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QUESTION NO: 1

According to the CFR, which of the following is a complete and accurate list of the signatures required on the short form consent document?

A. The subject or else the subject's legally authorized representative; the witness

B. The subject or else the subject's legally authorized representative

C. The subject or else the subject's legally authorized representative; the investigator or else the investigator's designee

D. The subject or else the subject's legally authorized representative; the investigator or else the investigator's designee; the witness

ANSWER: A

Explanation:

The subject or else the subject's legally authorized representative; the witness is the complete list of signatures required on the short-form written consent document. The short-form process may be used when a participant has limited English proficiency and the required consent information is presented orally in a language understandable to that participant. The short form itself is a written statement indicating that the elements required for informed consent have been presented orally. Under 21 CFR 50.27(b)(2), that document must be signed by the participant or the participant's legally authorized representative, as applicable, and by a witness to the oral presentation. These signatures document both the participant's agreement and the witness's presence during the oral consent discussion. The regulation separately requires preparation of a written summary of what was presented orally. That summary is signed by the witness and by the person obtaining consent; this separate signing requirement does not add the person obtaining consent as a required signer of the short-form document. This distinction is central to correctly documenting consent using this permitted alternative process. See the controlling regulation at 21 CFR 50.27 and the FDA's informed-consent guidance.

QUESTION NO: 2

In accordance with 21 CFR Part 11, in order for an electronic record to be equivalent to a paper record the electronic record must be:

A. Printed, signed, and dated

B. Managed within a validated computer system

C. Entered into an electronic case report form

D. Restricted to authorized clinical trial personnel

ANSWER: B

Explanation:

Managed within a validated computer system is correct because 21 CFR Part 11 establishes the conditions under which FDA considers electronic records and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures. A foundational Part 11 control is computer-system validation. Validation must provide assurance of the system's accuracy, reliability, consistent intended performance, and ability to distinguish invalid or altered records. In practical clinical research operations, this means the organization must use a controlled, documented validation approach that is appropriate to the system's intended use and risk. The validated environment supports the integrity of records throughout their lifecycle, including record creation, modification, review, retention, retrieval, and audit-trail handling where required. Part 11 also requires additional procedural and technical controls, such as limiting system access to authorized individuals, but the core condition reflected by this question is that the electronic record is maintained in a validated system. FDA's regulation states this requirement directly in 21 CFR 11.10(a). See 21 CFR Part 11 in the eCFR and FDA's Part 11 Scope and Application Guidance.

QUESTION NO: 3

According to the CFR and ICH GCP, an IRB/IEC must retain all relevant records for how many years after project completion?

A. One year

B. Two years

C. Three years

D. Four years

ANSWER: C

Explanation:

Three years is correct because the U.S. IRB record-retention requirement in 21 CFR 56.115(b) requires an institutional review board to retain required records for at least three years after completion of the research. The retained materials include items such as the IRB's written procedures, membership rosters, meeting minutes, submitted protocol materials, correspondence, and records of continuing review and IRB decisions. This retention period supports FDA inspection and enables verification that the IRB fulfilled its responsibilities for the ethical review and ongoing oversight of human-subject research.

This period is also consistent with ICH E6(R2) Good Clinical Practice section 3.4.3, which states that an IRB/IEC should retain relevant records for at least three years after completion of the trial and make them available upon request by regulatory authorities. "At least" establishes a minimum; an institution, sponsor agreement, other applicable regulation, or study-specific policy may require records to be retained longer. For the stated CFR and ICH GCP minimum following project or trial completion, the required period is three years. See 21 CFR 56.115 and the ICH E6(R2) Guideline.

QUESTION NO: 4

According to the ICH/GCP Guideline, which of the following should a sponsor provide to the clinical investigator before entering into a clinical trial agreement?

A. Staff training

B. Adequate resources

C. Proper equipment

D. The protocol

ANSWER: D

Explanation:

The protocol is correct because it defines the planned clinical trial and provides the essential scientific, operational, and ethical information an investigator needs before agreeing to conduct the study. Under ICH E6(R2), the sponsor should provide the investigator with the protocol and the current Investigator's Brochure, and allow sufficient time for review of the protocol and other supplied information. The protocol describes such core trial elements as the objectives, design, methodology, statistical considerations, participant eligibility, trial procedures, safety assessments, and data collection requirements. Having it available before execution of the clinical trial agreement enables the investigator to assess whether the site can conduct the study as specified and whether the investigator can accept responsibility for protocol-compliant conduct.

