

100% Pass Quiz 2026 SOCRA CCRP: Unparalleled Training Certified Clinical Research Professional (CCRP) Solutions

SOCRA - CCRP (high level) Quiz Questions with 100% Correct Solutions| Rated A+

Nuremberg Code (1947) - ✓✓ A research ethics code that arose in response to the Nazis' inhumane experimentation (nuremberg trials) - holocaust, racial hygiene / eugenics / master race.

The Nuremberg Code - 10 points - ✓✓

1. voluntary
2. necessary for results
3. logical design and results
4. avoid unnecessary harm
5. cannot result in death or disablement
6. risk assessment
7. protect subjects against harm
8. qualified investigators
9. right to withdrawal
10. right to end trial if needed

Belmont Report (1979) - ✓✓ Three core principles are identified: respect for persons, beneficence, and justice.

Arose in response to Tuskegee Syphilis Study - studying untreated syphilis on African-American men unaware of their true condition and tx plan.

Belmont Report - definitions of core - ✓✓

1. Respect for persons: informed consent + no deception
2. Beneficence: maximize benefits and minimize risk
3. Justice: fair procedures considering risk analysis.

Belmont Report - current role - ✓✓ Serves as a historical document and provides the moral framework for understanding regulations in the United States on the use of humans in experimental methods.

Belmont Report - review of 7 items for research trials - ✓✓

1. IRB approved
2. Obtain informed consent
3. Ensure understanding
4. No coercion
5. Monitor adverse events
6. Maintain privacy

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q25-Q30):

NEW QUESTION # 25

A coordinator for an ongoing industry-sponsored, multi-site Phase II clinical trial is taking an unexpected, long-term medical absence. The trial site retains coordinator services from an external source to support clinical trial activities. According to the ICH GCP Guideline, which of the following is responsible for implementing procedures to ensure the integrity of the clinical trial-related duties?

- A. The external source
- **B. The investigator/institution**
- C. The sponsor
- D. The IRB/IEC

Answer: B

Explanation:

The investigator/institution bears responsibility for site conduct, oversight of delegated tasks, and ensuring qualified, trained staff regardless of employment source. Exact extracts:

* ICH E6(R2) 4.1.1: "The investigator should be qualified... and have adequate resources to properly conduct the trial."

* ICH E6(R2) 4.1.5: "The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions."

* ICH E6(R2) 4.2.5: "The investigator may delegate... but retains responsibility for the conduct of the trial at the site." Therefore, the investigator/institution (B) must implement procedures and oversight to maintain integrity of trial duties.

References:

ICH E6(R2) Good Clinical Practice, §4.1.1; §4.1.5; §4.2.5 (Investigator responsibilities; delegation and oversight).=====

NEW QUESTION # 26

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

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

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 # 27

A company's CEO wants to commercially promote a device under an IDE study. This plan:

- A. Requires a large advertising budget
- B. Requires IRB/IEC approval
- C. Requires IDE approval
- **D. Would violate FDA regulations**

Answer: D

Explanation:

* 21 CFR 812.7: Prohibits promotion of investigational devices or claiming safety/effectiveness until FDA approval is granted.

* Investigational devices may only be used in clinical trials, not marketed.

Thus, promotion during an IDE study is an FDA violation.

References: 21 CFR 812.7.

NEW QUESTION # 28

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 IRB/IEC**
- D. The sponsor

Answer: C

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 # 29

In order to adequately monitor a clinical trial, the monitor must be familiar with each of the following, EXCEPT the:

- A. Sponsor's SOPs
- B. Written information to be provided to the subjects
- **C. IRB/IEC requirements for reporting to the regulatory authority**
- D. Requirements for storage of the investigational product

Answer: C

Explanation:

Monitors verify compliance with protocol, sponsor SOPs, GCP, and regulations.

* ICH E6(R2) 5.18.4: Outlines monitor responsibilities, including verifying informed consent, protocol compliance, investigational product accountability, and adherence to sponsor SOPs.

* Monitors must also be familiar with subject-facing documents (A) and storage requirements for investigational product (B).

However, IRB/IEC requirements for reporting to regulatory authorities are outside a monitor's scope.

That responsibility lies with investigators and IRBs under 21 CFR 56.108(b).

Thus, the correct answer is D.

References:

ICH E6(R2), §5.18.4.

21 CFR 56.108(b).

NEW QUESTION # 30

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