SOCRA CCRP Practice Exam (Sample)

Study Guide

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Questions

1. What is the first step in administering an investigational drug according to 21 CFR 312?

- **A. Administer drug only under the supervision of a sub-investigator**
- **B. Ensure all subjects have signed consent**
- **C. Administer drug only to subjects under the investigator's personal supervision**
- **D. Send all drugs back to the sponsor for approval**

2. What must sponsors provide procedures/instructions on to investigators according to ICH GCP 5.14.3?

- **A. Audit strategies**
- **B. Data management**
- **C. Handling and storage of investigational products (IP)**
- **D. Ethics submission**

3. What regulations do Non-Significant Risk studies need to adhere to?

- **A. Follow abbreviated IDE regulations, no FDA approval needed**
- **B. Must have FDA and IRB approval**
- **C. Are exempt from all regulations**
- **D. Must report to FDA prior to study start**

4. What should be included in the first section of the FDA progress report for drug studies?

- **A. Individual study information**
- **B. Summary information**
- **C. General investigational plan**
- **D. Conclusion of findings**

5. What is the role of a sub-investigator according to FDA regulations?

- **A. Leader of the investigative team**
- **B. Regulatory body member**
- **C. Individual member of the clinical investigator's team**
- **D. Sponsor's representative in a clinical trial**

6. What is a FDA Form 1571?

- **A. Statement of investigator**
- **B. Financial disclosure form**
- **C. Cover page for IND application**
- **D. Quality assurance audit form**

7. When should unused supplies of IP be returned to the sponsor or destroyed?

- **A. After every study visit**
- **B. At the end of each month**
- **C. Should investigation be terminated, suspended or completed**
- **D. Only if the IP has expired**

8. What FDA guideline lists the basic elements of informed consent?

- **A. 21 U.S.C. 355**
- **B. 21 CFR 50**
- **C. 10 CFR 20**
- **D. 45 CFR 46**

9. Which regulation dictates that investigators and staff should be adequately trained?

- **A. ICH GCP 5.14.3**
- **B. ICH GCP 5.18.4**
- **C. FDA 1572**
- **D. ICH GCP 5.1.1**

10. When can a CRF be considered a source document?

- **A. When it is submitted to the IRB**
- **B. When it is digitalized**
- **C. When it is stored in a secure location**
- **D. When CRF is signed, dated, and initialed by the person recording the information**

Answers

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

Explanations

1. What is the first step in administering an investigational drug according to 21 CFR 312?

A. Administer drug only under the supervision of a sub-investigator

B. Ensure all subjects have signed consent

C. Administer drug only to subjects under the investigator's personal supervision

D. Send all drugs back to the sponsor for approval

The first step in administering an investigational drug according to 21 CFR 312 is to ensure that the drug is only administered to subjects under the personal supervision of the investigator. This means that the investigator must be present while the drug is being administered and oversee the entire process. Option A is incorrect because while it is important for a sub-investigator to be involved in the administration, they should not be the only one supervising. Option B is incorrect because obtaining informed consent from all subjects is an important step, but it should not be the first step. Option D is incorrect because sending drugs back to the sponsor for approval would delay the administration process and is not the first step in administering an investigational drug.

2. What must sponsors provide procedures/instructions on to investigators according to ICH GCP 5.14.3?

A. Audit strategies

B. Data management

C. Handling and storage of investigational products (IP)

D. Ethics submission

Sponsors are responsible for providing investigators with procedures and instructions on how to handle and store investigational products (IP). This means that the sponsor must ensure that all investigational products are properly maintained and stored to guarantee their effectiveness and safety during the duration of the clinical trial. The other options, while also important in the overall conduct of a clinical trial, are not specifically mentioned in ICH GCP 5.14.3. Audit strategies (option A) are not required to be provided to investigators in this section, although it may be covered in other sections of the guideline. Data management (option B) is important for maintaining accurate and complete records, but is not directly related to the handling and storage of investigational products. Ethics submission (option D) is not mentioned at all in this section and is instead covered in ICH GCP 3.1. Therefore, the correct

3. What regulations do Non-Significant Risk studies need to adhere to?

A. Follow abbreviated IDE regulations, no FDA approval needed

B. Must have FDA and IRB approval

C. Are exempt from all regulations

D. Must report to FDA prior to study start

Non-Significant Risk studies are categorized under the "abbreviated" category in the FDA's Investigational Device Exemption (IDE) regulations. This means that they still need to adhere to certain regulations, but they do not require FDA approval before conducting the study. Options B, C, and D are all incorrect because they either require additional approvals or exemptions from regulations, which do not apply to Non-Significant Risk studies.

