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Question: 1744

A clinical trial site is conducting a double-blind study for a new anti-epileptic drug. The sponsor initiates a recall of the investigational product (IP) due to a manufacturing defect affecting dissolution rates. The IP is an oral tablet dispensed to subjects. According to 21 CFR Part 312.59, what is the most appropriate action for the PI to manage the recall?

- A. Continue dosing until replacement tablets arrive to maintain trial continuity
- B. Notify subjects to stop taking the IP, collect tablets, and monitor for seizure activity
- C. Destroy the affected IP and report the recall to the DSMB
- D. Consult the pharmacy to assess tablet dissolution before action

Answer: B

Explanation: Per 21 CFR Part 312.59 and ICH GCP E6(R2) section 4.6, the PI must protect subject safety during an IP recall by notifying subjects to stop using the affected IP, collecting dispensed tablets, and monitoring for related adverse events (e.g., seizures). Continuing dosing or assessing dissolution by the pharmacy risks subject safety, and destroying IP without subject notification is non-compliant.

Question: 1745

When contracting with a vendor, which of the following should the principal investigator emphasize to minimize potential liabilities?

- A. The length of the vendor's experience
- B. The specific terms of indemnification
- C. The vendor's public relations strategy
- D. The vendor's historical financial performance

Answer: B

Explanation: Emphasizing the specific terms of indemnification is crucial to minimize potential liabilities, ensuring that both parties understand their responsibilities in the event of claims.

Question: 1746

In a multi-center trial for a new oncology drug, a subject's screening labs reveal a hemoglobin level of 9.8 g/dL, slightly below the protocol's eligibility criterion of ≥ 10 g/dL. The PI believes the subject is otherwise suitable and considers enrolling them, citing clinical judgment that the anemia is mild and unrelated to the cancer. According to ICH-GCP E6(R2) Section 4.5, what is the most appropriate course

of action to ensure compliance with subject eligibility requirements?

- A. Enroll the subject and document the rationale for the deviation in the subject's file
- B. Exclude the subject and document the reason for screening failure
- C. Request a protocol amendment from the sponsor to adjust the hemoglobin criterion
- D. Consult the medical monitor and enroll the subject if approved

Answer: B

Explanation: ICH-GCP E6(R2) Section 4.5 requires strict adherence to the protocol, including eligibility criteria, unless a formal amendment is approved by the IRB/IEC and sponsor. Enrolling a subject who does not meet the hemoglobin criterion without an approved amendment violates protocol compliance. Consulting the medical monitor or documenting the deviation without prior approval does not align with GCP standards. The correct action is to exclude the subject and document the reason for screening failure, ensuring protocol adherence.

Question: 1747

What is the primary purpose of developing trial management tools for a clinical study, particularly concerning protocol compliance?

- A. To streamline communication among research staff and ensure compliance with study protocols
- B. To enhance marketing strategies for the investigational product
- C. To reduce the overall cost of the clinical trial
- D. To collect patient data more efficiently without additional training

Answer: A

Explanation: Trial management tools facilitate effective communication and oversight, which are crucial for maintaining compliance with study protocols.

Question: 1748

A subject has withdrawn consent after experiencing significant anxiety related to study requirements. What is the best approach for the investigator in this situation?

- A. Document the withdrawal and move on
- B. Attempt to persuade the subject to continue
- C. Respect the subject's decision and provide support resources
- D. Notify the IRB/IEC only if the subject's withdrawal affects the study

Answer: C

Explanation: Respecting the subject's decision while providing support resources shows ethical commitment and understanding of participant well-being, which is essential in clinical research.

Question: 1749

When developing a hypothesis for a clinical trial, which of the following should be considered to ensure that the study is adequately powered?

- A. The historical context of the disease
- B. The sample size required for statistical significance
- C. The marketing strategy for the investigational product
- D. The trial's budget constraints

Answer: B

Explanation: Considering the sample size required for statistical significance ensures that the study is adequately powered to detect meaningful differences, which is crucial for the validity of the trial results.

Question: 1750

A subject in a Phase II trial for a new antihypertensive reports dizziness (BP 90/60 mmHg) 5 days after starting the IP. The IB lists hypotension as an expected AE (incidence 10%). Per 21 CFR 312.32, what is the PI's reporting obligation?

