SOCRA CCRP Practice Exam (Sample)

Study Guide

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Questions

1. Which incidences must sponsors report to the FDA and/or investigators?

A. Withdrawal of IRB approval only

B. Recall and device disposition only

C. Withdrawal of FDA approval only

D. All listed incidences

2. What FDA regulation governs financial disclosure?

A. 21 CFR 312.53

B. 21 CFR 54

C. 21 CFR 50

D. 21 CFR 56

3. What criteria must be met for children to be involved in greater than minimal risk research with a prospect of benefit?

A. Risks are minimal and benefits are unknown

B. Risks are justified by the anticipated benefits and assent + consent is obtained

C. Only parental consent is required

D. Research can proceed without any ethical review

4. What is FDA Form 1572?

A. Cover page for IND application

B. Quality assurance audit form

C. Financial disclosure form

D. Statement of investigator

5. What is the regulatory process if a device meets even one criterion for exemption?

A. IRB review and approval, no FDA notification

B. FDA review and approval, then IRB

C. Direct FDA approval

D. Both FDA and IRB review concurrently

6. What is part of the individual study information included in FDA progress reports for drug studies?

- **A. Summary of IND safety reports**
- **B. Title, protocol number, and purpose**
- **C. Rationale for study**
- **D. Estimated number of patients in trials**

7. What regulatory body offers guidance on protocol structure/contents?

- **A. FDA**
- **B. EPA**
- **C. CDC**
- **D. ICH GCP guideline**

8. 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**

9. How is power in a clinical trial typically calculated?

- **A. Using effect size and variability**
- **B. Using the number of subjects alone**
- **C. Using the type of control group**
- **D. Using the study design (Parallel or Crossover)**

10. What is one of the most important points to consider when consenting patients according to 21 CFR 50?

- **A. No person can participate without their or LAR consent**
- **B. Patients must be over 18**
- **C. Consent must be verbally given**
- **D. Patients must consent on the same day as enrollment**

Answers

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

Explanations

1. Which incidences must sponsors report to the FDA and/or investigators?

A. Withdrawal of IRB approval only

B. Recall and device disposition only

C. Withdrawal of FDA approval only

D. All listed incidences

Sponsors are obligated to report all listed incidences to the FDA and/or investigators. This includes the withdrawal of IRB approval, recall and device disposition, as well as withdrawal of FDA approval. Therefore, options A, B, and C are all incomplete and do not fulfill the reporting requirements. It is crucial for sponsors to report all listed incidences to ensure the safety and effectiveness of the product and protect the participants involved in the trial.

2. What FDA regulation governs financial disclosure?

A. 21 CFR 312.53

B. 21 CFR 54

C. 21 CFR 50

D. 21 CFR 56

The correct regulation is 21 CFR 54. The other options, 21 CFR 312.53, 21 CFR 50, and 21 CFR 56, all relate to different regulations within the FDA's Title 21 of the Code of Federal Regulations. 21 CFR 312.53 relates to investigator disqualification and 21 CFR 50 and 56 relate to the protection of human subjects in clinical trials. Therefore, these options are incorrect as they do not specifically govern financial disclosure.

3. What criteria must be met for children to be involved in greater than minimal risk research with a prospect of benefit?

A. Risks are minimal and benefits are unknown

B. Risks are justified by the anticipated benefits and assent + consent is obtained

C. Only parental consent is required

D. Research can proceed without any ethical review

Involving children in research that carries more than minimal risk requires that specific ethical criteria are met to ensure their safety and uphold their rights. The correct answer indicates that the risks involved in the research are justified by the anticipated benefits. This means that the potential advantages for the child participants or for others are deemed significant in relation to the risks they may incur. Furthermore, obtaining assent from the children, as well as consent from their parents or guardians, is a crucial ethical requirement. Assent is the child's agreement to participate, recognizing their developing autonomy, while consent ensures that the parents or guardians have provided informed permission. This dual approach reinforces the protectiveness surrounding child participants in research settings. By ensuring that risks are justified and both assent and consent are obtained, researchers uphold ethical standards and safeguard the welfare of child participants, ultimately aiming to maximize benefits while minimizing harm.

