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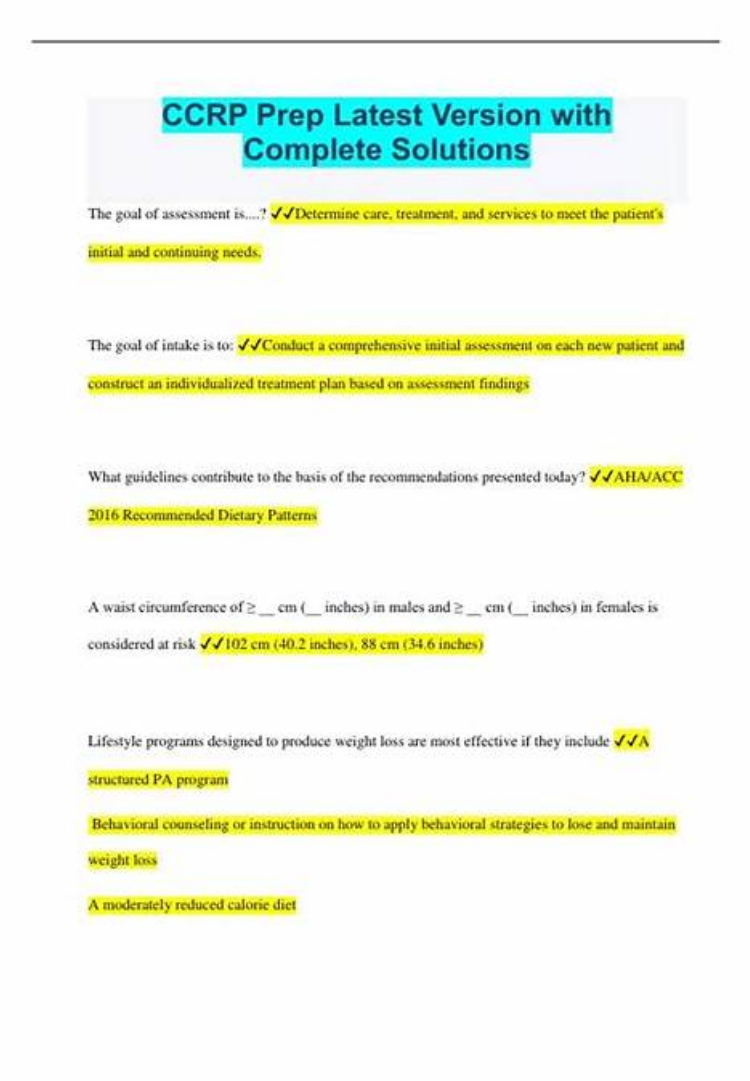

CCRP Prep Latest Version with Complete Solutions

The goal of assessment is....? ✓✓Determine care, treatment, and services to meet the patient's initial and continuing needs.

The goal of intake is to: ✓✓Conduct a comprehensive initial assessment on each new patient and construct an individualized treatment plan based on assessment findings

What guidelines contribute to the basis of the recommendations presented today? ✓✓AHA/ACC 2016 Recommended Dietary Patterns

A waist circumference of ≥ __ cm (__ inches) in males and ≥ __ cm (__ inches) in females is considered at risk ✓✓102 cm (40.2 inches), 88 cm (34.6 inches)

Lifestyle programs designed to produce weight loss are most effective if they include ✓✓A structured PA program

Behavioral counseling or instruction on how to apply behavioral strategies to lose and maintain weight loss

A moderately reduced calorie diet

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	• Research Study Closure: This section of the exam measures the skills of Clinical Research Coordinators and covers the activities required to properly conclude a clinical trial. It involves participating in the study closeout visit to verify documentation and account for the investigational product. The domain also includes developing and submitting final closure reports to the IRB, study sponsor, regulatory authorities, and clinicaltrials.gov. Finally, it covers the procedures for archiving study records.

Topic 2	• Research Study Start-Up: This section of the exam measures the skills of Clinical Research Coordinators and covers the initial planning and setup of a clinical trial. It involves coordinating the development of the study protocol, ensuring it considers ethical guidelines and regulatory pathways like IND or IDE. It also includes creating essential study documents like informed consent forms and case report forms. The domain covers obtaining necessary approvals from stakeholders like the IRB and sponsor, selecting study sites, training staff, and ensuring the study's compliance with various laws. Additionally, it involves obtaining the research product and preparing all necessary tools and documentation for the study's commencement.|Research Study Implementation: This section of the exam measures the skills of Clinical Research Associates and covers the active management and execution of the clinical trial. It focuses on following the study protocol and standard operating procedures, managing the investigational product, and ensuring ongoing regulatory compliance. The domain includes identifying, documenting, and reporting any study anomalies such as adverse events or protocol deviations. It also involves managing subject recruitment, consent, and retention, as well as maintaining all study records and essential documents. Furthermore, it covers communicating with all study stakeholders and participating in study audits to ensure quality and adherence to regulations.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q82-Q87):

NEW QUESTION # 82
Upon completion of a study, the investigator should do which of the following?

