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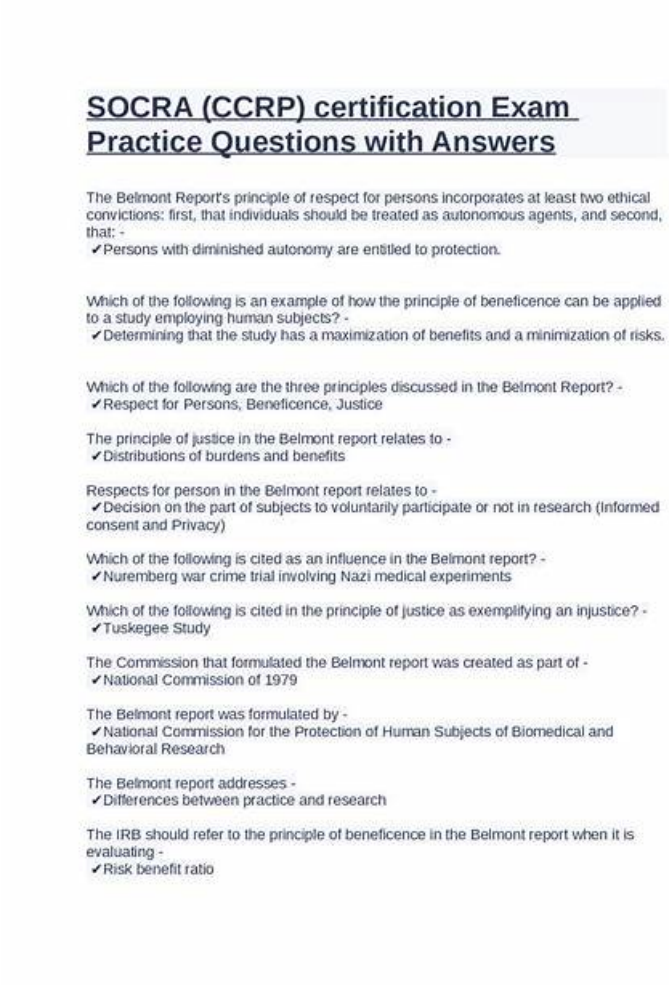

SOCRA (CCRP) certification Exam Practice Questions with Answers

The Belmont Report's principle of respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that: -
✔Persons with diminished autonomy are entitled to protection.

Which of the following is an example of how the principle of beneficence can be applied to a study employing human subjects? -
✔Determining that the study has a maximization of benefits and a minimization of risks.

Which of the following are the three principles discussed in the Belmont Report? -
✔Respect for Persons, Beneficence, Justice

The principle of justice in the Belmont report relates to -
✔Distributions of burdens and benefits

Respects for person in the Belmont report relates to -
✔Decision on the part of subjects to voluntarily participate or not in research (Informed consent and Privacy)

Which of the following is cited as an influence in the Belmont report? -
✔Nuremberg war crime trial involving Nazi medical experiments

Which of the following is cited in the principle of justice as exemplifying an injustice? -
✔Tuskegee Study

The Commission that formulated the Belmont report was created as part of -
✔National Commission of 1979

The Belmont report was formulated by -
✔National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

The Belmont report addresses -
✔Differences between practice and research

The IRB should refer to the principle of beneficence in the Belmont report when it is evaluating -
✔Risk benefit ratio

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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 (Q94-Q99):

NEW QUESTION # 94
A Phase I clinical trial is initiating. Who is responsible for ensuring that site staff are adequately informed about trial duties?

- A. Clinical investigator
- B. Sponsor
- C. IRB/IEC
- D. Program manager

Answer: A

Explanation:
* ICH E6(R2) 4.2.4:"The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, investigational product, and trial-related duties."This responsibility cannot be delegated to sponsor or IRB.
References:ICH E6(R2), §4.2.4.