4. What is FDA Form 1572?

A. Cover page for IND application

B. Quality assurance audit form

C. Financial disclosure form

D. Statement of investigator

FDA Form 1572 is a form used by the Food and Drug Administration (FDA) to document a Statement of Investigator (SOI). An SOI is a legally binding document that must be completed by the principal investigator (PI) for any clinical investigation in the United States subject to FDA regulations. It details the information about the PI such as their name and qualifications, the protocol of the study, and the commitments made by the PI to comply with FDA regulations. Therefore, options A, B, and C are incorrect as they do not accurately describe the purpose of FDA Form 1572.

5. What is the regulatory process if a device meets even one criterion for exemption?

A. IRB review and approval, no FDA notification

B. FDA review and approval, then IRB

C. Direct FDA approval

D. Both FDA and IRB review concurrently

If a device meets even one criterion for exemption, it means that the device does not need to go through the FDA review and approval process. Instead, the device can go through IRB review and approval. Option B is incorrect because it suggests that the device would still need to go through FDA review and approval before going through IRB review. Option C is incorrect because it suggests that the device would only need FDA approval and not IRB approval, which is not the case for exemption. Option D is incorrect because it suggests that both the FDA and IRB would need to review the device concurrently, which is not necessary for exemption. In summary, option A is the correct answer because it accurately explains the regulatory process for devices that meet even one criterion for exemption.

6. What is part of the individual study information included in FDA progress reports for drug studies?

A. Summary of IND safety reports

B. Title, protocol number, and purpose

C. Rationale for study

D. Estimated number of patients in trials

Progress reports for FDA-regulated drug studies share part of the individual study information with the FDA and include the title, protocol number, and purpose of the study. Option A is incorrect because a summary of IND safety reports is not considered individual study information and is not usually included in progress reports. Option C is incorrect because the rationale for the study is also not usually included in progress reports as it is typically provided in the initial IND submission. Option D is incorrect because the estimated number of patients in trials is not necessarily considered individual study information and is not always required to be included in progress reports.

7. What regulatory body offers guidance on protocol structure/contents?

A. FDA

B. EPA

C. CDC

D. ICH GCP guideline

The correct answer is based on the role of the ICH GCP (International Council for Harmonisation Good Clinical Practice) guidelines in providing comprehensive standards and recommendations for the design, conduct, recording, and reporting of clinical trials. These guidelines specifically address protocol structure and contents, ensuring that all necessary elements are included for the proper conduct of a trial and the protection of participants. The ICH GCP guidelines are internationally recognized and serve as a framework to bring consistency and quality across global clinical research practices. They outline the essential elements that a protocol must contain, such as objectives, methodology, statistical considerations, and ethical considerations, which are crucial for the integrity of clinical trials. While the FDA, EPA, and CDC have important regulatory roles and provide guidance in their respective domains, the ICH GCP guidelines are the primary reference for protocol structure and content in the context of clinical research, making this the most appropriate choice.

8. 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.

9. How is power in a clinical trial typically calculated?

A. Using effect size and variability

B. Using the number of subjects alone

C. Using the type of control group

D. Using the study design (Parallel or Crossover)

Power is typically calculated by using effect size and variability in a clinical trial. This is because the effect size measures the magnitude of the treatment effect and the variability measures the spread of the data. Using only the number of subjects may not accurately reflect the actual power of the study, as a small sample size may not be representative of the larger population. The type of control group or study design may also impact the power calculation, but these factors alone do not determine the overall power of the study. Therefore, option A is the most accurate and appropriate method for calculating power in a clinical trial.

10. What is one of the most important points to consider when consenting patients according to 21 CFR 50?

A. No person can participate without their or LAR consent

B. Patients must be over 18

C. Consent must be verbally given

D. Patients must consent on the same day as enrollment

One of the most important points to consider when consenting patients according to 21 CFR 50 is that no person can participate without their or their legally authorized representative's consent. This is because informed consent is a key principle in protecting patient rights and ensuring their autonomy in medical decision-making. Options B, C, and D are incorrect because they do not fully encompass all aspects of informed consent. Option B is incorrect because age alone does not determine an individual's ability to give informed consent. Option C is incorrect because consent must be given in writing, not just verbally. Option D is incorrect because there is no specific timeframe for when consent must be given, as long as it is obtained before the patient begins participating in the study.