SOCRA CCRP Practice Exam (Sample)

Study Guide

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Questions

1. What is not part of the ICH guidelines for maintaining essential study documents?

- **A. Organize into sections and file chronologically**
- **B. Store in a warm and humid environment**
- **C. Explain missing documents or documents at another location**
- **D. Avoid duplicate filing**

2. One of the scenarios that require financial disclosure is when there is:

- **A. A proprietary interest by the PI in the tested product.**
- **B. Government funding for the study.**
- **C. Use of over-the-counter medications.**
- **D. Testing of generic products.**

3. How does a sponsor ensure proper monitoring of the investigation?

- **A. By conducting periodic audits**
- **B. By hiring a study monitor**
- **C. Through daily meetings with the investigators**
- **D. By using trial management software**

4. FDA Form 3455 is used for what?

- **A. Certification of no financial interest by investigators**
- **B. Disclosure of financial interests by clinical investigators**
- **C. Application for drug testing in humans**
- **D. Emergency use authorization of investigational drugs**

5. When is father's consent not required for research involving neonates?

- **A. When there is prospect of benefit to mom, When dad unavailable, incompetent or temporarily incapacitated, Rape/incest**
- **B. Only if the mother gives consent, If the research is conducted in a hospital, If the neonate is not the biological child of the dad**
- **C. If the father is not a citizen of the country in which the research is being conducted, If the research does not require any form of sedation, When the mother decides it is not necessary**
- **D. If the father has not been involved in the pregnancy, If the research is purely observational, If the neonate has already been involved in other research**

6. What is the definition of a serious adverse event (SAE)?

- **A. An event that requires a simple medical treatment**
- **B. Any untoward occurrence that results in death, life-threatening situation, requires hospitalization or prolongation of hospitalization, results in significant disability, or a congenital abnormality/birth defect**
- **C. A minor side effect that does not require hospitalization**
- **D. An adverse event that can be treated with over-the-counter medication**

7. Which of the following is NOT one of the criteria for IRB approval of research?

- **A. Informed consent will not be documented**
- **B. Risks to subjects are minimized**
- **C. Selection of subjects is equitable**
- **D. There is adequate provision of monitoring**

8. What are historical controls?

- **A. Data from previous trials on the same disease**
- **B. Data from the general population**
- **C. Data from similar patients or the same patient in a crossover study**
- **D. Data from animal studies**

9. For device trials, to whom must sponsors submit semi-annual progress reports in addition to the annual report under a treatment IDE?

- **A. To all reviewing IRBs and FDA**
- **B. To the principal investigator only**
- **C. To the ethics committee only**
- **D. To the department of health**

10. What must a sponsor do if the FDA requests more information about an IND safety report for drug studies?

- **A. Respond within 7 days**
- **B. Respond no more than 15 calendar days from receipt of request**
- **C. Ignore the request as it's optional**
- **D. Request an extension**

Answers

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

Explanations

1. What is not part of the ICH guidelines for maintaining essential study documents?

A. Organize into sections and file chronologically

B. Store in a warm and humid environment

C. Explain missing documents or documents at another location

D. Avoid duplicate filing

The ICH guidelines emphasize the importance of organizing documents into sections and filing them chronologically, as this makes it easier to access relevant information during an audit or inspection. The guidelines also stress the importance of avoiding duplicate filing, as this can cause confusion and potentially lead to the wrong version of a document being used. Furthermore, the guidelines encourage properly explaining any missing documents or documents that are located in a different location, as this helps maintain transparency and accuracy in the study. However, storing documents in a warm and humid environment can damage the integrity of the documents and render them unreadable, making it an incorrect option according to the ICH guidelines.

2. One of the scenarios that require financial disclosure is when there is:

A. A proprietary interest by the PI in the tested product.

B. Government funding for the study.

C. Use of over-the-counter medications.

D. Testing of generic products.

A proprietary interest refers to a financial stake or ownership in a product or company. It is important for financial disclosure to occur in this scenario because the researcher may have a bias towards the product being tested, potentially leading to biased results. B, C, and D are incorrect because they do not involve a direct financial interest in the product being tested. While government funding and use of over-the-counter medications may have implications for financial disclosure in other contexts, in regards to this question, they are not the correct answer because they do not directly involve a proprietary interest in the tested product.

3. How does a sponsor ensure proper monitoring of the investigation?

A. By conducting periodic audits

B. By hiring a study monitor

C. Through daily meetings with the investigators

D. By using trial management software

A Periodic audits are necessary for ensuring that a study is conducted properly, but they do not specifically address the monitoring of an investigation. C: Daily meetings with investigators can be beneficial for communication and updates, but they do not provide a comprehensive monitoring process. D: Trial management software can aid in the organization and management of an investigation, but it does not replace the need for a dedicated study monitor. The best way for a sponsor to ensure proper monitoring of an investigation is to hire a study monitor who is specifically trained and responsible for monitoring the study process and ensuring compliance with protocols and regulations. This individual will have the expertise and knowledge to identify and address potential issues proactively, ensuring the integrity and success of the investigation.

