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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What historical document was born from the Nuremberg Military Tribunals?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 Certified Clinical Research Professional (CCRP) Sample Questions (Q32-Q37):

NEW QUESTION # 32

Which of the following statements about the initial IND application submission by a sponsor to the U.S. Food and Drug Administration is correct?

- A. It is an application for the sponsor to sell the drug for profit
- B. It includes a disclosure of the financial interests and arrangements of clinical investigators
- C. It is an application to export the investigational drug
- **D. It includes the rationale for human testing and a description of the general investigational plan**

Answer: D

Explanation:

An Investigational New Drug (IND) application provides FDA with data to justify human testing.

* 21 CFR 312.23(a)(3): The IND must contain "a description of the general investigational plan, including the rationale for the drug or the research study."

* The IND also includes preclinical safety data, manufacturing details, investigator qualifications, and study protocols.

Financial disclosures (D) are reported separately under 21 CFR Part 54, not as part of the initial IND. Export applications (A) are covered under 21 CFR 312 Subpart E. Profit sales (C) are not permitted under INDs.

Thus, the correct answer is B (Rationale and plan for human testing).

References:

21 CFR 312.23(a)(3) (IND contents).

21 CFR 312.20 (General IND requirements).

NEW QUESTION # 33

An investigator received \$60,000 equity interest three years after study completion. What is the financial reporting requirement?

- **A. None**
- B. Report to FDA
- C. Report to sponsor
- D. Report to OHRP

Answer: A

Explanation:

* 21 CFR 54.4(b): Requires disclosure during the study and for 1 year after completion.

* After three years, no disclosure is required.

References: 21 CFR 54.4(b).

NEW QUESTION # 34

Which of the following is considered a source document?

- A. Standard operating procedures (SOPs)
- **B. Pharmacy dispensing records**
- C. The subject instruction sheet
- D. The protocol

Answer: B

Explanation:

Source documents are the original records where trial data are first recorded, from which Case Report Form (CRF) entries are verified.

* ICH E6(R2) 1.52: Defines source documents as "original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, pharmacy dispensing records, recorded data from automated instruments, etc.)."

* ICH E6(R2) 8.3.13: Requires maintenance of "source documents" to verify data integrity and allow monitoring/audits.

Pharmacy dispensing records (D) fit this definition, as they show initial data on investigational product dispensing and accountability. In contrast, subject instruction sheets (A) are communication tools, SOPs (B) are procedural guides, and the protocol (C) is a

governing document, none of which qualify as original data records. Therefore, the correct answer is D (Pharmacy dispensing records).

References:

ICH E6(R2), §1.52 (Definition of source documents).

ICH E6(R2), §8.3.13 (Source documents in essential documentation).

NEW QUESTION # 35

A study coordinator is preparing an IRB submission for a Phase II oncology study. Which document must be included?

- A. Case report forms
- B. Record storage plan
- C. Recruitment materials
- D. List of potential subjects

Answer: C

Explanation:

* ICH E6(R2) 3.1.2 & FDA Recruitment Guidance (1998): Recruitment materials must be reviewed by IRB to ensure no coercion or misleading claims.

* CRFs and storage plans are sponsor/site tools, not IRB-reviewed documents.

References: ICH E6(R2) §3.1.2; FDA Recruitment Guidance, 1998.

NEW QUESTION # 36

A research protocol requires patients to complete a patient reported outcome questionnaire in the sponsor's electronic data capture (EDC) system. What is the source data?

- A. A printout of the EDC record
- B. The electronic medical record
- C. A printout of the electronic medical record
- D. The EDC record

Answer: D

Explanation:

Source data are original records where data are first recorded.

* ICH E6(R2) 1.51: Defines source data as "all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial." Since subjects directly enter responses into the EDC, the EDC record itself is the original source document.

EMRs (B, C) and printouts (D) are secondary records.

Correct answer: A (The EDC record).

References:

ICH E6(R2), §1.51 (Definition of source data).

NEW QUESTION # 37

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