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Certified Clinical Research Professional (CCRP) Exam | 100% Correct Answers | Verified | Latest 2024 Version

When isn't an IND application needed? - ✓✓ IND Application is not needed if investigation does not support change in labeling

What information must the general IND include? (21 CFR Part 312.23) - ✓✓

FDA Form 1571:

- FDA Form 1571 cover sheet
- Table of contents
- Investigative plan
- Investigator's brochure
- Protocol
- Chemistry/Manufacturing information
- Pharmacology/toxicology
- Previous human research/literature information
- Additional information (drug dependence and abuse potential)

How many days after FDA receives IND submission does the IND go into effect? (21 CFR 312.40) - ✓✓ An IND goes into effect 30 days after the FDA receives the submission unless the FDA notifies the Sponsor of a clinical hold

When must an IND amendment be submitted? (21 CFR Part 312.31) - ✓✓ If there are changes to the protocol that affects safety of subjects, scientific quality of the study, or scope of investigation

- If a new investigator is added to the study
- Information amendments must be submitted for chemistry/microbiology, pharm/toxicology, or clinical

OTHER SUBMISSIONS:

- IND safety reports

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none">• Research Study Start-Up: This section of the exam measures the skills of Clinical Research Coordinators and covers the initial planning and setup of a clinical trial. It involves coordinating the development of the study protocol, ensuring it considers ethical guidelines and regulatory pathways like IND or IDE. It also includes creating essential study documents like informed consent forms and case report forms. The domain covers obtaining necessary approvals from stakeholders like the IRB and sponsor, selecting study sites, training staff, and ensuring the study's compliance with various laws. Additionally, it involves obtaining the research product and preparing all necessary tools and documentation for the study's commencement.• Research Study Implementation: This section of the exam measures the skills of Clinical Research Associates and covers the active management and execution of the clinical trial. It focuses on following the study protocol and standard operating procedures, managing the investigational product, and ensuring ongoing regulatory compliance. The domain includes identifying, documenting, and reporting any study anomalies such as adverse events or protocol deviations. It also involves managing subject recruitment, consent, and retention, as well as maintaining all study records and essential documents. Furthermore, it covers communicating with all study stakeholders and participating in study audits to ensure quality and adherence to regulations.
Topic 2	<ul style="list-style-type: none">• Research Study Closure: This section of the exam measures the skills of Clinical Research Coordinators and covers the activities required to properly conclude a clinical trial. It involves participating in the study closeout visit to verify documentation and account for the investigational product. The domain also includes developing and submitting final closure reports to the IRB, study sponsor, regulatory authorities, and clinicaltrials.gov. Finally, it covers the procedures for archiving study records.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q125-Q130):

NEW QUESTION # 125

Which of the following statements about the FDA's authority to inspect IRB/IEC records is correct?

- A. The FDA does not have regulatory authority to inspect them
- B. The FDA may inspect them at reasonable times, in a reasonable manner, but may not take copies unless requested with an affidavit
- C. The FDA may inspect them only if the IRB/IEC formally requests inspection
- D. The FDA may inspect them at reasonable times, in a reasonable manner, and may take copies of IRB /IEC records

Answer: D

Explanation:

The FDA has full regulatory authority to inspect IRB/IEC records.

* 21 CFR 56.115(b): "The IRB shall permit representatives of the Food and Drug Administration to inspect and copy all records maintained... at reasonable times and in a reasonable manner." Thus, FDA may inspect and copy IRB/IEC records without requiring an affidavit or invitation. This ensures regulatory oversight and human subject protection.

Incorrect options:

- * (A) limits authority incorrectly.
- * (C) is false - FDA explicitly regulates IRBs.
- * (D) is false - FDA does not need IRB invitation.

Correct answer: B.

References:

21 CFR 56.115(b).

NEW QUESTION # 126

In accordance with the CFR, which body must determine that a study meets the criteria for minimal risk?

- A. The reviewing IRB/IEC

- B. The clinical investigator
- C. The medical monitor
- D. A data safety monitoring board

Answer: A

Explanation:

Minimal risk determination is a regulatory function of the IRB/IEC.

* 45 CFR 46.102(j):Defines minimal risk as harm or discomfort not greater than those ordinarily encountered in daily life.

* 45 CFR 46.109(a):The IRB has authority to approve, require modifications, or disapprove research, including assessment of risk level.

* Investigators may propose a study as minimal risk, but only the IRB/IEC can formally classify it.

This ensures independent, unbiased evaluation of risk, protecting participants from investigator or sponsor bias.

References:45 CFR 46.102(j), 46.109(a).

NEW QUESTION # 127

Which case history documents must be at both sponsor and site?

- A. Study visit notes
- B. Signed informed consent forms
- **C. Case report forms (CRFs)**
- D. Medical records

Answer: C

Explanation:

* ICH E6(R2) 1.11:CRFs are documents used to record protocol-required data reported to sponsor.

* Sites keep originals; sponsor retains copies. Consent forms and medical records stay at site only.

References:ICH E6(R2), §1.11.

NEW QUESTION # 128

A monitor is conducting a site closeout visit. The study site kept electronic medical records and source documents in a system verified to be 21 CFR Part 11 compliant. The monitor reviewed all electronic documents by logging into the system with a unique login ID and password. In addition to the essential document file, which of the following sets of documents should be provided to the monitor during the study closeout visit?

- A. Informed consent documents and printouts of electronic source documents
- B. Printouts of electronic source documents and the remaining investigational product
- **C. Informed consent documents and investigational product documentation**
- D. A copy of the final report for the IRB and investigational product shipment records

Answer: C

Explanation:

During study closeout, the monitor verifies subject protection, protocol compliance, and investigational product accountability.

* ICH E6(R2) 8.1 & 8.4:Lists essential documents to be verified at closeout, including signed informed consent forms and investigational product accountability records.

* 21 CFR Part 11:Ensures electronic records are valid, so printed copies are not always necessary unless required for auditing. Thus, the critical items for monitor review at closeout are informed consent forms(to confirm subject protection) and investigational product documentation(to confirm reconciliation and disposition).

Correct answer:D.

References:

ICH E6(R2), §8.1, §8.4.

NEW QUESTION # 129

Which of the following should a clinical investigator include in a submission to an IRB/IEC for a Phase IV drug study?

- **A. The amount of payments and compensation to subjects**

- B. The investigator's clinical trial agreement with the sponsor
- C. The itemized study budget
- D. The drug development and marketing plan

Answer: A

Explanation:

For IRB/IEC submissions, investigators must disclose subject-related information that may impact voluntariness or fairness of participation.

* 21 CFR 56.111(a)(3):The IRB must ensure that subject selection is equitable.

* 21 CFR 50.25(a)(3):Requires disclosure of "any compensation and/or medical treatments available if injury occurs."

* ICH E6(R2) 4.8.10(n):Informed consent should describe "any compensation and/or reimbursement to subjects."

Thus, compensation amounts must be reviewed by IRB/IEC to ensure they are not coercive or excessive.

Budgets (A), marketing plans (C), and contracts (D) are administrative and not part of IRB submission requirements.

Correct answer:B (The amount of payments and compensation to subjects).

References:

References:

21 CFR 36.25(a)(5);

NEW QUESTION # 130

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