- A. Document and report to sponsor per protocol
- B. Report to sponsor within 24 hours
- C. Notify IRB/IEC within 7 days
- D. Report to FDA within 15 days

Answer: A

Explanation: Dizziness with hypotension is a non-serious AE and is expected per the IB. Per 21 CFR 312.32, non-serious AEs are documented and reported to the sponsor per protocol timelines (e.g., at study visits or periodic reports). IRB/IEC or FDA reporting is not required for non-serious, expected AEs unless specified by IRB/IEC policies or protocol requirements.

Question: 1751

If a principal investigator discovers that an investigational product was stored inappropriately for an extended period, what is the most responsible action to take?

- A. Document the incident and continue using the product
- B. Discard the product without notification
- C. Notify the sponsor and follow their guidance
- D. Wait for the next audit to address the issue

Answer: C

Explanation: Notifying the sponsor allows for proper management of the situation and ensures compliance with study protocols.

Question: 1752

In a clinical trial, a principal investigator needs to ensure that study-related logs, such as the site signature log and screening log, are maintained accurately. Which practice should be implemented to enhance compliance and traceability?

- A. Regularly auditing logs and requiring dual sign-off
- B. Allowing site staff to log entries without supervision
- C. Storing logs in a central location without access controls
- D. Using informal notes for logging purposes

Answer: A

Explanation: Regular auditing and requiring dual sign-off on logs enhance compliance and traceability, ensuring that all entries are accurate and verifiable.

Question: 1753

You are assessing a protocol that includes a complex randomization process. What is the most significant risk associated with improper execution of this process in a clinical trial?

- A. Introduction of bias in treatment allocation
- B. Increased participant dropout rates
- C. Difficulty in recruiting participants
- D. Inaccurate data reporting in the final analysis

Answer: A

Explanation: Improper execution of the randomization process can introduce bias in treatment allocation, undermining the integrity of the trial and the validity of the results.

Question: 1754

During a study, the PI discovers that a participant experienced a serious adverse event that was not reported according to protocol. What should the PI do immediately upon discovering this oversight?

- A. Inform the participant and document the event in their file
- B. Ignore the oversight if it has already been a month since the event occurred
- C. Report the event to the IRB and sponsor as soon as possible, providing all necessary details
- D. Wait for the next scheduled meeting to discuss the issue

Answer: C

Explanation: Timely reporting of serious adverse events is crucial for participant safety and compliance, regardless of the time elapsed since the event.

Question: 1755

During a monitoring visit, you are asked about the informed consent process. What is the most critical aspect to highlight?

- A. The number of participants who signed consent forms
- B. The variety of recruitment strategies used
- C. The length of the consent form
- D. The thoroughness of discussions with participants regarding their rights

Answer: D

Explanation: Highlighting the thoroughness of discussions ensures that the informed consent process is understood as a critical ethical obligation, emphasizing participant rights.

Question: 1756

During staff selection for a trial involving a new chemotherapy agent, the PI evaluates a candidate with 5 years of oncology nursing experience but no prior clinical trial experience. The trial requires precise administration of the agent based on body surface area (BSA) calculations (dose = 50 mg/m²). What is the most critical step to qualify the candidate per ACRP standards?

- A. Verify the candidate's oncology nursing certification
- B. Train the candidate on GCP and document the training
- C. Request a trial-specific reference from a prior employer
- D. Confirm the candidate's proficiency in BSA calculations

Answer: D

Explanation: Staff must be qualified for trial-specific tasks. The precise administration of chemotherapy based on BSA calculations is critical to patient safety and protocol compliance, making proficiency in this area the most important qualification. While GCP training and certifications are necessary, BSA calculation proficiency is the priority for this role. A reference is not a standard requirement.

Question: 1757

A PI is tasked with ensuring accurate data collection in a trial measuring systolic blood pressure (SBP) as a primary endpoint. A site reports SBP values (e.g., 145 mmHg) that deviate significantly from source data (EMR: 142 mmHg) due to manual transcription errors. What should the PI implement to ensure accurate and verifiable data reporting?

