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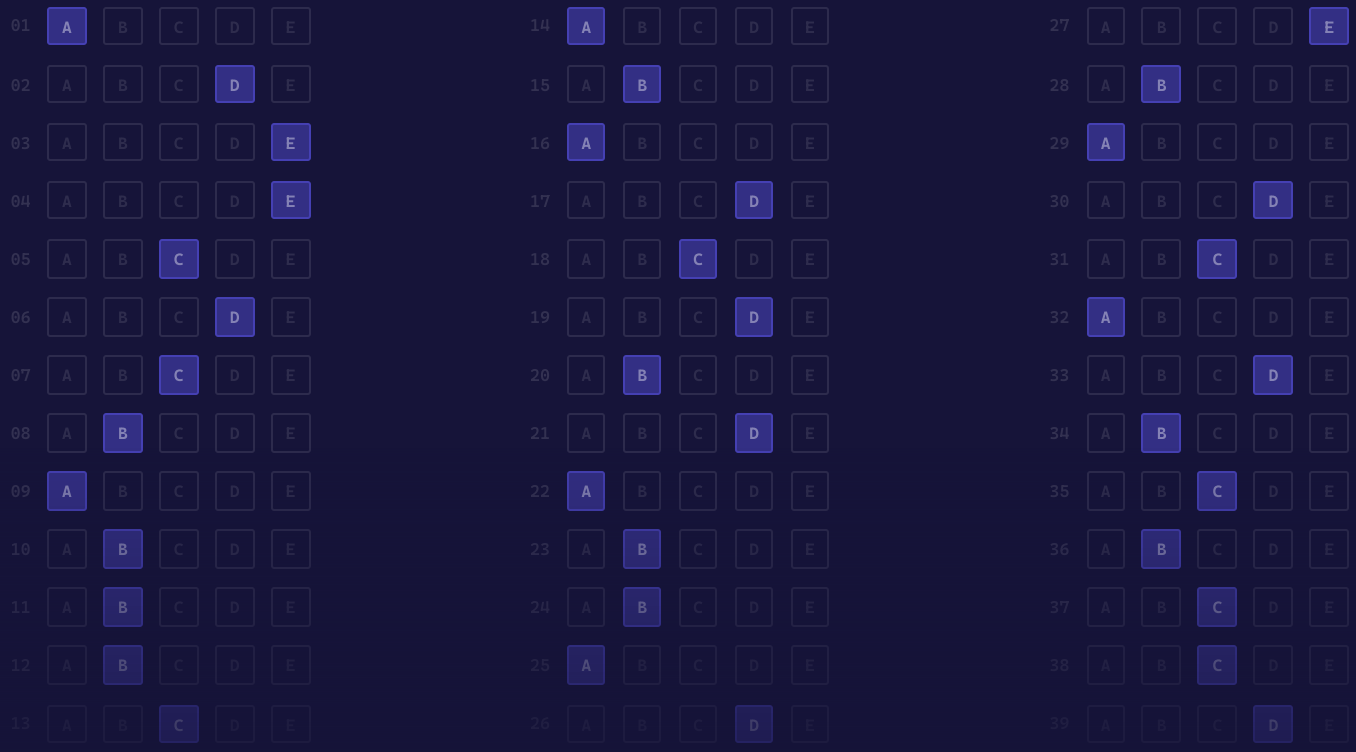

PRACTICE QUESTIONS

ACRP - Association of Clinical Research Professionals

HRX6U6JP

Certified Principal Investigator

EDITION	QUESTIONS	FORMAT
Demo	9	Limited Edition PDF

Before you begin

What this is

9 practice questions for ACRP - Association of Clinical Research Professionals `HRX6U6JP`, each with its answer key and an explanation. Answer a question before you read its key — the explanation is worth more once you have committed.

If something looks wrong

Send us three things and we will check it:

- the exam code, `HRX6U6JP`
- the question number
- the email address on your order

Write to **support@mometrix.net**. We reply within one business day.

