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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	• 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.

Topic 2	• 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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q25-Q30):

NEW QUESTION # 25
While reviewing site records during a monitoring visit, a monitor can cite which of the following as a site violation of informed consent regulations?

- A. Only the signatures of the person obtaining consent and the witness appear on the copy of the summary of the short form consent
- B. A subject's signature is missing on the copy of the summary of the short form consent
- C. The sponsor-generated informed consent template is missing required elements
- D. A copy of the consent document was not provided to a subject

Answer: D

Explanation:
Providing acopy of the signed consent formto subjects is a mandatory requirement.
* 21 CFR 50.27(a):"A copy shall be given to the person signing the form."
* ICH E6(R2) 4.8.11:Reinforces that "a copy of the signed and dated written informed consent form should be given to the subject."
Failure to provide this copy constitutes adirect violation of informed consent regulations.
Other issues:
* A & C concern proper short form process but do not invalidate informed consent if a copy was provided.
* D concerns sponsor template, but the site's responsibility is ensuring use of IRB-approved version.
Correct answer:B.
References:
21 CFR 50.27(a).
ICH E6(R2), §4.8.11.

NEW QUESTION # 26
For a Significant Risk device study, an investigator must report within 5 working days which event?

- A. Withdrawal of FDA approval
- B. Completion of investigation
- C. Emergency deviation
- D. Unanticipated adverse effect

Answer: C

Explanation:
* 21 CFR 812.150(a)(4):Any deviation from investigational plan made to protect the life or physical well- being of a subject in an emergency must be reported to the sponsor and IRBwithin 5 working days.
* Unanticipated adverse device effects have a 10-day reporting window.
References:21 CFR 812.150(a)(4).

NEW QUESTION # 27
For a study with a significant risk investigational medical device that could optimize the effects of radiation therapy on cancer tumors, the investigational plan states mild burns are an anticipated effect. One subject developed severe burns with blistering. In accordance with the CFR, this effect must be reported to the sponsor and the IRB/IEC as soon as possible and at most how long after the investigator first learns of the effect?

- A. 7 working days
- B. 5 working days
- C. 10 working days
- D. 2 working days

Answer: C

Explanation:
In device trials,unanticipated adverse device effects (UADEs)must be promptly reported.
* 21 CFR 812.150(a)(1):"An investigator shall submit to the sponsor and the reviewing IRB a report of anyunanticipated adverse device effectas soon as possible, but in no event later than10 working days after the investigator first learns of the effect." In this case,severe burns with blisteringgo beyond the anticipated effect of mild burns listed in the investigational plan. Therefore, it qualifies as aUADEand triggers expedited reporting. Options A, B, and C are too short; the regulation specifically mandates a10 working day maximumtimeframe.
Thus, the correct answer isD (10 working days).
References:
21 CFR 812.150(a)(1) (Reporting requirements for investigators).

NEW QUESTION # 28
In accordance with the ICH GCP Guideline and the CFR, who is directly responsible for ensuring that an IRB /IEC will conduct the initial and continuing review of a study?

- A. The investigator
- B. The monitor
- C. The sponsor
- D. The study coordinator

Answer: A

Explanation:
Theinvestigatoris directly responsible for ensuring that the IRB/IEC reviews and approves the research both initially and on a continuing basis. This responsibility is not delegable to the sponsor or study staff.
* ICH E6(R2) 4.4.1:"Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC for the trial protocol, written informed consent form, consent form updates, and any other written information to be provided to subjects."
* 21 CFR 312.66:"An investigator shall assure that an IRB that complies with the requirements... will be responsible for the initial and continuing review and approval of the proposed clinical study." This means that while the sponsor submits documents to the FDA and oversees general compliance, the investigator has the obligation to obtain and maintain IRB approvalat their site. The monitor or study coordinator may assist in documentation, but legal responsibility rests with the investigator.
Thus, the correct answer isC (The investigator).

References:
ICH E6(R2), §4.4.1 (Investigator responsibility before initiation).
21 CFR 312.66 (IRB responsibility in clinical investigations).

NEW QUESTION # 29
When can an IRB/IEC review a study using expedited review?

- A. For minor changes to previously approved protocol
- B. For initial review of a study using specimens with identifiers
- C. For initial review of Phase III IND protocol
- D. For protocol changes involving more than minimal risk

Answer: A

Explanation:
* 21 CFR 56.110(b):IRBs may use expedited review forminor changesin previously approved research.
* Expedited review cannot be used for initial reviews of high-risk protocols or major modifications.
Correct answer isD.
References:21 CFR 56.110(b).

NEW QUESTION # 30
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