- A. Implement double data entry to cross-check CRF values against source data

- B. Increase the frequency of onsite monitoring visits to detect errors
- C. Train staff to use automated blood pressure monitors with direct data upload
- D. Allow minor discrepancies within ± 5 mmHg as acceptable variability

Answer: C

Explanation: Automating data collection with devices that upload SBP values directly to the EDC system minimizes transcription errors, ensuring accurate and verifiable data per ICH-GCP. Double data entry is labor-intensive and error-prone, increased monitoring detects but does not prevent errors, and allowing discrepancies compromises data integrity.

Question: 1758

In the context of investigational product management, what is the significance of maintaining a detailed inventory log?

- A. It helps in preparing for audits and monitoring visits
- B. It is unnecessary if the product is used quickly
- C. It only serves as a reference for staff
- D. It can be discarded after the study ends

Answer: A

Explanation: Maintaining a detailed inventory log is crucial for preparing for audits and monitoring visits, ensuring accountability and compliance.

Question: 1759

In preparing for a regulatory audit, what is the most critical step a principal investigator should take regarding study records?

- A. Minimize the number of records to present
- B. Organize records without reviewing their content
- C. Hide any discrepancies found in the records
- D. Ensure that all records are up-to-date and complete

Answer: D

Explanation: Ensuring that all records are up-to-date and complete is vital for passing a regulatory audit and demonstrating compliance with study protocols.

Question: 1760

In a clinical trial assessing a new drug, which of the following is the most important consideration when selecting a comparator product?

- A. The market availability of the comparator
- B. The ease of administration of the comparator during the trial
- C. The preference of the study sponsor for a specific comparator
- D. The pharmacological profile of the comparator in relation to the investigational product

Answer: D

Explanation: The pharmacological profile of the comparator is crucial for ensuring that it provides a valid basis for comparison to the investigational product, impacting the study's validity.

Question: 1761

During an EMA inspection, the inspector notes that the site's adverse event log lacks entries for 2 participants with documented SAEs. The coordinator cites an oversight. Per ICH E6(R2) Section 4.11, what is the most appropriate response?

- A. Report the SAEs to the regulatory authority
- B. Retrain staff on SAE reporting
- C. Update the adverse event log immediately
- D. Implement a corrective action plan

Answer: A

Explanation: ICH E6(R2) Section 4.11 mandates prompt SAE reporting. Reporting the SAEs to the regulatory authority corrects the oversight and ensures compliance. Updating the log is necessary but secondary, retraining is long-term, and a corrective plan follows reporting.

Question: 1762

A sponsor initiates a recall of an investigational product (IP) batch in a Phase III trial for a new anticoagulant due to incorrect potency detected during quality control. The IP is an injectable administered weekly. Subjects have received the affected batch for 4 weeks. According to 21 CFR Part 312.59, what is the most appropriate action for the PI to manage the recall?

- A. Notify subjects to stop injections, collect unused IP, and monitor for bleeding events
- B. Continue injections until replacement IP arrives to maintain trial continuity
- C. Destroy the affected IP and report the recall to the DSMB
- D. Consult the IRB/IEC to assess the need for subject notification

Answer: A

Explanation: Per 21 CFR Part 312.59 and ICH GCP E6(R2) section 4.6, the PI must protect subject safety during an IP recall by notifying subjects to stop using the affected IP, collecting unused product, and monitoring for related adverse events (e.g., bleeding due to incorrect potency). Continuing use of

defective IP is unsafe, and destroying IP without subject notification or monitoring is non-compliant. IRB/IEC consultation is secondary to immediate action.

Question: 1763

As part of your study's protocol, you are required to keep detailed records of investigational product dispensation to ensure accountability. What is the most effective way to ensure that these records are accurate and up to date?

- A. Rely on the principal investigator to manage records
- B. Use a standardized electronic record-keeping system
- C. Maintain a physical logbook that is rarely checked
- D. Update records only at the end of the study

Answer: B

Explanation: Using a standardized electronic record-keeping system ensures that records are accurate, up-to-date, and easily accessible for audits and compliance checks, thereby enhancing accountability.

Question: 1764

A clinical research site is preparing source document templates for a cardiovascular trial involving complex lab assessments, including troponin levels and ejection fraction measurements. The PI must ensure that the templates capture data per the protocol, which specifies troponin levels <0.04 ng/mL as normal and ejection fraction $>50\%$ as inclusion criteria. During template development, the PI notices that the electronic case report form (eCRF) lacks fields for raw lab values and only includes categorical data (e.g., "normal/abnormal"). What is the most appropriate action to ensure data integrity and compliance with ALCOA-C principles?

