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Preparing for the Certified Clinical Research Professional (CCRP) (CCRP) certification test can be a difficult task for candidates. They often face several challenges during their preparation for the Certified Clinical Research Professional (CCRP) (CCRP) exam, including fear, lack of updated CCRP Exam Dumps, and time constraints. Fortunately, there is a solution to these challenges. DumpStillValid is a reliable website that provides genuine and updated CCRP Practice Test.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q19-Q24):

NEW QUESTION # 19
A revised protocol added genomic testing to banked tissue samples. Before shipping samples, what must the site do?

- A. Ship under dangerous goods requirements
- B. Obtain IRB/IEC approval for revised protocol and ICF
- C. Execute material transfer agreement
- D. Notify enrolled subjects

Answer: B

Explanation:
* 21 CFR 56.109(a):IRB must review and approve any protocol amendments before implementation.
* ICH E6(R2) 4.5.2:Changes affecting subjects (e.g., genomic testing) require IRB/IEC approval and updated consent.
Thus, site must first obtainIRB approval for revised protocol and ICF.
References:21 CFR 56.109(a); ICH E6(R2) §4.5.2.

NEW QUESTION # 20
A research protocol requires patients to complete a patient reported outcome questionnaire in the sponsor's electronic data capture (EDC) system. What is the source data?

- A. A printout of the electronic medical record
- B. A printout of the EDC record
- C. The electronic medical record
- D. The EDC record

Answer: D

Explanation:
Source data areoriginal records where data are first recorded.
* ICH E6(R2) 1.51:Defines source data as "all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial." Since subjects directly enter responses into the EDC, theEDC record itself is the original source document.
EMRs (B, C) and printouts (D) are secondary records.
Correct answer:A (The EDC record).
References:
ICH E6(R2), §1.51 (Definition of source data).

NEW QUESTION # 21
An investigator received an updated informed consent form (ICF) from the sponsor for a study closed to enrollment. Subjects are only in long-term follow-up. The change related to frequent radiation imaging at screening, with no change to drug safety profile. Who must the investigator notify first?

- A. Participants in long-term follow-up
- B. The IRB/IEC
- C. Sub-investigators
- D. No notification is required

Answer: B

Explanation:
* 21 CFR 56.109(a):IRBs must review all changes to informed consent before implementation.
* ICH E6(R2) 4.8.2:If new information could affect willingness to continue, consent forms must be revised and approved by the IRB.
Even though screening is closed, the IRB/IEC must review the updated form before any subject re-consenting.
References:21 CFR 56.109(a); ICH E6(R2) §4.8.2.

NEW QUESTION # 22
During an audit of a sponsor, the following documents and activities were reviewed: the protocol, applicable regulatory requirements, and compliance with Good Clinical Practice (GCP). What additional documents must be reviewed during the sponsor audit?

- A. Financial reports
- B. Personnel records
- C. Audit reports
- D. Standard Operating Procedures (SOPs)

Answer: C

Explanation:

Sponsor audits ensure systems comply with GCP.
* ICH E6(R2) 5.19.3:"The sponsor's auditing procedures should include a review ofquality assurance audits and audit reports."
* Audit reports document findings from independent evaluations and are essential for ensuring compliance.
SOPs (A) are reviewed during audits but are not mandated as standalone "audit review documents." Personnel files (B) and financial reports (C) are not required under GCP auditing provisions.
Correct answer:D (Audit reports).
References:
ICH E6(R2), §5.19.3.

NEW QUESTION # 23
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 study coordinator
- B. The monitor
- C. The investigator
- D. The sponsor

Answer: C

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 # 24
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