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CCRP Patient Assessment Test with complete solutions.

Assessment ✓ an objective evaluation or appraisal of an individual's health status, including acute and chronic conditions

How does an assessment gather information? ✓ through collection of data, observation, and physical examination

What type of assessment?

•Gather information about the patient from available sources such as medical records or reports from diagnostic studies
• Perform direct measurements on the patient such as 12-lead EKG, blood pressure, or body mass index ✓ objective assessment

What type of assessment?

• Conduct standardized tests, such as a 12-lead EKG or a 6 minute walk test
• Observe patient responses or reactions such as cardiac rhythms on telemetry, oxygen saturation on pulse oximetry ✓ objective assessment

In what type of assessment does the patient provides the information, usually as solicited ✓ Subjective assessment

What type of assessment does the patient?

• Describing their cardiac event
• Rating their level of pain or exertion ✓ Subjective assessment

What type of assessment does the patient?

• Reporting on recent behavior, eg, diet, smoking, exercise
• Evaluating their own status by completing surveys ✓ Subjective assessment

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q88-Q93):

NEW QUESTION # 88
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 bequalified... and haveadequate resourcesto properly conduct the trial."
* ICH E6(R2) 4.1.5: "The investigatorshould ensure that all persons assistingwith the trial are adequately informedabout the protocol, the investigational product(s), and their trial-related duties and functions."
* ICH E6(R2) 4.2.5: "The investigatormay delegate... butretains responsibilityfor 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 # 89
According to ICH GCP, sponsor-specific essential documents must be retained until:

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

Answer: A

Explanation:
* ICH E6(R2) 5.5.12 & 8.1:Essential documents must be retained2 years after the last approval of a marketing application in an ICH region and until no applications are pending, or2 years after discontinuation of development.
This ensures availability for inspection.
References:ICH E6(R2) §§5.5.12, 8.1.

NEW QUESTION # 90
For a study with a significant risk investigational medical device that could optimize the effects of radiation therapy on cancer tumors, the investigational plan states mild burns are an anticipated effect. One subject developed severe burns with blistering. In accordance with the CFR, this effect must be reported to the sponsor and the IRB/IEC as soon as possible and at most how long after the investigator first learns of the effect?

- A. 2 working days
- B. 5 working days
- C. 7 working days
- D. 10 working days

Answer: D

Explanation:
In device trials,unanticipated adverse device effects (UADEs)must be promptly reported.
* 21 CFR 812.150(a)(1):"An investigator shall submit to the sponsor and the reviewing IRB a report of anyunanticipated adverse

device effectas soon as possible, but in no event later than10 working days after the investigator first learns of the effect." In this case,severe burns with blisteringgo beyond the anticipated effect of mild burns listed in the investigational plan. Therefore, it qualifies as aUADEand triggers expedited reporting. Options A, B, and C are too short; the regulation specifically mandates a10 working day maximumtimeframe.
Thus, the correct answer isD (10 working days).
References:
21 CFR 812.150(a)(1) (Reporting requirements for investigators).

NEW QUESTION # 91
Which of the following is one of the responsibilities of an investigator who is NOT a sponsor?

- A. Ensuring that all participating investigators are promptly informed of significant new adverse events
- B. Ensuring proper monitoring of an investigation at all investigational sites
- C. Reporting serious adverse events to the applicable regulatory agency
- D. Maintaining control of the investigational product

Answer: D

Explanation:
For non-sponsor investigators, responsibilities are limited tosite-level conduct and product accountability.
* ICH E6(R2) 4.6.1:"Responsibility for investigational product(s) accountability at the trial site rests with the investigator/institution."
* 21 CFR 312.61:Requires the investigator to administer investigational drugs only to subjects under their supervision and maintain control.
Other responsibilities listed belong tosponsors:
* A: Reporting SAEs to FDA is a sponsor duty (investigators report to sponsor, not directly to FDA).
* B: Monitoring at all sites is a sponsor responsibility.
* C: Disseminating safety updates is a sponsor's role.
Correct answer:D (Maintaining control of IP).
References:
ICH E6(R2), §4.6.1.
21 CFR 312.61.

NEW QUESTION # 92
A Phase I study of a new blood pressure medication has been submitted for initial approval to an IRB/IEC. In accordance with the CFR, the IRB/IEC must consider which of the following criteria when determining whether to approve the study?

- A. The equitability of the selection of subjects
- B. The educational background of the study team
- C. The funding source for the trial
- D. The availability of the patient population

Answer: A

Explanation:
When reviewing protocols, IRBs/IECs are primarily responsible forsafeguarding human subjectsby evaluating risks, benefits, and fairness in subject selection.
* 21 CFR 56.111(a)(3):"In making its determination the IRB shall determine that... selection of subjects is equitable."
* 45 CFR 46.111(a)(3):Repeats this requirement, emphasizing fairness across gender, race, age, and socioeconomic status.
Other options:
* Patient population availability (A) is afeasibility issue, addressed by investigators and sponsors, not IRBs.
* Education of the study team (C) is confirmed by thesponsor and investigator, not IRB.
* Funding sources (D) may raise conflict of interest concerns, but they are not IRB approval criteria per federal regulations.
Thus, IRBs focus onjustice and fairness in subject selectionas part of the Belmont Report principles.
References:
21 CFR 56.111(a)(3).
Belmont Report (Justice principle).

NEW QUESTION # 93
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