruitment of new trial participants**
- **B. Data mining for statistical significance**
- **C. Identification of root cause of issues**
- **D. Publishing of trial results**

7. What is an open system characterized by?

- **A. Encryption of all documents**
- **B. Access not controlled by overseers of content**
- **C. Access only via biometric scanning**
- **D. Use exclusively in government facilities**

8. What must happen to the advocate's role once a child ward's participation in a study concludes?

- **A. Continue to monitor the child's welfare**
- **B. Become the child's legal guardian**
- **C. Their role ends with the study**
- **D. Report findings to the federal government**

9. What is the first component of a Quality System?

- **A. Training**
- **B. Policies/procedures**
- **C. Personnel roles/responsibilities**
- **D. Document management, record retention, reporting**

10. 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**

Answers

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

Explanations

1. Which of the following is an example of a Class I device?

A. Bandages

B. X-ray machines

C. Infusion pumps

D. Physiologic monitors

Context A Class I device is a medical device with minimal potential for harm to the patient, often used to support or sustain life, or used in a non-invasive manner. B, C, and D are all examples of Class II and Class III devices, as they have a higher potential for harm to the patient and involve more invasive methods. X-ray machines use radiation, infusion pumps directly deliver medication into the body, and physiologic monitors often involve invasive procedures such as inserting probes or sensors into the body. These devices require more regulation and oversight to ensure patient safety. Bandages, on the other hand, are considered Class I devices because they are non-invasive and have minimal potential for harm. They are used to cover and protect wounds or support injured limbs, but do not directly interact with the body. Therefore, they are subject to less regulation and oversight compared to

2. What is required in an IRB application regarding inc/exc criteria?

A. A detailed plan for data analysis

B. Documentation of IRB meetings

C. Inclusion and exclusion criteria

D. A list of potential side effects

Inclusion and exclusion criteria are essential components of an IRB (Institutional Review Board) application because they define the specific characteristics that determine who can and cannot participate in a clinical trial. These criteria help ensure that the study population is appropriate for the research question being investigated and that the safety and welfare of participants are adequately protected. By providing clear inclusion and exclusion criteria, researchers can ensure that they are recruiting a representative sample, minimize potential risks, and enhance the validity of the study's findings. This helps IRBs evaluate whether the study design is ethical and whether the potential benefits of the research outweigh any risks to participants. The other aspects of the question, such as a detailed plan for data analysis, documentation of IRB meetings, or a list of potential side effects, while relevant to the broader context of a research study, do not directly address the foundational requirements for participant selection and protection, which inclusion and exclusion criteria specifically pertain to.

3. What criterion must otherwise unapprovable research involving children meet to be considered by an IRB?

A. Guaranteed to provide direct benefits to participants

B. Presents an opportunity to understand significant problems affecting children's welfare

C. Must have parental consent

D. Approved by all guardians

To be considered by an IRB, research involving children must meet the criterion of presenting an opportunity to understand significant problems affecting children's welfare. This is because the primary concern of IRBs when reviewing research involving children is the protection of their welfare and rights. This option is correct because it ensures that the research will be of benefit to children and will contribute to their well-being. Options A and C are not sufficient criteria on their own, as direct benefits to participants may not always outweigh any potential risks, and parental consent does not guarantee the ethical conduct of the research. Option D does not specify the need for approval from all guardians, which could potentially compromise the rights and welfare of the child. Therefore, option B is the most appropriate criterion for otherwise unapprovable research involving children to be considered by an IRB.

4. What is a consideration for maintaining documentation electronically?

A. Social media integration

B. IRB records should be secure

C. Unlimited access

D. Decorative themes

One important factor to consider when maintaining documentation electronically is the security of the records. IRB records often contain sensitive information and need to be protected from unauthorized access. While social media integration and unlimited access may seem convenient, they do not address the security and confidentiality concerns associated with maintaining documentation. Decorative themes, on the other hand, are not directly related to the main purpose of documentation and should not be a top priority when considering electronic documentation. Therefore, the most significant consideration for maintaining documentation electronically is ensuring the security and confidentiality of the records.

5. What is a requirement for IRB approval of research in children with more than minimal risk and no prospect of direct benefit?

A. High risk, high reward

B. Risk must be a minor increase over minimal

C. Children must receive some form of compensation

D. Parental consent is enough for approval

Research with children requires special precautions as they are considered a vulnerable population. IRB approval is necessary for research involving children who are at more than minimal risk with no prospect of direct benefit. This ensures that the potential risks to participants are carefully evaluated and minimized to the greatest extent possible. Option A is incorrect because high reward is not a requirement for IRB approval and may introduce undue influence on the children. Option C is incorrect because compensation is not a requirement for IRB approval and may also introduce undue influence. Option D is incorrect because parental consent alone is not enough for approval, as children are considered a separate and protected population with specific requirements for research involving them. Option B is the correct answer, as it emphasizes the importance of keeping risks minimal and carefully evaluating them to protect the well-being of child participants.

6. Which of the following is part of the CAPA process?

A. Recruitment of new trial participants

B. Data mining for statistical significance

C. Identification of root cause of issues

D. Publishing of trial results

The CAPA process (Corrective and Preventive Action) is a systematic approach to identifying, investigating, and addressing issues or non-conformities within a system or process. This process involves identifying the root cause of the issue, implementing corrective and preventive actions, and verifying their effectiveness. In this case, options A and D are incorrect because they do not involve addressing issues or non-conformities. Option B is incorrect because data mining is not a part of the CAPA process. Only option C, identification of root cause of issues, aligns with the definition and purpose of the CAPA process.

7. What is an open system characterized by?

A. Encryption of all documents

B. Access not controlled by overseers of content

C. Access only via biometric scanning

D. Use exclusively in government facilities

An open system is one in which the access is not controlled by overseers of content. This means that anyone with proper authorization can access the system, instead of just a select group. Options A, C, and D are all features that may be found in different types of systems, but they do not fully define an open system. Option A, encryption of all documents, is a security measure used in many systems to protect sensitive information. Option C, access only via biometric scanning, is a security measure that verifies the identity of the user before granting access. Option D, use exclusively in government facilities, restricts the use of the system to certain locations, but it does not define the type of access or control.

8. What must happen to the advocate's role once a child ward's participation in a study concludes?

A. Continue to monitor the child's welfare

B. Become the child's legal guardian

C. Their role ends with the study

D. Report findings to the federal government

Once a child ward's participation in a study concludes, the advocate's role also concludes. This is because the advocate was assigned specifically to oversee the child's welfare and rights during the study period, and their involvement is no longer needed once the study is completed. Continuing to monitor the child's welfare (option A) would not be necessary as the study is over and any necessary follow-up would be the responsibility of the study team. Becoming the child's legal guardian (option B) is not a necessary or appropriate role for the advocate, as the child likely already has a legal guardian in place and the advocate's role is to ensure the child's rights are protected during the study. Reporting findings to the federal government (option D) may be required for the study, but it is not the advocate's role to do so.

9. What is the first component of a Quality System?

A. Training

B. Policies/procedures

C. Personnel roles/responsibilities

D. Document management, record retention, reporting

Personnel roles/responsibilities are the first component of a Quality System because it establishes the roles and responsibilities of individuals within an organization in performing quality activities. This is important because it ensures that everyone is aware of their responsibilities and can contribute to maintaining and improving the quality of the organization's products or services. The other options may be important components of a Quality System, but they are not the first component. For example, training is necessary for employees to understand quality processes, but without clearly defined roles and responsibilities, their training may not be effectively utilized. Policies/procedures and document management are also important, but they come after establishing personnel roles and responsibilities.

10. 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