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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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q32-Q37):

NEW QUESTION # 32
In accordance with ICH, which of the following is an acceptable protocol review frequency for an IRB?

- A. 24 months
- B. 12 months
- C. 36 months
- D. 6 months

Answer: B

Explanation:
IRBs must review protocols at least annually to ensure ongoing subject protection.
* 21 CFR 56.109(f):"An IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year."
* ICH E6(R2) 3.1.4:"The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk, but at least once per year." This establishes12 monthsas the minimum required interval. More frequent reviews (e.g., 6 months) may occur for higher-risk studies, but longer intervals (24-36 months) are not permitted.
Correct answer:B (12 months).
References:
21 CFR 56.109(f).
ICH E6(R2), §3.1.4.

NEW QUESTION # 33
An investigator discovered a new serious unanticipated adverse device effect. Who must they notify?

- A. Sponsor
- B. OHRP
- C. FDA
- D. Research pharmacist

Answer: A

Explanation:
* 21 CFR 812.150(a)(1):Investigators must report unanticipated adverse device effects to thesponsor within 10 working days.
* Sponsor is then responsible for notifying FDA and all investigators.
References:21 CFR 812.150(a)(1).

NEW QUESTION # 34
In determining the classification of risk for a study involving a medical device, it is necessary to consider the:

- A. Use of the device in the particular study
- B. Investigators' prior training and experience
- C. Number of patients to be treated with the device
- D. Cost of device

Answer: A

Explanation:
FDA regulations for investigational devices are found under 21 CFR 812. Risk classification determines whether a device is considered Significant Risk (SR) or Non-Significant Risk (NSR). The critical factor is how the device will be used in the specific study.
21 CFR 812.3(m): Defines a "significant risk device study" as one that "is intended as an implant, is purported or represented to be for a use in supporting or sustaining human life, or otherwise presents a potential for serious risk to the health, safety, or welfare of a subject." Risk is judged within the context of the protocol - i.e., use of the device in that particular study (D).
Number of patients (A), device cost (B), or investigator experience (C) are irrelevant to FDA's risk classification. For example, a stent used in an approved indication may be NSR, but if used in a new anatomical location, it may be SR.
Therefore, the correct answer is D. This ensures ethical review bodies and FDA assess safety in the intended clinical context rather than device attributes alone.
References:
21 CFR 812.3(m) (Definition of significant risk device).
FDA Guidance on Significant Risk and Nonsignificant Risk Medical Device Studies.

NEW QUESTION # 35
According to the CFR, when children who are wards of the state are enrolled into a clinical trial, what is required?

- A. Assenting children must self-represent
- B. The investigator must represent the children
- C. The IRB/IEC must include a member who advocates for the children
- D. Each child must have a patient advocate

Answer: C

Explanation:
Children who are wards of the state receiveadditional protectionsin clinical research.
* 45 CFR 46.409(b):For research involving wards, "the IRB shall require appointment of an advocate for each child, in addition to any guardian or other advocate who would ordinarily be provided."
* The advocate must have background and experience to act in the child's best interest and cannot be associated with the research.
Thus, anIRB-appointed advocateis mandatory to ensure independent representation of the ward's rights.
References:45 CFR 46.409(b).

NEW QUESTION # 36
In accordance with the CFR, the IRB/IEC membership must have:

- A. At least one cleric
- B. A majority of individuals whose primary area of expertise is nonscientific
- C. At least one individual who is not affiliated with the institution
- D. At least seven individuals

Answer: C

Explanation:
IRBs must be diverse and independent to protect human subjects.
* 21 CFR 56.107(d):"Each IRB shall include at least one member whose primary concerns are in nonscientific areas... andat least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person affiliated with the institution." There is no minimum requirement of seven members (A). Nonscientists must be represented but not a majority (B). Clergy are not mandated (C). The critical safeguard is inclusion of at leastone unaffiliated member (D)to ensure independence.
Thus, the correct answer isD (At least one unaffiliated individual).
References:
21 CFR 56.107(d) (IRB membership requirements).

NEW QUESTION # 37
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