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Who was tried in the Nuremberg Military Tribunals and why? - ✓✓Doctors who committed war crimes against humanity including medical experiments on concentration camp inmates and other human subjects without consent

What was the outcome of the Nuremberg Military Tribunals? - ✓✓After 140 days of proceedings with testimony of 85 witnesses and submission of 1,500 documents, American judges convicted 16 doctors on 8/20/1947. Seven were sentenced to death and executed 6/2/1948.

What historical document was born from the Nuremberg Military Tribunals? - ✓✓The Nuremberg Code (1947)

According to the Nuremberg Code (1947), all unnecessary physical and mental suffering and injury... - ✓✓should be avoided

According to the Nuremberg Code (1947), voluntary consent of the human subject is... - ✓✓absolutely essential

According to the Nuremberg Code (1947), the experiment must yield.... - ✓✓generalizable knowledge that could not be obtained in any other way and is not random and unnecessary in nature

According to the Nuremberg Code (1947), animal experimentation should... - ✓✓precede human experimentation

According to the Nuremberg Code (1947), no experiment should be conducted if there is reason to believe... - ✓✓death of disabling injury will occur

According to the Nuremberg Code (1947), the degree of risk to subject should... - ✓✓never exceed the humanitarian importance of the problem

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details

Topic 1	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 (Q45-Q50):

NEW QUESTION # 45

During the closeout visit, a monitor is completing the documentation of reconciliation of investigational product. All packaging, as well as the used and unused investigational product, are being returned to the sponsor for disposition. Which of the following documents would NOT be required to be filed at the research site?

- A. Investigational product accountability forms
- B. Investigational product inventory forms
- C. Records of investigational product shipment
- **D. A certificate of investigational product destruction**

Answer: D

Explanation:

Investigators must document the receipt, use, return, or alternative disposition of investigational product (IP).

* ICH E6(R2) 4.6.3: Requires investigators to maintain records of IP delivery, inventory, use by subjects, and return/disposition.

* ICH E6(R2) 8.2.14-8.2.16: Essential documents include shipment records, accountability logs, and inventory records.

However, certificates of destruction are generated and retained by the sponsor (or authorized destruction facility), not required at the site unless the destruction occurred there. In this scenario, all IP was returned to the sponsor, so no destruction certificate would exist at the site.

Thus, the correct answer is D (Certificate of destruction).

References:

ICH E6(R2), §4.6.3 (Investigator product accountability).

ICH E6(R2), §8.2.14–8.2.16 (Essential documents).

NEW QUESTION # 46

If a subject experiences a serious adverse event related to the study drug and only minimal information is available, the investigator must submit the information to the:

- A. Sponsor and IRB/IEC within seven days
- B. IRB/IEC immediately, then sponsor when full details are available
- C. Sponsor and IRB/IEC within five days
- **D. Sponsor and IRB/IEC immediately, then update later**

Answer: D

Explanation:

* ICH E6(R2) 4.11.1: Investigators must "immediately report all serious adverse events to the sponsor except for those the protocol identifies as not requiring immediate reporting."

* IRB must also be informed promptly per 21 CFR 312.64(b).

* Follow-up information is submitted later as available.

References: ICH E6(R2), §4.11.1; 21 CFR 312.64(b).

NEW QUESTION # 47

In accordance with the CFR, which of the following statements regarding the informed consent document is correct?

- A. It is signed and dated by the subject's legally authorized representative
- B. It does not identify some of the applicable mandated basic elements
- **C. It identifies all of the applicable mandated basic elements**
- D. It is signed and dated by the IRB/IEC chair

Answer: C

Explanation:

The informed consent document (ICD) is a cornerstone of ethical clinical research, ensuring voluntary participation and protection of subject rights.

* 21 CFR 50.25(a): Requires the consent form to contain all basic elements, including study purpose, risks, benefits, alternatives, confidentiality, compensation, and voluntariness.

* ICH E6(R2) 4.8.10: Expands on these requirements, ensuring the ICD contains every mandated element without omission.

Thus, the correct statement is that the ICD must include all applicable mandated basic elements (D).

Options A and B confuse who signs—subjects or legally authorized representatives sign when applicable, not the IRB chair. Option C is incorrect because leaving out elements would violate compliance.

Correct answer: D.

References:

21 CFR 50.25(a).

ICH E6(R2), §4.8.10.

NEW QUESTION # 48

In accordance with the Belmont Report, obtaining voluntary informed consent from subjects prior to enrolling them in a clinical trial is an example of which of the following ethical principles?

- A. Do no harm
- B. Justice
- C. Beneficence
- **D. Respect for persons**

Answer: D

Explanation:

The Belmont Report (1979) established three key ethical principles:

* Respect for Persons: Requires informed consent, recognition of autonomy, and protection of vulnerable individuals.

* Beneficence: Obligation to maximize benefits and minimize harm.

* Justice: Ensuring fairness in subject selection and distribution of research burdens/benefits.

Voluntary informed consent embodies Respect for Persons, as subjects are given adequate information and freedom of choice. "Do no harm" (A) is a Hippocratic principle but not Belmont terminology.

Thus, the correct answer is B (Respect for persons).

References:

The Belmont Report (1979), Part B: Basic Ethical Principles.

NEW QUESTION # 49

A research site was invited to participate in an investigational drug study. Which of the following parties is responsible for determining the risk-benefit ratio at the site?

- A. The site's legal counsel
- B. The clinical investigator
- C. The sponsor
- **D. The IRB/IEC**

Answer: D

Explanation:

The risk-benefit ratio is a core responsibility of the IRB/IEC.

* 21 CFR 56.111(a)(2): "Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."

* ICH E6(R2) 3.1.2: IRB/IEC must safeguard rights, safety, and well-being of subjects, with special attention to risk-benefit evaluation.

Investigators (A) provide medical judgment but do not formally approve the risk-benefit balance. Sponsors (D) design studies but must submit to IRB for independent review. Legal counsel (C) is not part of the scientific/ethical evaluation.

Thus, IRB/IEC is directly responsible for approving the risk-benefit ratio.

References:

21 CFR 56.111(a)(2).

ICH E6(R2), §3.1.2.

NEW QUESTION # 50

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