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SOCRA CCRP Certification Exam Study Guide 2024 Update.

Nuremburg Code - Correct answer the first set of principles outlining professional ethics for clinical research.

Nuremburg Code elements - Correct answer 1. Voluntary informed consent
2. Research benefits society
3. Should be based on prior animal work
4. Avoid suffering and injury
5. Research where death and disabling injury is expected shouldn't be conducted
6. Risks should be justified
7. Proper preparations and adequate facilities
8. Conducted by scientifically qualified
9. Subjects can withdraw
10. Research must end the study if there is probable because that continuing would lead to injury, disability, or death.

Timeline of Historical Events - Correct answer Nuremberg Code first (1947). Declaration of Helsinki second (1964). Belmont Report third (1979).

Belmont Report Principles and Application - Correct answer there are 3:
1. Respect for persons = informed consent
2. Beneficence = risk/benefit analysis
3. Justice = appropriate selection of patients

Language Level Recommended for Informed Consent - Correct answer 6th-8th grade

8 Basic Elements of informed Consent - Correct answer 1. Statement explaining the study involves research.
2. Description of risks or discomforts.
3. Description of benefits.
4. Alternative treatments/procedures.
5. Confidentiality.
6. Compensation for involvement and/or injury.
7. Who to contact.
8. Voluntary and can discontinue

Additional Elements of Informed Consent - Correct answer 1. Unforeseeable risks to subject.
2. Participation can be terminated by investigator.
3. Any additional costs.
4. Consequences of the subject's decision to withdraw
5. Significant new findings will be shared
6. approx. # of subjects in the study.

Differences between short and long informed consent form - Correct answer Long = the standard consent form.
Short = document states that the elements have been presented orally to and understood by the subject or LAR.

ICF Monitoring Considerations - Correct answer 1. Subject has signed most recent IRB approved version
2. Subject signature is present in addition to subject name

Page 1 | 9

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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 (Q56-Q61):

NEW QUESTION # 56
According to the CFR and the ICH GCP Guideline, which of the following must be submitted to the IRB after completion of the trial at the site?

- A. The monitoring close-out visit report
- B. The final subject enrollment log
- C. The data safety monitoring summary
- D. The final report

Answer: D

Explanation:
When a trial ends at a site, the investigator has an obligation to submit a final report to the IRB/IEC. This is outlined in both ICH and CFR:
ICH E6(R2) 4.13: "Upon completion of the trial, the investigator should provide the IRB/IEC with a summary of the trial's outcome."
21 CFR 312.66: Requires investigators to "report to the IRB all changes in the research activity and all unanticipated problems involving risk, and to provide reports at the end of the study." The final report provides closure and documentation that the study was conducted ethically and in compliance with regulatory standards. Other documents listed in the options (monitoring reports, DSMB summaries, subject logs) may be retained by the sponsor or site, but they are not mandated for IRB submission.
Thus, the correct answer is A (Final Report). This ensures the IRB/IEC has an accurate record of study completion, outcome, and compliance with ethical oversight.
References:
ICH E6(R2), §4.13 (Final reporting to IRB/IEC).

21 CFR 312.66 (IRB review and reporting).

NEW QUESTION # 57
After the sponsor's auditor completes the final audit report for a Phase II trial with an investigational new drug, which of the following is responsible for providing the audit certificate to the clinical site?

- A. The IRB/IEC
- B. The sponsor
- C. The Data Safety Monitoring Board
- D. The regulatory authority

Answer: B

Explanation:
Audits are part of sponsor quality assurance to ensure trial compliance.
* ICH E6(R2) 5.19.3:"The sponsor's auditing procedures should include the provision of anaudit certificatewhere required."
* ICH E6(R2) 8.2.20:Audit certificates are essential documents generated and retained by the sponsor.
IRBs (A), regulators (B), and DSMBs (C) are not responsible for audit documentation. Therefore, only the sponsorissues and maintains audit certificates, providing them to sites when appropriate.
Correct answer:D.
References:
ICH E6(R2), §5.19.3.
ICH E6(R2), §8.2.20.

NEW QUESTION # 58
Which of the following identifies content that should be included in a clinical research protocol?

- A. Criteria for the selection of an investigator
- B. A summary of findings of nonclinical studies that potentially have clinical significance
- C. IRB/IEC approval and meeting minutes
- D. Standard operating procedures for data collection

Answer: B

Explanation:
Theprotocolmust provide scientific rationale, including prior nonclinical findings that justify human research.
* ICH E6(R2) 6.2.2:"The protocol should include... a summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial." Other listed options belong elsewhere:
* IRB approvals (A) are separate administrative records.
* SOPs for data collection (B) are sponsor-level procedural documents.
* Investigator selection (C) is a sponsor's responsibility, not protocol content.
Thus, the correct answer isD (Summary of nonclinical findings with clinical relevance).
References:
ICH E6(R2), §6.2.2 (Protocol contents).

NEW QUESTION # 59
Protecting prisoners' rights to voluntarily participate in research is an example of which Belmont principle?

- A. Beneficence
- B. Dignity
- C. Respect for Persons
- D. Justice

Answer: C

Explanation:
* Belmont Report:"Respect for Persons" incorporates two ethical convictions: treating individuals as autonomous agents and protecting those with diminished autonomy (e.g., prisoners).

* Prisoners require special safeguards because of restricted liberty and potential coercion.
References:Belmont Report (1979).

NEW QUESTION # 60
An investigator received an updated investigator's brochure from the sponsor; the update did not include changes related to subject safety. Which of the following parties, if any, is the investigator required to notify?

- A. The Data Safety Monitoring Board (DSMB)
- B. The IRB/IEC
- C. No notification is required
- D. The regulatory authority

Answer: C

Explanation:
TheInvestigator's Brochure (IB)is updated by the sponsor to reflect new scientific or clinical information.
* ICH E6(R2) 7.3:"The sponsor should revise the IB as soon as new, significant information becomes available."
* ICH E6(R2) 4.1.5:Requires the investigator to ensure staff are informed, but there isno requirementto notify IRB/IEC unless subject safety, rights, or risk profile is affected.
Since this update containedno changes related to subject safety, the investigator is not obligated to notify IRB/IEC, DSMB, or regulators. The updated IB must simply be filed in theregulatory binderand implemented at the site.
Thus, the correct answer isD (No notification is required).
References:
ICH E6(R2), §7.3 (Updating the Investigator's Brochure).
ICH E6(R2), §4.1.5 (Investigator responsibilities for informing staff).

NEW QUESTION # 61
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