

# New CCRP Exam Guide - Reliable CCRP Test Blueprint

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Terms in this set (72)

What influences a persons metabolic rate?	Exercise, gender, genetics, age
Which is the macronutrient that provides more than twice as many calories as the other two	Fat
Foods that raise insulin levels have...	added sugar
When feeling stressed, you may feel relief after eating a piece of chocolate because...	it will raise dopamine levels
What reduces the number of receptors for dopamine	insulin
What percentage of Cardiac Rehab patients are overweight or obese	80%
Why is fructose a promoter of obesity?	promotes liver fat accumulation which promotes metabolic syndrome

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## SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none"><li>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.</li></ul>
Topic 2	<ul style="list-style-type: none"><li>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.</li><li>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.</li></ul>

## SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q23-Q28):

### NEW QUESTION # 23

Which of the following statements about the investigator's brochure is correct?

- A. It contains a summary of the pharmacological and toxicological effects of the drug in animals, and to the extent known, in humans
- B. It provides documents that permit the evaluation of the conduct of the study and the quality of the data
- C. It includes financial disclosure information from investigators
- D. It consists of the instructions for the investigator to conduct the study

### Answer: A

Explanation:

The Investigator's Brochure (IB) is a critical regulatory document designed to provide investigators with comprehensive knowledge about an investigational product.

\* ICH E6(R2) 7.1: Defines the IB as "a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects."

\* ICH E6(R2) 7.2.2: Specifies the IB should contain a summary of pharmacological, toxicological, pharmacokinetic, and metabolic studies in animals, as well as results from previous human experience.

\* The purpose is to allow investigators to make risk-benefit assessments, support protocol design, and ensure subject safety.

Incorrect options:

- \* A (instructions to conduct study) describes the protocol, not the IB.
- \* C (financial disclosures) are required under 21 CFR 54, not part of the IB.
- \* D refers to trial master file/essential documents, not the IB.

Therefore, the IB's defining function is to provide a scientific summary of preclinical and clinical data supporting safe human use.

References:

ICH E6(R2), §7.1, §7.2.2.

### NEW QUESTION # 24

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

**Answer: A**

Explanation:

The Belmont Report (1979), issued by the U.S. National Commission, identifies three 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).

\* The Nuremberg Code (1947) was developed post-WWII to prevent unethical experiments.

\* The Declaration of Helsinki (1964, updated) is a World Medical Association document guiding international physician research ethics.

\* The ICH 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 is D (The Belmont Report).

References:

The Belmont Report (1979), National Commission for the Protection of Human Subjects.  
45 CFR 46 (Human Subject Protections).

**NEW QUESTION # 25**

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 would NOT be required to be filed at the research site?

- A. Records of investigational product shipment
- B. Investigational product inventory forms
- C. Investigational product accountability forms
- 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 destruction are 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 is D (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 # 26**

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 funding source for the trial
- C. The availability of the patient population
- D. The educational background of the study team

## Answer: A

Explanation:

When reviewing protocols, IRBs/IECs are primarily responsible for safeguarding human subjects by 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 a feasibility issue, addressed by investigators and sponsors, not IRBs.
- \* Education of the study team (C) is confirmed by the sponsor 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 on justice and fairness in subject selection as part of the Belmont Report principles.

References:

21 CFR 56.111(a)(3).

Belmont Report (Justice principle).

## NEW QUESTION # 27

A study coordinator is developing an informed consent form for the first time. As per the CFR and ICH GCP Guideline, which of the following elements must be included?

- A. A note that the qualified investigator could be financially compensated by the sponsor to conduct the clinical trial
- B. An explanation of the person to contact at the sponsor for further information regarding research subjects' rights
- C. A statement confirming that the subject has received a copy of the signed consent document
- D. **A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject**

## Answer: D

Explanation:

The informed consent process must include all basic elements listed in federal regulations.

- \* 21 CFR 50.25(a)(4): Requires "a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject."

\* ICH E6(R2) 4.8.10(c): Mirrors this, requiring subjects to be informed of alternatives to participation, including available standard treatments.

This ensures the ethical principle of Respect for Persons (Belmont Report), giving subjects the autonomy to choose among reasonable medical options.

Incorrect options:

- \* A: Contact information must be provided, but it is for the investigator (or IRB), not sponsor.
- \* B: Financial disclosures may be required for IRB review, not subject-facing.
- \* C: Subjects do receive a copy, but it is not a required consent element in regulations.

Correct answer: D.

References:

21 CFR 50.25(a)(4).

ICH E6(R2), §4.8.10(c).

## NEW QUESTION # 28

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