ACRP
CCRC
ACRP Certified Clinical Research Coordinator

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Question: 1

A CRC is enrolling participants recruited from a community clinic that primarily serves people with limited health literacy and significant financial hardship. The PI asks the CRC to proceed with consent visits as usual.
Which action best protects the quality of informed consent for this population while staying within the CRC's role?

A. Have a family member or guardian co-sign the consent form for these participants so the decision is shared.
B. Use plain-language materials and a teach-back check of understanding, and allow extra time for questions.
C. Shorten the consent discussion to reduce burden, since a lengthy document may overwhelm participants with limited literacy.
D. Ask the participant to bring proof of income so eligibility for the enhanced consent process can be confirmed.

Answer: B

Question: 2

A principal investigator at an infectious disease trial site signs the delegation of authority log after reviewing the qualifications and assigned tasks of each study team member.
What does the investigator's signature on the delegation log represent?

A. Confirmation that each individual is qualified to perform the tasks assigned to them.
B. A guarantee that no protocol deviations will occur for the duration of the trial.
C. A record that team members completed their tasks correctly throughout the study.
D. A transfer of the investigator's overall responsibility for the trial to the listed team members.

Answer: A

Question: 3

A sponsor representative visits a prospective site before any study agreement is finalized, reviewing the facility, prior enrollment records, and staff qualifications. Several weeks later, after the site is selected, a different sponsor representative returns for a separate visit.
How does the purpose of this earlier visit primarily differ from the purpose of the site initiation visit?

A. The earlier visit focuses on training the coordinator, while initiation focuses on training the PI
B. The earlier visit occurs after enrollment begins, while initiation occurs before the protocol is finalized
C. The earlier visit is conducted by the IRB, while initiation is conducted by the sponsor
D. The earlier visit assesses site capability, while initiation confirms enrollment readiness

Answer: D

Question: 4

During a site initiation visit, the monitor walks through each delegated task with the study team, asking coordinators and sub-investigators to describe how they will perform specific protocol procedures and confirming that training records support their answers.
What is the monitor primarily confirming through this part of the visit?

A. That study staff are trained and ready for their protocol duties
B. That the site has finished screening its first prospective participant
C. That the study budget has been finalized between the sponsor and the institution
D. That the pharmacy has dispensed investigational product for the first time

Answer: A

Question: 5

Partway through an ongoing trial, new safety data emerge suggesting an increased risk for a subgroup of participants.
Which statement correctly reflects how risk-benefit information should be treated at this point, consistent with GCP and Declaration of Helsinki principles?

A. New safety information of this kind only affects the risk-benefit assessment for individuals who have not yet enrolled in the trial.
B. Once the IRB/IEC has approved the protocol's initial risk-benefit assessment, no further reassessment is required unless a participant specifically requests one.
C. The risk-benefit assessment is not a one-time determination made only at initial approval — it must be reassessed as new safety information emerges.
D. Risk-benefit determinations are made solely by the coordinator at each visit, based on how comfortable the participant currently feels about continuing.

Answer: C

Question: 6

What is the main purpose of a data query?

A. To resolve a specific inconsistency or missing clarification with traceable evidence
B. To replace the source record
C. To conceal discrepancies before review
D. To instruct the site which answer to enter

Answer: A

Question: 7

While reviewing a draft informed consent form for completeness, a coordinator checks that it clearly tells participants they may leave the study at any time without losing any benefits to which they are otherwise entitled.
Which required element of informed consent does this statement represent?

A. A description of anticipated expenses the participant may incur by taking part in the study.
B. A statement of the extent to which confidentiality of the participant's records will be maintained, including limits on who may access identifiable information.
C. An identification of which procedures in the protocol are experimental.
D. The statement that participation is voluntary and that the participant may withdraw at any time without penalty.

Answer: D

Question: 8

What response best addresses a full health record sent through an unapproved channel to answer one eligibility query?

A. Repeat the export through the approved channel without addressing the first transmission
B. Contain the disclosure, preserve evidence, report it through the privacy process, and provide only necessary source access
C. Delete the sent message and take no further action because the eligibility value was correct
D. Ask the recipient to ignore unrelated pages and retain the full record

Answer: B

Question: 9

An independent data monitoring committee recommends pausing enrollment while a safety imbalance is evaluated. The site has not yet received the sponsor's operational notice.
What should the coordinator do?

A. Continue enrolling until the next routine newsletter
B. Post the confidential recommendation publicly
C. Escalate the information immediately to the investigator and obtain controlled sponsor instructions before further enrollment
D. Pause local enrollment solely on the committee recommendation without escalating to the investigator or obtaining controlled sponsor instructions

Answer: C

Question: 10

A site enrolls participants correctly but delays entering baseline disease severity until after randomization. Investigators can see assigned treatment before recording that baseline value, which is later used for adjusted analysis.
What is the main data-quality risk?

A. Biased baseline assessment affecting the adjusted analysis
B. The delayed entry changes the randomized treatment sequence
C. The issue matters only if the participant later withdraws
D. Adjusted analysis is prohibited in randomized trials

Answer: A

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