QUESTION 1 SINGLE CHOICE

According to the Belmont Report, which of the three core ethical principles specifically requires that the benefits of research be maximized and the risks to participants be minimized?

A Respect for Persons

B Beneficence

C Justice

D Non-maleficence

ANSWER B

WHY The Belmont Report identifies three core ethical principles: Respect for Persons, Beneficence, and Justice. Beneficence specifically requires that researchers (1) do not harm participants and (2) maximize possible benefits while minimizing possible harms. Respect for Persons addresses autonomy and informed consent, and Justice addresses the fair distribution of the benefits and burdens of research. Non-maleficence, while related, is one of the four principles of medical ethics (Beauchamp and Childress) and is not one of the three Belmont principles.

QUESTION 2 SINGLE CHOICE

Under ICH GCP E6(R2), which of the following responsibilities is the Principal Investigator explicitly required to personally fulfill rather than delegate to other members of the study team?

A **Obtaining informed consent from each trial participant prior to any study procedures**

B Dispensing investigational product to enrolled subjects

C Documenting adverse events in the case report form

D Performing routine protocol-specified vital sign measurements

ANSWER **A**

WHY Although the PI may delegate many study-related tasks, ICH GCP E6(R2) is explicit that the PI is responsible for the medical care and treatment of subjects and for ensuring that informed consent is obtained and documented appropriately prior to any study-specific procedures. While the PI can delegate the mechanical act of obtaining consent to a qualified, delegated sub-investigator in some settings, the ultimate accountability and oversight of the informed consent process rests with the PI. The other tasks (dispensing IP, documenting AEs, performing vital signs) are routinely delegated to qualified team members.

QUESTION 3 SINGLE CHOICE

A 78-year-old participant with mild cognitive impairment is enrolled in a dementia treatment trial. Which of the following is required for the informed consent process to be considered valid?

A Consent must be obtained from the participant's legally authorized representative only; the participant need not be informed.

B Consent must be obtained from the participant directly, regardless of cognitive capacity.

C **If the participant lacks decision-making capacity, consent must be obtained from a legally authorized representative and, where applicable, the participant's assent should also be sought.**

D Consent may be waived entirely if the IRB determines the research poses minimal risk.

ANSWER C

WHY When a potential participant lacks the cognitive capacity to provide legally effective informed consent, regulations (21 CFR 50.20-50.25 and ICH GCP) require consent from a legally authorized representative (LAR). Additionally, the IRB must determine that consent is still obtained from the participant themselves where they are capable of providing assent, and that the participant's objection to participation must be respected. Option A is incorrect because the participant's wishes and, where possible, their direct involvement, still matter. Option B ignores the reality of impaired capacity, and Option D misapplies the minimal-risk waiver, which applies in specific narrow circumstances.

QUESTION 4 SINGLE CHOICE

What is the minimum number of members required to constitute an Institutional Review Board (IRB) under U.S. regulations (21 CFR 56.107)?

A Three

B Five

C Seven

D There is no regulatory minimum; membership is determined by the institution.

ANSWER B

WHY Under 21 CFR 56.107(a), each IRB shall have at least five members of varying backgrounds. The regulation further specifies required diversity considerations including at least one member whose primary concerns are in scientific areas, at least one whose primary concerns are in nonscientific areas, and at least one who is not affiliated with the institution conducting the research. Three or seven are not the regulatory minimum, and there is no provision allowing institutions to operate an IRB with fewer than five members.

QUESTION 5 SINGLE CHOICE

An investigator must assess the causality of an adverse event to the investigational product. According to standard conventions, an adverse event for which a causal relationship with the study drug cannot be ruled out is typically classified as which of the following?

