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CERTIFIED CLINICAL RESEARCH PROFESSIONAL (CCRP) EXAM QUESTIONS WITH CORRECT ANSWERS

When isn't an IND application needed? - Answer IND Application is not needed if investigation does not support change in labeling

What information must the general IND include? (21 CFR Part 312.23) - Answer

- FDA Form 1571:
- FDA Form 1571 cover sheet
- Table of contents
- Investigative plan
- Investigator's brochure
- Protocol
- Chemistry/Manufacturing information
- Pharmacology/toxicology
- Previous human research/literature information
- Additional information (drug dependence and abuse potential)

How many days after FDA receives IND submission does the IND go into effect? (21 CFR 312.40) - Answer An IND goes into effect 30 days after the FDA receives the submission unless the FDA notifies the Sponsor of a clinical hold

When must an IND amendment be submitted? (21 CFR Part 312.31) - Answer -If there are changes to the protocol that affects safety of subjects, scientific quality of the study, or scope of investigation

- If a new investigator is added to the study
- Information amendments must be submitted for chemistry/microbiology, pharm/toxicology, or clinical

OTHER SUBMISSIONS:

- IND safety reports
- Response to clinical hold
- Response to FDA request for information
- IRB Annual report

What are the requirements for expanded access? (21 CFR Part 312.300 - Subpart 1) - Answer

- Population must have serious or life-threatening disease or condition
- No comparable/significant alternate therapy/treatment
- Patient cannot obtain drug under another IND or protocol
- Potential benefit outweighs risks of treatment

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q126-Q131):

NEW QUESTION # 126

A research assistant on a study was recently promoted to a clinical research coordinator (CRC) role after one year on the study. In order to fulfill the significant new responsibilities, the CRC completed additional institutional training. According to ICH GCP Guidelines and 21 CFR, which of the following must be filed in the regulatory binder?

- A. The letter documenting the promotion to a CRC
- B. A brochure from the training course
- **C. An updated curriculum vitae**
- D. An updated performance review summary

Answer: C

Explanation:

The regulatory binder (investigator site file) must contain documents verifying qualifications of all personnel.

These include curricula vitae (CVs), professional licenses, and training certificates.

ICH E6(R2) 4.1.5: "The investigator should ensure that all persons assisting with the trial are qualified by education, training, and experience... Current curriculum vitae and/or other relevant documents evidencing qualifications should be maintained."

21 CFR 312.53(c)(1): Sponsors must select investigators qualified "by training and experience," and investigators must provide sufficient documentation, typically updated CVs.

Letters of promotion (A), training brochures (B), or performance reviews (C) may remain in personnel files but are not required regulatory documents. The only acceptable regulatory proof is an updated CV (D), which reflects the individual's training and qualifications for their new role.

Therefore, the correct answer is D (Updated CV). This ensures compliance with ICH and FDA requirements for staff qualification documentation in clinical research.

References:

ICH E6(R2) Good Clinical Practice, §4.1.5 (Investigator responsibilities for staff qualification).

21 CFR 312.53(c)(1) (Investigator qualifications and documentation).

NEW QUESTION # 127

A subject currently on a clinical trial was hospitalized for 2 days due to a SAE. The subject reported the hospitalization to the investigator at the next study visit. According to the ICH GCP Guideline, when should the investigator report the SAE to the sponsor?

- **A. Immediately**
- B. Within 7 working days
- C. Within 10 working days
- D. Within 15 working days

Answer: A

Explanation:

ICH requires immediate reporting of all SAEs to the sponsor (except those protocol-identified as not requiring immediate reporting).

Exact extract:

* ICH E6(R2) 4.11.1: "The investigator should report all serious adverse events immediately to the sponsor except for those SAEs that the protocol... identifies as not needing immediate reporting." Therefore, "Immediately" (A) is correct. The other timeframes are not aligned with ICH GCP for initial SAE notification from investigator to sponsor.

References:

ICH E6(R2) Good Clinical Practice, §4.11.1 (Safety reporting by investigators).=====

NEW QUESTION # 128

Protocol increases drug dose by 20%. Baseline: 370 mg/m². New dose = ?

- A. 492 mg/m²
- B. 420 mg/m²
- C. 444 mg/m²
- D. 400 mg/m²

Answer: C

Explanation:

$370 \times 1.20 = 444 \text{ mg/m}^2$.

Accurate dosing calculations are critical for protocol adherence and patient safety.

References: Standard pharmacology dose adjustment principles; ICH E6(R2) §4.5.1.

NEW QUESTION # 129

According to ICH GCP, sponsor-specific essential documents must be retained until:

- A. 25 years after last approval
- B. 3 years after last approval
- C. 5 years after last approval
- D. 2 years after last approval and no pending applications

Answer: D

Explanation:

* ICH E6(R2) 5.5.12 & 8.1: Essential documents must be retained 2 years after the last approval of a marketing application in an ICH region and until no applications are pending, or 2 years after discontinuation of development.

This ensures availability for inspection.

References: ICH E6(R2) §§5.5.12, 8.1.

NEW QUESTION # 130

In accordance with the CFR, which body must determine that a study meets the criteria for minimal risk?

- A. A data safety monitoring board
- B. The medical monitor
- C. The reviewing IRB/IEC
- D. The clinical investigator

Answer: C

Explanation:

Minimal risk determination is a regulatory function of the IRB/IEC.

* 45 CFR 46.102(j): Defines minimal risk as harm or discomfort not greater than those ordinarily encountered in daily life.

* 45 CFR 46.109(a): The IRB has authority to approve, require modifications, or disapprove research, including assessment of risk level.

* Investigators may propose a study as minimal risk, but only the IRB/IEC can formally classify it.

This ensures independent, unbiased evaluation of risk, protecting participants from investigator or sponsor bias.

References: 45 CFR 46.102(j), 46.109(a).

NEW QUESTION # 131

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Naturally, several things had to change to support the new protocol—not the least CCRP of which is the IP packet. The following article addresses how to detect and troubleshoot unicast flooding issues due to spanning tree topology changes.

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