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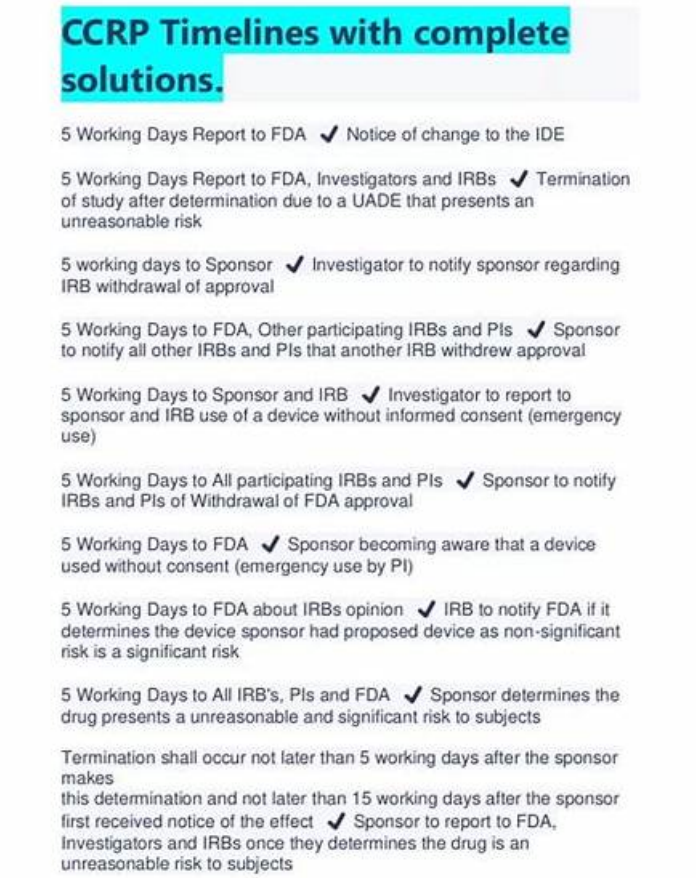
CCRP Timelines with complete solutions.

5 Working Days Report to FDA ✓ Notice of change to the IDE

5 Working Days Report to FDA, Investigators and IRBs ✓ Termination of study after determination due to a UADE that presents an unreasonable risk

5 working days to Sponsor ✓ Investigator to notify sponsor regarding IRB withdrawal of approval

5 Working Days to FDA, Other participating IRBs and PIs ✓ Sponsor to notify all other IRBs and PIs that another IRB withdrew approval

5 Working Days to Sponsor and IRB ✓ Investigator to report to sponsor and IRB use of a device without informed consent (emergency use)

5 Working Days to All participating IRBs and PIs ✓ Sponsor to notify IRBs and PIs of Withdrawal of FDA approval

5 Working Days to FDA ✓ Sponsor becoming aware that a device used without consent (emergency use by PI)

5 Working Days to FDA about IRBs opinion ✓ IRB to notify FDA if it determines the device sponsor had proposed device as non-significant risk is a significant risk

5 Working Days to All IRB's, PIs and FDA ✓ Sponsor determines the drug presents a unreasonable and significant risk to subjects

Termination shall occur not later than 5 working days after the sponsor makes
this determination and not later than 15 working days after the sponsor first received notice of the effect ✓ Sponsor to report to FDA, Investigators and IRBs once they determines the drug is an unreasonable risk to subjects

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q12-Q17):

NEW QUESTION # 12
What is included in the Statement of Investigator (Form FDA 1572)?

- A. A statement disclosing investigator financial interests
- B. A statement agreeing to comply with FDA regulations
- C. A statement responding to FDA inspection observations
- D. A statement describing preclinical and human safety data

Answer: B

Explanation:
FormFDA 1572is the investigator's signed agreement to follow regulations.
* 21 CFR 312.53(c)(1)(vi)(c):Requires investigators to sign Form 1572, committing to conduct trials in accordance withFDA regulations (21 CFR 50 & 56).
* The form includes commitments to personally supervise, obtain informed consent, maintain records, and permit FDA inspections.
It does not include financial disclosures (covered under21 CFR 54) or preclinical data (in theIB).
References:21 CFR 312.53(c)(1)(vi)(c).

NEW QUESTION # 13
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 wouldNOTbe required to be filed at the research site?

- A. Investigational product inventory forms
- B. Investigational product accountability 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 destructionare 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 isD (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 # 14
In accordance with the ICH GCP Guideline, when a sponsor transfers trial-related duties andfunctions to a contract research organization (CRO), who is ultimately responsible for the quality and integrity of the trial data?

- A. The IRB/IEC
- B. The sponsor
- C. The CRO

- D. The investigator

Answer: B

Explanation:
Outsourcing does not shift ultimate responsibility away from the sponsor. Exact extract:
* ICH E6(R2) 5.2.1: "A sponsor may transfer any or all of the sponsor's trial-related duties... to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor."Hence, D is correct.
References:
ICH E6(R2) Good Clinical Practice, §5.2.1 (Sponsor/CRO).==========

NEW QUESTION # 15
An investigator received $60,000 equity interest three years after study completion. What is the financial reporting requirement?

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

Answer: A

Explanation:
* 21 CFR 54.4(b):Requires disclosureduring the study and for 1 year after completion.
* After three years, no disclosure is required.
References:21 CFR 54.4(b).

NEW QUESTION # 16
Which document was created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and summarizes the basic ethical principles and guidelines for the conduct of research involving human subjects?

- A. The ICH Guidelines
- B. The Nuremberg Code
- C. The Declaration of Helsinki
- D. The Belmont Report

Answer: D

Explanation:
TheBelmont Report (1979), issued by the U.S. National Commission, identifiesthree core ethical principles guiding human subject research:
* Respect for Persons(informed consent, autonomy, protection of vulnerable populations).
* Beneficence(maximize benefits, minimize harms).
* Justice(fairness in subject selection and treatment).
* TheNuremberg Code (1947)was developed post-WWII to prevent unethical experiments.
* TheDeclaration of Helsinki (1964, updated)is a World Medical Association document guiding international physician research ethics.
* TheICH Guidelines (1996)outline harmonized regulatory requirements for good clinical practice.
Only the Belmont Report fits the description of a U.S.-based, principle-driven framework for human research ethics.
Thus, the correct answer isD (The Belmont Report).
References:
The Belmont Report (1979), National Commission for the Protection of Human Subjects.
45 CFR 46 (Human Subject Protections).

NEW QUESTION # 17
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