- A. Ensure that all payments from sponsor have been received
- B. Compile site data, publish the study results, and submit the publication to the IRB/IEC as the final report
- C. Provide the IRB/IEC a final report, but only if the study has a positive outcome
- D. As soon as possible, provide the IRB/IEC with a final report that summarizes the trial's outcome

Answer: D

Explanation:
Investigators must formally close out a trial with the IRB/IEC.
* ICH E6(R2) 4.13.2:"Upon completion of the trial, the investigator/institution should provide the IRB /IEC with a summary of the trial's outcome."
* 21 CFR 312.66:Reinforces investigator's duty to keep IRB informed throughout study lifecycle.
This applies regardless of whether outcomes were positive, negative, or inconclusive. IRBs are not concerned with sponsor payments (B) or publications (D).
Thus, the correct answer isA (Provide final report to IRB/IEC).
References:
ICH E6(R2), §4.13.2 (Final reporting requirement).

NEW QUESTION # 83
Which of the following statements about the FDA's authority to inspect IRB/IEC records is correct?

- A. The FDA may inspect them at reasonable times, in a reasonable manner, but may not take copies unless requested with an affidavit
- B. The FDA does not have regulatory authority to inspect them
- C. The FDA may inspect them at reasonable times, in a reasonable manner, and may take copies of IRB

/IEC records
- D. The FDA may inspect them only if the IRB/IEC formally requests inspection

Answer: C

Explanation:
The FDA has full regulatory authority to inspect IRB/IEC records.
* 21 CFR 56.115(b):"The IRB shall permit representatives of the Food and Drug Administration to inspect and copy all records maintained... at reasonable times and in a reasonable manner." Thus, FDA mayinspect and copyIRB/IEC records without requiring an affidavit or invitation. This ensures regulatory oversight and human subject protection.
Incorrect options:
* (A) limits authority incorrectly.
* (C) is false - FDA explicitly regulates IRBs.
* (D) is false - FDA does not need IRB invitation.
Correct answer:B.
References:
21 CFR 56.115(b).

NEW QUESTION # 84
A sponsor received a report from an investigator regarding the investigator's use of an investigational device without having obtained informed consent. The sponsor must submit a copy of the report to the FDA within:

- A. 5 working days
- B. 1 day
- C. 30 working days
- D. 10 working days

Answer: A

Explanation:
Informed consent is a fundamental ethical requirement. If it is violated in a device trial, the FDA requires rapid reporting.
* 21 CFR 812.150(b)(5):States that a sponsor shall submit to FDA "any report of use of a device without obtaining informed consent, within5 working daysafter the sponsor first receives notice of such use."
* This expedited reporting ensures FDA oversight of serious violations and protection of human subjects.
Incorrect options:
* A (1 day) is overly strict and not codified.
* C (10 days) and D (30 days) are too delayed to meet regulatory intent of immediate oversight.
Thus, the correct timeline iswithin 5 working days.
References:
21 CFR 812.150(b)(5).

NEW QUESTION # 85
Which of the following is an adequate definition of quality assurance for the conduct of a clinical trial?

- A. The systematic plan to review, approve, and monitor biomedical and behavioral research involving human subjects
- B. The planned and systematic actions established to ensure that the trial is performed and the data are generated, documented, and reported in compliance with GCP and the applicable regulatory requirements
- C. The act of reviewing and approving the investigational protocol and informed consent document
- D. An official review by a regulatory authority of documents, facilities, records, and any other resources that are deemed to be related to the trial

Answer: B

Explanation:
Quality assurance (QA)is proactive and systematic, designed to prevent errors and ensure compliance.
* ICH E6(R2) 1.46:Defines QA as "all those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented, and reported in compliance with GCP and applicable regulatory requirements." Option A describes IRB responsibilities, Option C describesaudit, and Option D describes protocol approval processes. OnlyBaccurately matches the ICH definition of QA. QA is distinct fromquality control (QC), which is operational and focused on detection of issues

during conduct.
Thus, the correct answer isB.
References:
ICH E6(R2), §1.46 (Definition of Quality Assurance).

NEW QUESTION # 86
Which of the following elements should NOT influence the investigator's ability to obtain endpoint data?

- A. Complexity of study
- B. Participant compliance
- C. Complexity of CRFs
- D. Length of study follow-up

Answer: C

Explanation:
* Endpoint data collection is based onprotocol designand subject compliance, not CRF formatting.
* ICH E6(R2) 4.9.0:Investigator responsible for data accuracy regardless of CRF complexity.
References:ICH E6(R2), §4.9.0.

NEW QUESTION # 87
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