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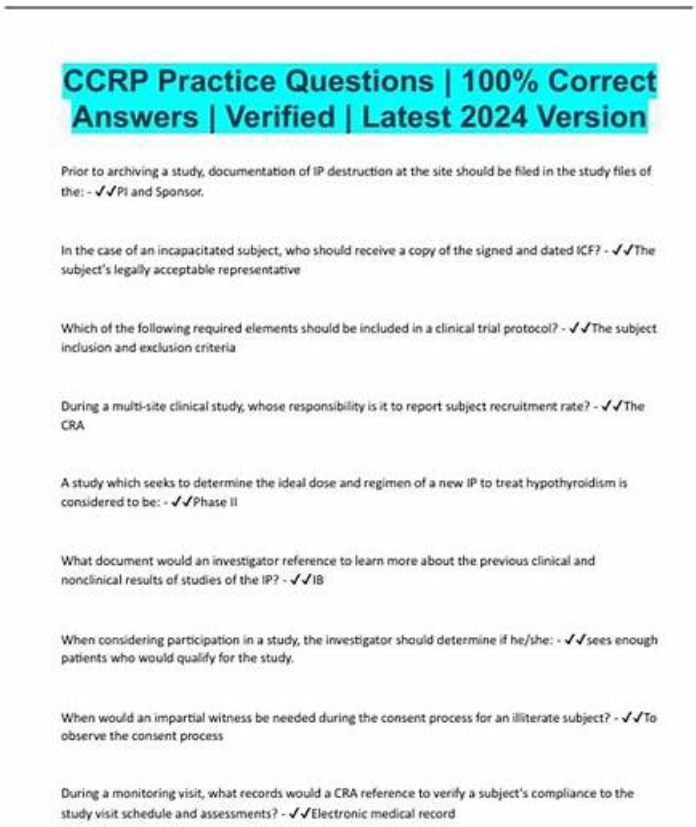

CCRP Practice Questions | 100% Correct Answers | Verified | Latest 2024 Version

Prior to archiving a study, documentation of IP destruction at the site should be filed in the study files of the: - ✓✓PI and Sponsor.

In the case of an incapacitated subject, who should receive a copy of the signed and dated ICF? - ✓✓The subject's legally acceptable representative

Which of the following required elements should be included in a clinical trial protocol? - ✓✓The subject inclusion and exclusion criteria

During a multi-site clinical study, whose responsibility is it to report subject recruitment rate? - ✓✓The CRA

A study which seeks to determine the ideal dose and regimen of a new IP to treat hypothyroidism is considered to be: - ✓✓Phase II

What document would an investigator reference to learn more about the previous clinical and nonclinical results of studies of the IP? - ✓✓IB

When considering participation in a study, the investigator should determine if he/she: - ✓✓sees enough patients who would qualify for the study.

When would an impartial witness be needed during the consent process for an illiterate subject? - ✓✓To observe the consent process

During a monitoring visit, what records would a CRA reference to verify a subject's compliance to the study visit schedule and assessments? - ✓✓Electronic medical record

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details

Topic 1	• 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	• 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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q50-Q55):

NEW QUESTION # 50
Which of the following is an example of an additional protection required when conducting research on children?

- A. The investigator must obtain age-appropriate assent as determined by the IRB/IEC
- B. Parents must be present during all procedures
- C. There must be an impartial advocate present during the consent process
- D. The study must be approved by a central pediatric IRB

Answer: A

Explanation:
Children are a vulnerable population. U.S. regulations require IRB/IEC judgment about when and howassent is obtained, in addition to parental permission. Exact extracts:
* 45 CFR 46.408(a): "The IRB shall determine...whether and to what extent children are capable of providing assent."
* ICH E6(R2) 4.8.12: "Where a subject is unable to give consent personally,assent should be obtained when appropriate, in accordance with applicable regulatory requirement(s)."Thus, the additional protection is IRB-determined, age-appropriate assent (B). Options A, C, and D are not universal requirements for all pediatric research.
References:
ICH E6(R2) Good Clinical Practice, §4.8.12 (Informed consent/assent).
45 CFR 46 Subpart D-Additional Protections for Children, §46.408(a).==========

NEW QUESTION # 51
In accordance with 45 CFR 46, in addition to the Office for Human Research Protections (OHRP), a suspension of IRB/IEC approval must be reported to which of the following?

- A. The local hospital's medical director
- B. The appropriate institutional officials
- C. The Scientific Review Committee
- D. The local hospital's bioethics committee

Answer: B

Explanation:
If IRB/IEC approval is suspended or terminated, reporting is required to protect oversight and accountability.
* 45 CFR 46.113:"An IRB shall notify theinstitutional officials, the department or agency head, and OHRP(when applicable) of any suspension or termination of IRB approval." This ensures transparency and institutional responsibility for compliance. Internal hospital committees or directors (A, C, D) are not mandated reporting entities.
Thus, the correct answer isB (Appropriate institutional officials).
References:
45 CFR 46.113 (Suspension or termination of IRB approval).

NEW QUESTION # 52
A subject on a multi-drug regimen could not tolerate a non-investigational drug. Can the investigational regimen continue?

- A. Only after sponsor and IRB approval
- B. Only for a short time, then change to placebo
- C. Only after medical monitor approval
- D. Yes, per protocol

Answer: A

Explanation:
* ICH E6(R2) 4.5.1:Investigators must follow the protocol approved by the IRB/IEC.
* Any modification that is not pre-specified must be approved by sponsor and IRB before continuing.
Only deviations eliminating immediate hazard can be done without prior approval; in this case, continuation requires sponsor + IRB agreement.
References:ICH E6(R2) §4.5.1.

NEW QUESTION # 53
Which document was created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and summarizes the basic ethical principles and guidelines for the conduct of research involving human subjects?

- A. The Belmont Report
- B. The Declaration of Helsinki
- C. The Nuremberg Code
- D. The ICH Guidelines

Answer: A

Explanation:
TheBelmont Report (1979), issued by the U.S. National Commission, identifiesthree core ethical principles guiding human subject research:
* Respect for Persons(informed consent, autonomy, protection of vulnerable populations).
* Beneficence(maximize benefits, minimize harms).
* Justice(fairness in subject selection and treatment).
* TheNuremberg Code (1947)was developed post-WWII to prevent unethical experiments.
* TheDeclaration of Helsinki (1964, updated)is a World Medical Association document guiding international physician research ethics.
* TheICH Guidelines (1996)outline harmonized regulatory requirements for good clinical practice.

Only the Belmont Report fits the description of a U.S.-based, principle-driven framework for human research ethics.
Thus, the correct answer isD (The Belmont Report).
References:
The Belmont Report (1979), National Commission for the Protection of Human Subjects.
45 CFR 46 (Human Subject Protections).

NEW QUESTION # 54
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 investigator
- C. The sponsor
- D. The monitor

Answer: B

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 # 55
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