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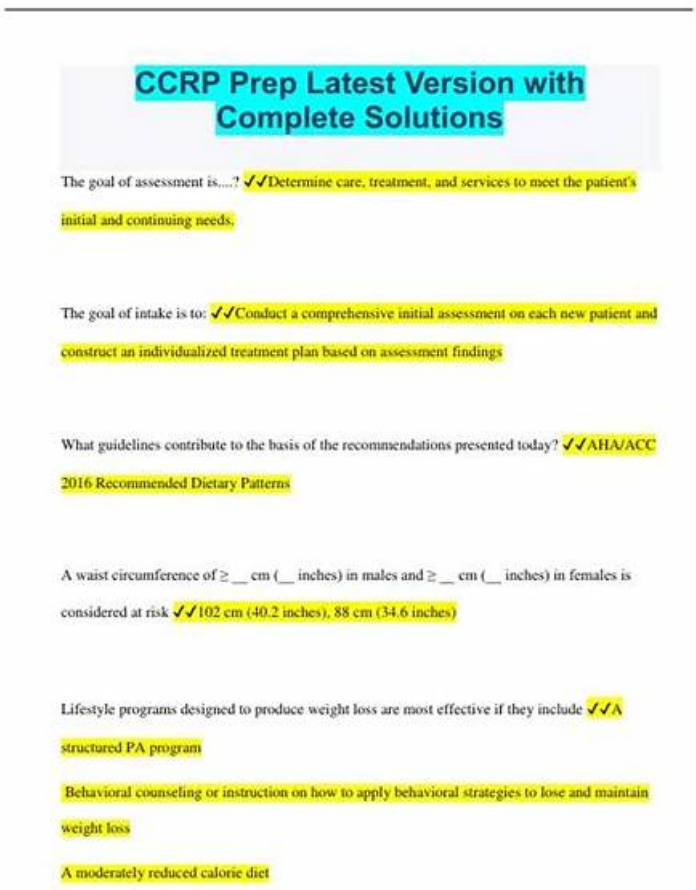

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The goal of assessment is....? ✓✓Determine care, treatment, and services to meet the patient's initial and continuing needs.

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 Certified Clinical Research Professional (CCRP) Sample Questions (Q25-Q30):

NEW QUESTION # 25
An investigator is working with a new sponsor to submit a cardiovascular trial to the IRB/IEC. In accordance with the ICH GCP Guidelines, which parties should sign the protocol to confirm agreement that the trial will be conducted as agreed?

- A. The investigator/institution and the sponsor
- B. The investigator/institution and the delegated site staff
- C. The sponsor and the FDA
- D. The sponsor and the IRB/IEC

Answer: A

Explanation:
Theprotocol signature pagedocuments agreement between the sponsor and the investigator/institution to conduct the trial in compliance with ICH GCP, the protocol, and regulatory standards.
* ICH E6(R2) 8.2.2 (Signed protocol and amendments):Requires "the sponsor and investigator /institution to sign the protocol and amendments, confirming agreement."
* ICH E6(R2) 4.5.1:"The investigator should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, approved by the regulatory authority(ies) and by the IRB/IEC." The sponsor-investigator signatures ensure shared accountability for subject protection, data integrity, and adherence to trial methodology. Neither delegated staff (B) nor IRB/IEC (C) nor FDA (D) sign protocols.
These bodies approve or oversee, but do not formally enter into execution of the protocol.
Thus, the correct answer isA (The investigator/institution and the sponsor).
References:
ICH E6(R2), §8.2.2 (Signed protocol and amendments).
ICH E6(R2), §4.5.1 (Investigator compliance with protocol).

NEW QUESTION # 26
An investigator reports a serious adverse event suspected to be drug-related. By CFR, the sponsor must notify FDA no later than:

- A. 7 days
- B. 15 days
- C. 1 day
- D. 10 days

Answer: A

Explanation:
* 21 CFR 312.32(c)(2):Life-threatening or fatal unexpected adverse events must be reported within7 calendar days.Other serious unexpected events are reported within 15 days.
References:21 CFR 312.32(c)(2).

NEW QUESTION # 27
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 data safety monitoring summary
- B. The monitoring close-out visit report
- C. The final report
- D. The final subject enrollment log

Answer: C

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.
References:
ICH E6(R2), §4.13 (Final reporting to IRB/IEC).
21 CFR 312.66 (IRB review and reporting).

NEW QUESTION # 28
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. 1 day
- B. 10 working days
- C. 30 working days
- D. 5 working days

Answer: D

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 # 29
A pharmaceutical company is developing a biologic study. In accordance with ICH, which of the following items should be included in an investigator's brochure (IB)?

- A. Lab draw requirements
- B. Dispensing instructions
- C. Results of recent nude mouse study
- D. Schedule of events

Answer: C

Explanation:
TheInvestigator's Brochure (IB)compilesclinical and nonclinical dataon an investigational product relevant to human study.
* ICH E6(R2) 7.2.3:The IB should summarizenonclinical pharmacology, toxicology, pharmacokinetics, and efficacy data, including results of animal studies.
* ICH E6(R2) 7.2.4:It should also includeavailable clinical trial dataand safety experience.
The "results of recent nude mouse study" (B) are nonclinical data, which appropriately belong in the IB. Lab draw requirements (A), dispensing instructions (C), and schedules of events (D) are operational/procedural and are found in theprotocol, not the IB.
Thus, the correct answer isB (Results of recent nude mouse study).
References:
ICH E6(R2), §7.2.3-7.2.4 (Contents of Investigator's Brochure).

NEW QUESTION # 30
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