ACRP

ACRP-CP

ACRP Certified Professional Exam

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Question: 1

Investigators designing enrollment criteria debate whether to restrict a trial to a narrow, easily managed group or to include the broader range of people who could benefit from the therapy.
Fairly distributing the burdens and potential benefits of research across the population most directly reflects which principle?

A. Respect for persons, which calls for honoring individual autonomy and protecting those with diminished autonomy from harm.
B. Beneficence, which calls for maximizing the potential benefits while minimizing the potential harms to each individual participant.
C. Confidentiality, which calls for safeguarding the private information that participants share over the course of the study.
D. Justice, which calls for equitable subject selection so that no group unfairly bears the burdens or is denied the benefits.

Answer: D

Question: 2

During a study visit, the investigator learns that a subject was hospitalized because of a medical event that occurred after the subject received the investigational product.
How should the investigator classify and handle this event?

A. As a serious adverse event to be documented and reported to the sponsor per the protocol's safety reporting requirements.
B. As a protocol deviation that should be reported to the IRB/IEC only, and not to the trial sponsor.
C. As information to be disclosed only to the affected subject, carrying no external safety reporting obligation whatsoever.
D. As a non-serious adverse event requiring only routine documentation in the subject's own source records.

Answer: A

Question: 3

An investigator identifies a serious event that is unexpected and has at least a reasonable possibility of being related to the investigational product. Duties for safety reporting had been delegated by the sponsor to a contract research organization.

Which statement best reflects the reporting responsibilities in this situation?

A. The contract research organization now holds ultimate responsibility, because the sponsor formally delegated all of the safety reporting duties to it.
B. The investigator reports the serious event to the sponsor, which keeps ultimate responsibility for expedited reporting despite delegating to the CRO.
C. The IRB/IEC is responsible for the expedited reporting of this serious reaction to all the other participating trial sites.
D. No expedited handling applies here, because the serious reaction was observed at only one single participating study site.

Answer: B

Question: 4

A study team has finished data cleaning, resolved outstanding queries, and completed reconciliation, then formally locks the database. Shortly afterward, someone proposes editing a value directly without any documented process.
Why is making such a change inappropriate after the lock?

A. Post-lock changes need a controlled, documented, justified process
B. Locking transfers all data ownership to the site investigator
C. Locking permanently prevents any correction under all circumstances
D. Locking automatically unblinds the trial's treatment assignments

Answer: A

Question: 5

A site enrolls a subject who did not meet a key safety-related inclusion criterion. As a result, the subject undergoes a study procedure whose risk that criterion was specifically designed to screen out.
How is this event best classified?

A. An acceptable enrollment, because the investigator exercised clinical judgment in admitting the subject.
B. A protocol violation, because it affected subject safety; it must be documented and reported to the appropriate parties.
C. An adverse event to be handled solely through the safety reporting channels, rather than as a protocol-compliance matter.
D. A minor deviation that requires no reporting at all, because only a single subject was ultimately affected.

Answer: B

Question: 6

A participant experiences two serious events. One is listed in the current investigator's brochure as a known reaction; the other is not listed and is assessed as possibly related to the product.
Which statement correctly characterizes these events for expedited (SUSAR-type) consideration under ICH E2A principles?

A. Only the unlisted, possibly related serious event is unexpected and central to SUSAR consideration; the listed one is expected.
B. Neither event qualifies, because a merely possible causal relationship is too weak to support expedited handling.
C. Only the listed event qualifies, because reactions already described in the current brochure are the ones reported expeditiously.
D. Both events qualify as SUSARs, since each one meets the seriousness criterion for a reaction.

Answer: A

Question: 7

A dataset is being prepared to share with the trial statistician, and the team wants to protect participant confidentiality while keeping the data analytically useful.
Which approach best supports both goals?

A. Replace each participant's name with the participant's initials and full date of birth for tracking.
B. Replace direct identifiers with a coded ID, keeping the linking key secured and stored separately.
C. Remove the treatment assignment so that the data can no longer be linked to individual outcomes.
D. Include the full medical record number so that the records can be reconciled later if needed.

Answer: B

Question: 8

A coordinator files essential documents into the Investigator Site File only during the week before each monitoring visit, leaving long stretches when recently generated documents sit unfiled.
Why is this filing practice a concern?

A. Documents should be filed only when a monitor is physically present so that filing choices can be supervised.
B. The file should instead be assembled only once, entirely at the trial's closeout, to save effort.
C. Essential documents should be filed contemporaneously so the file continuously reflects actual trial conduct.

D. Timing of filing is irrelevant provided every document is present by the last day of the trial.

Answer: C

Question: 9

A sponsor is planning a new multi-site trial and adopts a quality-by-design approach.
What does quality by design mean in this context?

A. Logging every protocol deviation in a tracking file so that inspectors can review the complete list when the study eventually concludes.
B. Building quality into the trial's design and processes from the outset by identifying factors critical to participant protection and data reliability.
C. Detecting and correcting data errors through complete source data verification of every case report form once the study database has been locked at study end.
D. Assigning an independent auditor to re-check each monitor's work and visit findings before any report is filed with the sponsor.

Answer: B

Question: 10

The ACRP-CP exam grounds its standards in ICH guidelines rather than any single country's law.
What is the primary purpose of the ICH guidelines that candidates reference?

A. To set commercial pricing and reimbursement standards for investigational products across participating regions.
B. To establish a single global regulatory authority that issues marketing approvals for every region.
C. To harmonize technical and scientific standards so trials meet consistent quality and ethics across regions.
D. To serve as legally binding regulations that replace each participating country's national medicines law.

Answer: C

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