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ACRP Certified Professional Exam Sample Questions (Q50-Q55):

NEW QUESTION # 50
What is a systematic and independent examination of trial-related activities and documents todetermine whether the evaluated trial-related activities were conducted and the data were recorded, analyzed, and accurately reported according to the protocol, sponsors, SOPs, GCP, and the applicable regulatory requirements?

- A. Routine monitoring
- B. Audit
- C. Site qualification
- D. Inspection

Answer: B

Explanation:
An audit is a systematic and independent examination of trial-related activities and documents. Its purpose is to determine whether the study was conducted in compliance with the protocol, GCP, and regulatory requirements. Audits are usually performed by the sponsor or an independent auditor and focus on evaluating data integrity and trial conduct.
GCP guidelines define an audit as a thorough examination to ensure adherence to protocol and regulatory requirements.
"An audit is a systematic and independent examination of trial-related activities to verify compliance with the protocol and regulatory

standards." Objectives:
Ensure compliance and data integrity.
Identify any gaps in trial conduct.

NEW QUESTION # 51
Who is responsible to ensure training for key staff members unable to attend the site initiation visit?

- A. Coordinator
- B. Sponsor
- C. Monitor
- D. Investigator

Answer: D

Explanation:
The Principal Investigator (PI) is responsible for ensuring that all site staff involved in the study are adequately trained, even if they were unable to attend the Site Initiation Visit (SIV). This responsibility includes organizing training sessions or providing relevant training materials to maintain consistency and compliance with study protocols.
According to GCP guidelines, the PI must ensure that all staff members involved in the trial are adequately informed and trained on their specific responsibilities.
"The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions." Objectives:
* Maintain consistent training for all clinical staff.
* Ensure compliance with study procedures.

NEW QUESTION # 52
Confidentiality and privacy rules for protection of human subjects at research sites are determined by the:

- A. Applicable regulatory authorities
- B. Sponsor
- C. PI
- D. Applicable site SOPs

Answer: A

Explanation:
The confidentiality and privacy rules protecting human subjects in clinical research are established by applicable regulatory authorities, such as the FDA or EMA, and must be followed by all research sites. These regulations ensure that participants' personal data are handled securely and ethically.
GCP guidelines mandate compliance with local, national, and international regulations regarding data confidentiality and privacy.
"Confidentiality and privacy protections are determined by applicable regulatory authorities and must be adhered to by all study sites." Objectives:
* Protect participant privacy.
* Ensure compliance with data protection regulations.

NEW QUESTION # 53
All of the following are examples of what monitors review EXCEPT:

- A. Potential patient medical records for eligibility prior to the informed consent process.
- B. Documentation in the participant's medical record of study drug administration.
- C. The signed ICF retained in the participant's study file.
- D. Regulatory binder which includes copies of current certifications for all laboratories.

Answer: A

Explanation:
Monitors are responsible for reviewing documents that pertain to study conduct and data integrity,including regulatory binders, informed consent forms (ICFs), and documentation of study drug administration.

However, reviewing potential patient medical records for eligibility prior to the informed consent process is not part of a monitor's responsibilities, as this would violate patient confidentiality and GCP standards.
According to GCP guidelines, monitors should ensure compliance with the protocol and data integrity but should not access non-consented patient records.
"Monitors should verify that only enrolled and consented subjects' data are reviewed, ensuring compliance with privacy regulations."
Objectives:
* Understand the scope of monitoring responsibilities.
* Protect patient confidentiality during the monitoring process.

NEW QUESTION # 54
After enrolling and treating a few subjects on an investigator-initiated trial, the PI would like to include a subject diary for each trial subject to capture their activities and experiences on the trial regimen. After the PI has generated a diary, what should the PI do next?

- A. Submit the diary to the IRB/IEC for approval.
- B. Submit the diary to the regulatory authority for approval.
- C. Submit the diary to the sponsor for approval.
- D. No approval is necessary: give the diary to each subject.

Answer: A

Explanation:
Any new data collection tool introduced during a clinical trial, including subject diaries, must be reviewed and approved by the IRB/IEC before implementation. This ensures that the new tool is ethically appropriate, respects subject privacy, and aligns with the approved protocol.
This answer aligns with ICH E6(R2) GCP guidelines, which mandate IRB/IEC approval for any new or modified subject-related documents introduced during a trial.
"All changes in study documents, including subject diaries, must be submitted for IRB/IEC review to ensure compliance with ethical standards." Objectives:
* Maintain compliance with IRB/IEC requirements.
* Ensure ethical handling of subject data.

NEW QUESTION # 55
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