A Definitely unrelated

B Possibly related

C Definitely related

D Unrelated by definition

ANSWER B

WHY Standard causality categories generally include: definitely related, probably related, possibly related, unlikely/unlikely related, and unrelated. When a causal relationship cannot be ruled out, the event is classified as at least 'possibly related' (and frequently 'probably related' if the evidence is stronger). 'Definitely unrelated' and 'unrelated by definition' describe situations where the investigator is confident no causal association exists; 'definitely related' requires a stronger evidentiary link such as positive rechallenge. The 'cannot rule out' standard places the event on the related side of the spectrum.

QUESTION 6 SINGLE CHOICE

Under ICH GCP E6(R2), what is the maximum time period within which a clinical investigator must submit written progress reports to the sponsor and the IRB/IEC after the study's completion?

A Immediately upon completion of the study

B Within three months of study completion

C Within six months of study completion

D Within one year of study completion

ANSWER D

WHY ICH GCP E6(R2) Section 4.13 requires the investigator to provide written reports to the sponsor, the IRB/IEC, and (where required) regulatory authorities within one year of study completion, with more frequent reporting if specified by the protocol, sponsor, or applicable regulations. There is no requirement to report immediately or at three or six months; the one-year maximum is the recognized standard for the final study report.

QUESTION 7 SINGLE CHOICE

Which party has primary responsibility for the ongoing review of accumulating safety data in a clinical trial and for determining whether the conduct of the trial should be modified, suspended, or terminated to protect participant safety?

A The Institutional Review Board (IRB/IEC)

B The Sponsor's Data Monitoring Committee (DMC) / Independent Data Monitoring Committee (IDMC)

C The Principal Investigator

D The local Regulatory Authority

ANSWER B

WHY An Independent Data Monitoring Committee (IDMC), also known as a Data Monitoring Committee (DMC), is specifically constituted to periodically review accumulating safety and efficacy data and to recommend to the sponsor whether the trial should continue unchanged, be modified, suspended, or terminated based on those reviews. The IRB/IEC reviews the protocol and ongoing consent and risk-benefit considerations but typically does not have access to unblinded interim data. The PI monitors safety at the site level for individual participants, and regulatory authorities may inspect and intervene but do not perform ongoing interim review.

QUESTION 8 SINGLE CHOICE

A Principal Investigator must ensure accountability of the investigational product at the study site. Which of the following records must be maintained throughout the trial and made available for monitoring and regulatory inspection?

A A sponsor-issued randomization schedule

B A master randomization code maintained only by the sponsor's statistician

C **Drug accountability logs documenting receipt, dispensing, returns, and destruction of investigational product**

D A list of all clinical supplies shipped between the sponsor and the site

ANSWER C

WHY Investigational product accountability at the site is documented through drug accountability logs that record receipt dates and quantities, dispensing to each subject (including subject identifier and date), returns from subjects, and final disposition (destruction or return to sponsor). Per ICH GCP E6(R2) Section 4.6 and 5.14, the investigator is responsible for maintaining accurate accountability records, while the randomization schedule and sponsor-shipment documentation are sponsor-level documents not maintained at the site. Master randomization codes are typically held by the sponsor's pharmacist or statistician and not by the PI.

QUESTION 9 MULTIPLE CHOICE

According to ICH GCP principles, source documents used for clinical trial data must possess certain essential attributes to support the reliability of trial data. Which of the following are required characteristics of source documents? (Choose two.)

A **They are attributable, legible, contemporaneous, original, accurate, and complete (ALCOA-C).**

B They must be stored exclusively in electronic format using a 21 CFR Part 11 compliant system.

C **They must be available for review by monitors, auditors, and regulatory inspectors during and after the trial.**

D They must be pre-approved by the FDA before the trial begins.

ANSWER **A · C**

WHY ICH GCP and FDA guidance on source data and records emphasize that source documents must be attributable, legible, contemporaneous, original, accurate, and complete (the ALCOA-C principles), and they must be available for inspection by monitors, auditors, the IRB/IEC, and regulatory authorities. Source documents are not required to be stored exclusively in electronic format (paper source documents are permitted), and they do not require pre-approval by the FDA; only the protocol and related submissions are reviewed in advance.