- A. Train staff to manually calculate categorical data from raw values during data entry
- B. Use the existing eCRF and document raw values in paper source documents only
- C. Request the sponsor to revise the protocol to align with the eCRF structure
- D. Modify the eCRF to include fields for raw lab values and reconcile with source documents

Answer: D

Explanation: ALCOA-C principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete) require that source data, such as raw lab values, are accurately captured and verifiable. Modifying the eCRF to include fields for raw troponin and ejection fraction values ensures that data entered is consistent with source documents, facilitating reconciliation and audit readiness. Relying solely on paper source documents risks data discrepancies, while revising the protocol is unnecessary and impractical. Manual calculations during data entry introduce errors and violate contemporaneous data capture.

Question: 1765

A Phase I trial site receives a monitor's report indicating that a subject's informed consent form (ICF) was signed after the first dose of the study drug, violating ICH E6 GCP. The principal investigator must ensure compliance with study requirements. What is the most appropriate corrective action?

- A. Ignore the violation, as it affects only one subject
- B. Exclude the subject from the trial and destroy the ICF
- C. Obtain a retrospective consent and continue the trial
- D. Report the violation to the IRB and retrain staff on consent procedures

Answer: D

Explanation: Signing the ICF after dosing is a serious GCP violation, as informed consent must precede trial procedures. Reporting to the IRB and retraining staff corrects the issue and prevents recurrence. Excluding the subject may be required but does not address systemic issues, retrospective consent is unethical, and ignoring the violation risks regulatory action.

Question: 1766

A site is conducting a multi-center trial with an oral IP requiring storage at 15–25°C. The pharmacy receives a shipment with a temperature excursion to 30°C for 8 hours, as indicated by the data logger. The sponsor's stability data confirm the IP remains viable for up to 12 hours at 30°C. However, the pharmacy technician fails to document the excursion in the IP accountability log. As the Principal Investigator, how should you address this non-compliance to align with 21 CFR Part 312.62 and ICH GCP requirements?

- A. Instruct the technician to retrospectively document the excursion and continue IP use.
- B. Report the excursion to the IRB and request a protocol amendment.
- C. Train the technician on documentation and use the IP, as it is still viable.
- D. Quarantine the IP and halt dispensing until the sponsor approves its use.

Answer: D

Explanation: Per ICH GCP E6(R2) Section 4.6.3 and 21 CFR Part 312.62, investigators are responsible for maintaining accurate IP accountability records, including documentation of any storage deviations. The failure to document the excursion is a non-compliance issue, and while the IP remains viable per stability data, its use without proper documentation and sponsor approval risks regulatory non-compliance. Quarantining the IP and halting dispensing until the sponsor reviews the excursion ensures compliance and patient safety. Retrospective documentation without oversight could be viewed as falsification, training does not address the immediate issue, and IRB reporting is unnecessary unless the deviation impacts subject safety or trial conduct.

Question: 1767

In a phase III trial for a new diabetes drug, you develop a scheduling tool to improve subject retention. The protocol requires weekly visits for the first 12 weeks. Which tool is most effective for ensuring

subjects adhere to this schedule?

- A. A printed schedule card with fixed visit dates given at enrollment.
- B. A manual phone call system where staff call subjects 1 week before each visit.
- C. A shared online calendar with visit dates accessible to subjects.
- D. An automated text messaging system with visit reminders and rescheduling options.

Answer: D

Explanation: An automated text messaging system provides timely reminders and rescheduling options, improving adherence and retention (ICH E6(R2) 5.8). Printed cards, online calendars, or manual calls are less flexible and more resource-intensive.

Question: 1768

In preparing for an upcoming audit, the principal investigator realizes that the facility's equipment has not been calibrated recently. What should be the most immediate action taken?

- A. Schedule the necessary calibrations before the audit
- B. Document the calibration issue and hope it will not be noticed
- C. Inform the auditor that the equipment is functioning properly
- D. Provide alternative equipment that is not calibrated

Answer: A

Explanation: Scheduling necessary calibrations before the audit is essential to ensure that all equipment is compliant and functioning properly, which reflects the site's commitment to quality.

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