4. FDA Form 3455 is used for what?

A. Certification of no financial interest by investigators

B. Disclosure of financial interests by clinical investigators

C. Application for drug testing in humans

D. Emergency use authorization of investigational drugs

FDA Form 3455 is used to disclose financial interests by clinical investigators when conducting clinical trials. Option A is not correct because it refers to a different form, FDA Form 3454, which is used to certify that the investigators have no financial interests. Option C is incorrect because FDA Form 3455 is not used for drug testing in humans, but rather for the disclosure of financial interests. Option D is also incorrect as it pertains to a different form, FDA Form 1572, which is used for emergency use authorization of investigational drugs. It is important for clinical investigators to disclose their financial interests to avoid any potential conflicts of interest.

5. When is father's consent not required for research involving neonates?

A. When there is prospect of benefit to mom, When dad unavailable, incompetent or temporarily incapacitated, Rape/incest

B. Only if the mother gives consent, If the research is conducted in a hospital, If the neonate is not the biological child of the dad

C. If the father is not a citizen of the country in which the research is being conducted, If the research does not require any form of sedation, When the mother decides it is not necessary

D. If the father has not been involved in the pregnancy, If the research is purely observational, If the neonate has already been involved in other research

Father's consent is not required for research involving neonates when there is prospect of benefit to the mother, or when the father is unavailable, incompetent, or temporarily incapacitated. Option B is not correct because the research must still obtain consent from the father even if the mother gives consent. Option C is also not correct because citizenship and sedation are not relevant factors in determining if father's consent is necessary. Option D is incorrect because whether the father has been involved in the pregnancy or not does not determine the need for his consent, and whether the research is observational or not does not impact the requirement for father's consent.

6. What is the definition of a serious adverse event (SAE)?

A. An event that requires a simple medical treatment

B. Any untoward occurrence that results in death, life-threatening situation, requires hospitalization or prolongation of hospitalization, results in significant disability, or a congenital abnormality/birth defect

C. A minor side effect that does not require hospitalization

D. An adverse event that can be treated with over-the-counter medication

A serious adverse event (SAE) is an untoward occurrence that can have significant consequences, such as death, a life-threatening situation, hospitalization or prolonged stay in a hospital, or a significant disability. This means that options A, C and D are incorrect because they do not meet the criteria of a serious adverse event. Option A only requires simple medical treatment, while option C only refers to minor side effects that do not require hospitalization. Option D also only mentions treatment with over-the-counter medication, which would not fall under the definition of a serious adverse event. Therefore, the correct definition of an SAE is option B.

7. Which of the following is NOT one of the criteria for IRB approval of research?

A. Informed consent will not be documented

B. Risks to subjects are minimized

C. Selection of subjects is equitable

D. There is adequate provision of monitoring

Informed consent is a crucial criteria for IRB approval of research, as it ensures that participants understand the risks and benefits associated with the study and are giving their voluntary permission to participate. Omitting the documentation of informed consent would not meet ethical standards for protecting research participants. Risks minimization, equitable selection of subjects, and adequate monitoring are all important criteria for protecting the rights and well-being of research participants.

8. What are historical controls?

A. Data from previous trials on the same disease

B. Data from the general population

C. Data from similar patients or the same patient in a crossover study

D. Data from animal studies

Historical controls refer to data from similar patients in a study or the same patient in a crossover study, while options A, B, and D refer to data from different sources that may not be as relevant or applicable to the current study. Option A specifically refers to data from previous trials on the same disease, which may have different variables and outcomes, making it difficult to compare to the current study. Option B refers to data from the general population, which may not accurately represent the specific population being studied. Option D refers to data from animal studies, which may not always translate to human results. Therefore, option C is the most accurate and relevant answer for historical controls in a study.

9. For device trials, to whom must sponsors submit semi-annual progress reports in addition to the annual report under a treatment IDE?

A. To all reviewing IRBs and FDA

B. To the principal investigator only

C. To the ethics committee only

D. To the department of health

Device sponsors must submit semi-annual progress reports in addition to the annual report to all reviewing IRBs and the FDA. This is because all regulatory bodies involved in the oversight and approval of the device trial should be kept informed of the progress and any potential issues that may arise. This level of communication and transparency is necessary to ensure the safety and ethical conduct of the trial. Neither the principal investigator only, the ethics committee only, nor the department of health are sufficient recipients for these reports, as they do not encompass the full range of regulatory entities involved.

10. What must a sponsor do if the FDA requests more information about an IND safety report for drug studies?

A. Respond within 7 days

B. Respond no more than 15 calendar days from receipt of request

C. Ignore the request as it's optional

D. Request an extension

The FDA requires sponsors to respond within 15 calendar days from receipt of a request for more information about an IND safety report for drug studies. Option A is incorrect because it states a specific time frame of 7 days, which is not in line with the FDA's regulations. Option C is incorrect because the request for more information is not optional - it is a requirement from the FDA. Option D is also incorrect because the sponsor cannot request an extension; they must respond within the specified time frame.