DirectCertify

Unlock Your Potential, Certify Your Success

SOCRA

CCRP Exam

Certified Clinical Research Professional (CCRP)

Exam Latest Version: 6.0

DEMO Version

Full Version Features:

• 90 Days Free Updates

• 30 Days Money Back Guarantee

• Instant Download Once Purchased

• 24 Hours Live Chat Support

Full version is available at link below with affordable price.

https://www.directcertify.com/socra/ccrp

Question 1. (Single Select)

Which of the following is an example of an additional protection required when conducting research on children?

A: There must be an impartial advocate present during the consent process
B: The investigator must obtain age-appropriate assent as determined by the IRB/IEC
C: Parents must be present during all procedures
D: The study must be approved by a central pediatric IRB

Correct Answer: B

Explanation:

Children are a vulnerable population. U.S. regulations require IRB/IEC judgment about when and how assent is obtained, in addition to parental permission. Exact extracts:

45 CFR 46.408(a): “The IRB shall determine … whether and to what extent children are capable of providing assent.”

ICH E6(R2) 4.8.12: “Where a subject is unable to give consent personally, assent should be obtained when appropriate, in accordance with applicable regulatory requirement(s).”

Thus, the additional protection is IRB-determined, age-appropriate assent (B). Options A, C, and D are not universal requirements for all pediatric research.

ICH E6(R2) Good Clinical Practice, §4.8.12 (Informed consent/assent).

45 CFR 46 Subpart D—Additional Protections for Children, §46.408(a).

==========

Question 2. (Single Select)

In accordance with the CFR, a sponsor must submit a protocol amendment to the FDA for which

of the following?

A: The addition of a new test that is intended to improve monitoring the subject for an adverse effect
B: A significant change in an investigator's financial interest in the investigational product
C: The addition of a sub-investigator with the scientific training and expertise to conduct the investigation
D: A change in the manufacturing site for the investigational product

Correct Answer: D

Explanation:

The U.S. Code of Federal Regulations (CFR) specifies when sponsors must notify FDA of changes to investigational drug studies under 21 CFR 312.30. A protocol amendment is required if there is:

A change to the protocol (e.g., objectives, design, subject population, dosing, or procedures).

The addition of a new investigator.

A change in the chemistry, manufacturing, or controls (CMC) that could significantly affect product quality or safety.

Among the listed options, a change in the manufacturing site (D) directly falls under significant manufacturing changes, requiring FDA submission. Changes in investigator financial interests (B) are covered under 21 CFR 54 and reported separately, not as protocol amendments. Addition of a sub-investigator (C) does not require a formal amendment, only site-level documentation and delegation log update. Addition of a monitoring test (A) may affect the protocol, but not necessarily mandate an amendment unless it changes objectives or subject safety endpoints.

Therefore, the correct answer is D. This ensures FDA oversight of product safety, efficacy, and compliance with CMC standards before investigational use.

21 CFR 312.30 (Protocol amendments).

21 CFR 312.23(a)(7) (Chemistry, manufacturing, and controls information).

Question 3. (Single Select)

In an IND study, the specified dosage of an investigational product is 2 mg twice a day for 10 days. The product is available in 1 mg tablets. The subject was given 45 tablets and was instructed to take 2 mg of the product twice a day for 10 days. How many tablets should the subject have after the 10 days?

A: 0
B: 1
C: 5
D: 20

Correct Answer: C

Explanation:

This question tests drug accountability and dosing calculation, which is central to ICH E6(R2) 4.6 (Investigational product management). Subjects must receive the correct supply and any discrepancy must be reconciled.

The prescribed regimen is 2 mg twice daily = 4 mg per day. With 1 mg tablets, this equals 4 tablets daily. Over 10 days, the subject should consume 40 tablets (4 × 10 = 40). Since 45 tablets were dispensed, the subject should have 5 tablets remaining after 10 days.

Accurate accountability ensures trial integrity and subject safety. Investigators are responsible for maintaining investigational product (IP) records, including dispensing, usage, and returns. According to ICH:

4.6.3: “The investigator/institution should maintain records of the product’s delivery to the trial site, the inventory, the use by each subject, and the return to the sponsor or alternative disposition.”

4.6.5: “The investigator should ensure that investigational products are used only in accordance with the approved protocol.”

Thus, the correct answer is C (5 tablets remain). This reflects proper dosing compliance and highlights the importance of meticulous IP tracking in clinical trials.

ICH E6(R2), §4.6 (Investigational Product(s)).

Question 4. (Single Select)

According to the CFR and the ICH GCP Guideline, which of the following must be submitted to the IRB after completion of the trial at the site?

A: The final report
B: The monitoring close-out visit report
C: The data safety monitoring summary
D: The final subject enrollment log

Correct Answer: A

Explanation:

When a trial ends at a site, the investigator has an obligation to submit a final report to the IRB/IEC. This is outlined in both ICH and CFR:

ICH E6(R2) 4.13: “Upon completion of the trial, the investigator should provide the IRB/IEC with a summary of the trial’s outcome.”

21 CFR 312.66: Requires investigators to “report to the IRB all changes in the research activity and all unanticipated problems involving risk, and to provide reports at the end of the study.”

The final report provides closure and documentation that the study was conducted ethically and in compliance with regulatory standards. Other documents listed in the options (monitoring reports, DSMB summaries, subject logs) may be retained by the sponsor or site, but they are not mandated for IRB submission.

Thus, the correct answer is A (Final Report). This ensures the IRB/IEC has an accurate record of study completion, outcome, and compliance with ethical oversight.

ICH E6(R2), §4.13 (Final reporting to IRB/IEC).

21 CFR 312.66 (IRB review and reporting).

Question 5. (Single Select)

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

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

Correct Answer: D

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.

21 CFR 812.3(m) (Definition of significant risk device).

FDA Guidance on Significant Risk and Nonsignificant Risk Medical Device Studies.

DirectCertify

Unlock Your Potential, Certify Your Success

Full version is available at link below with affordable price.

https://www.directcertify.com/socra/ccrp

30% Discount Coupon Code: LimitedTime2025