NEW QUESTION # 95
An unconscious patient experiencing life-threatening cardiac arrhythmias has been admitted to an emergency room. No FDA-approved treatment is available, and no legal representative is present. The clinical investigator determined that the use of an investigational antiarrhythmic drug is required. In accordance with the CFR, who must certify the investigator's determination?

- A. An independent physician
- B. The sponsor's medical monitor

- C. The sponsor's study monitor
- D. A sub-investigator

Answer: A

Explanation:
This scenario falls underemergency use of investigational drugs without informed consent.
* 21 CFR 50.23(a):Allows waiver of informed consent if subject faces a life-threatening condition, available treatments are unproven, and immediate use is required.
* 21 CFR 50.23(a)(3):Requires that "the determination... be reviewed and concurred with by a physician who is not otherwise participating in the clinical investigation." Thus, anindependent physician(not part of the trial team) must certify the necessity of emergency investigational use.
Sponsors and monitors (C, D) are not authorized by regulation to make such determinations. Sub-investigators (A) lack independence and would be conflicted.
Correct answer:B (Independent physician).
References:
21 CFR 50.23(a)(3).

NEW QUESTION # 96
A study subject in a double-blinded, placebo-controlled Phase III study experienced a serious adverse event that could be related to the study drug. The clinical investigator is out of town, and the sub-investigator needs to break the blind. Where can the sub-investigator find a description of the unblinding procedure?

- A. The study protocol
- B. The case report form
- C. The Investigator's Brochure
- D. The informed consent form

Answer: A

Explanation:
Unblinding procedures are aprotocol-level responsibilitybecause they involve trial design, safety management, and subject protection.
* ICH E6(R2) 6.0 (Protocol and amendments):Requires the protocol to specify "the treatment(s) and treatment periods, procedures for randomization and blinding, andprocedures for breaking codes."
* ICH E6(R2) 4.7:"The investigator should follow the trial's randomization procedure, if any, and should ensure that the code is broken only in accordance with the protocol." The informed consent (A) explains risks and rights but does not include operational unblinding procedures.
The Investigator's Brochure (B) summarizes preclinical/clinical data but does not dictate site-specific trial management. The CRF (D) is for data capture and has no procedural detail.
Therefore, the correct answer isC (The study protocol), as it outlines unblinding steps and documentation requirements.
References:
ICH E6(R2), §6.0 (Protocol content).
ICH E6(R2), §4.7 (Randomization and unblinding).

NEW QUESTION # 97
Why would a Phase IV study be conducted?

- A. Different schedule of administration
- B. Different marketing strategy
- C. Different dosage
- D. Different off-label population

Answer: D

Explanation:
Phase IV studies (post-marketing) examine real-world safety and effectiveness.
* ICH E8(R1):Describes Phase IV as "studies performed after drug approval to delineate additional information including the drug's risks, benefits, and optimal use."

* They often test drugs innew or broader populationsbeyond original approval.
While dosing and schedules are Phase I-III, Phase IV focuses onnew patient populationsor long-term outcomes.
References:ICH E8(R1).

NEW QUESTION # 98
Which of the following entities, if any, must provide an approval before an investigator may enroll subjects in a quality-of-life research questionnaire study?

- A. The Department of Health and Human Services
- B. No approvals are necessary if no pharmaceutical drugs are involved
- C. The IRB/IEC
- D. The FDA or another regulatory authority

Answer: C

Explanation:
Even if a study does not involve drugs, devices, or biologics, it still involveshuman subjectsand therefore requiresethical review by an IRB/IEC.
* 45 CFR 46.109(a):"An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy."
* ICH E6(R2) 3.1.2:"The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects." Quality-of-life (QOL) studies may involve surveys, interviews, or questionnaires, but since they involve human participants, they are subject to human research protection regulations. FDA involvement is not required unless drugs or devices are tested. Similarly, HHS approval is not required unless the study is federally funded.
Thus, the correct answer isC (The IRB/IEC).
References:
45 CFR 46.109(a) (IRB review of research).
ICH E6(R2), §3.1.2 (IRB/IEC role in subject protection).

NEW QUESTION # 99
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