4. What should be included in the first section of the FDA progress report for drug studies?

A. Individual study information

B. Summary information

C. General investigational plan

D. Conclusion of findings

Individual study information should be included in the first section of the FDA progress report for drug studies because it provides detailed and specific data on each study that was conducted. This information is essential for the FDA to understand the progress and results of the drug studies. Summary information (option B) provides a brief overview of the entire drug study progress, but it does not go into the depth necessary for the FDA to evaluate the studies. General investigational plan (option C) outlines the overall plan for the drug studies, but it does not provide specific data on individual studies that are required in the first section. Conclusion of findings (option D) should be included at the end of the FDA progress report, not in the first section. This section should summarize the overall findings of the drug studies, not individual study information.

5. What is the role of a sub-investigator according to FDA regulations?

A. Leader of the investigative team

B. Regulatory body member

C. Individual member of the clinical investigator's team

D. Sponsor's representative in a clinical trial

Sub-investigators play a crucial role in assisting the clinical investigator with conducting a study. This includes tasks such as recruiting participants, obtaining informed consent, and collecting and managing data. They also help ensure that the study is conducted in compliance with FDA regulations and the protocol. Option A, B, and D are incorrect because they do not accurately describe the role of a sub-investigator according to FDA regulations. The leader of the investigative team is typically the clinical investigator, while the regulatory body member is usually a different position within the FDA. The sponsor's representative may be involved in a clinical trial, but their role is not specific to FDA regulations and the sub-investigator's responsibilities. Therefore, option C is the most accurate answer.

6. What is a FDA Form 1571?

A. Statement of investigator

B. Financial disclosure form

C. Cover page for IND application

D. Quality assurance audit form

The FDA Form 1571 is the cover page for an Investigational New Drug (IND) application. This form is used to provide basic information about the sponsor, the drug, and the proposed clinical trials. Option A, the Statement of Investigator, is used to document the investigator's compliance with FDA regulations and commitments to the study. Option B, the Financial Disclosure form, is used to disclose any potential financial conflicts of interest for the sponsor, investigators, and institutional review board members. Option D, the Quality Assurance Audit form, is used to document the results of an audit performed to ensure compliance with FDA regulations.

7. When should unused supplies of IP be returned to the sponsor or destroyed?

A. After every study visit

B. At the end of each month

C. Should investigation be terminated, suspended or completed

D. Only if the IP has expired

It is important to return or destroy any unused supplies of IP (investigational product) when clinical investigation is terminated, suspended, or completed. Options A, B, and D are incorrect because they do not account for other situations in which the investigation may end before completion, such as a suspension or early termination. By choosing option C, you ensure that no unused IP is left unaccounted for, which could have implications for patient safety and follow-up of study participants. Option A is too frequent and may result in unnecessary waste of IP, while options B and D are not comprehensive enough.

8. What FDA guideline lists the basic elements of informed consent?

A. 21 U.S.C. 355

B. 21 CFR 50

C. 10 CFR 20

D. 45 CFR 46

The Food and Drug Administration (FDA) sets guidelines and regulations for medical research involving human subjects to ensure their safety and rights are protected. The basic elements of informed consent, which include information about the study, potential risks and benefits, and the voluntary nature of participation, are outlined in FDA's Code of Federal Regulations (CFR) section titled "Protection of Human Subjects" or 21 CFR 50. This is why option B is the correct answer. Option A, 21 U.S.C. 355, refers to the U.S. Code section about new drug applications, and option C, 10 CFR 20, pertains to radiation protection standards. These have no direct relation to informed consent in medical research. Option D, 45 CFR 46, is the correct code for the Department of Health and Human Services' regulations for human subjects research. However, this code is not

9. Which regulation dictates that investigators and staff should be adequately trained?

A. ICH GCP 5.14.3

B. ICH GCP 5.18.4

C. FDA 1572

D. ICH GCP 5.1.1

All of the options listed refer to different guidelines and regulations related to clinical trials. However, only option B specifically addresses the requirement for adequate training for investigators and staff. Option A discusses the reporting of adverse events, option C refers to the submission of Form FDA 1572, and option D pertains to the qualifications of investigators. Therefore, option B is the most appropriate and relevant answer to the question.

10. When can a CRF be considered a source document?

A. When it is submitted to the IRB

B. When it is digitalized

C. When it is stored in a secure location

D. When CRF is signed, dated, and initialed by the person recording the information

A CRF (Case Report Form) is a document used to collect and record data during a clinical trial or patient study. A CRF can be considered a source document when it is the original document that contains the raw data, such as a patient's medical history, lab results, or other study-related information. This means that the data on the CRF is directly obtained from the source, without any alterations or interpretations. Therefore, options A, B, and C are incorrect because they do not relate to the originality of the data on the CRF. Option A refers to the submission of the CRF to the IRB (Institutional Review Board), which is a process that ensures the protection of human subjects in a research study but does not affect the CRF's status as a source document. Option B refers to the digitalization of the CRF, which is simply a