The investigator's subsequent responsibility is to conduct the trial in compliance with the protocol that has received the required sponsor and IRB/IEC approval. Accordingly, providing the protocol is a foundational sponsor activity during site selection and agreement discussions, supporting informed investigator commitment and appropriate planning for trial conduct. See ICH E6(R2), sections 5.6.3 and 4.5.1, in the ICH E6(R2) Addendum. Current ICH Good Clinical Practice materials are also available through the ICH Efficacy Guidelines page.

QUESTION NO: 5

A subject develops an acute allergic reaction during a trial procedure. The protocol prohibits administration of a particular rescue medication, but the investigator determines that the medication is immediately necessary to protect the subject's health. What should the investigator do?

A. Wait for sponsor approval before administering the rescue medication

B. Wait for IRB/IEC approval before administering the rescue medication

C. Administer the medication and promptly report the deviation

D. Withdraw the subject before providing any nonprotocol treatment

ANSWER: C

Explanation:

The investigator should administer the necessary medication to eliminate the immediate hazard to the subject and promptly report the deviation to the sponsor and IRB/IEC in accordance with applicable requirements. ICH GCP permits an investigator to deviate from the protocol without prior sponsor agreement or prior IRB/IEC approval when the change is necessary to eliminate an immediate hazard to trial subjects.

Protecting the subject takes priority over prospective approval in this emergency circumstance. However, the deviation must be documented and reported so that the sponsor and IRB/IEC can assess the event, determine whether additional safeguards are needed, and evaluate whether the protocol requires amendment.

QUESTION NO: 6

A Phase I study of a new blood pressure medication has been submitted for initial approval to an IRB/IEC. In accordance with the CFR, the IRB/IEC must consider which of the following criteria when determining whether to approve the study?

A. The availability of the patient population

B. The equitability of the selection of subjects

C. The educational background of the study team

D. The funding source for the trial

ANSWER: B

Explanation:

The equitability of the selection of subjects is a required criterion for IRB approval under the federal human-subject protection regulations. Under 21 CFR 56.111(a)(3), an IRB must determine that subject selection is equitable, taking account of the purposes and setting of the research and being particularly attentive to populations that may be vulnerable to coercion or undue influence. For FDA-regulated research, this criterion applies when an IRB reviews a Phase I investigational drug study, including a study of a new blood pressure medication. The parallel HHS requirement at 45 CFR 46.111 likewise requires equitable selection of subjects. This review supports the ethical principle of justice: the burdens and potential benefits of research should be distributed fairly, and recruitment should not inappropriately target or exclude groups without a scientifically and ethically appropriate reason. In practice, the IRB evaluates the proposed inclusion and exclusion criteria, recruitment sources and methods, and the rationale for involving any vulnerable populations. This determination is part of the IRB's formal approval assessment and must be satisfied before the research may be approved. See 21 CFR 56.111 and 45 CFR 46.111.

QUESTION NO: 7

During source-data review, a monitor finds that a research nurse changed a paper source record by covering the original entry with correction fluid and writing a new value. Which action is most appropriate?

A. Document a traceable correction that preserves the original entry

B. Accept the corrected entry because the nurse made the change

C. Replace the page with a newly transcribed source record

D. Delete the corresponding electronic case report form data

ANSWER: A

Explanation:

The site should document and correct the data issue using a traceable correction process that preserves the original entry. Source-document corrections should not obscure the original information. A proper correction generally leaves the original entry readable, records the corrected information, and includes the initials and date of the person making the correction, with an explanation when needed.

Correction fluid prevents reconstruction of what was originally recorded and undermines data integrity. The monitor should document the finding, ensure that the discrepancy is addressed according to site and sponsor procedures, and verify that any corresponding case report form data are accurate.

QUESTION NO: 8

A physician wants to conduct research using an approved/marketed cardiac stent for use in the carotid artery, which is not an indication for which the device is approved. In this case, the physician must obtain which of the following?

A. The Office for Human Research Protections (OHRP) and manufacturer approvals

B. IRB/IEC approval and an FDA IND

C. IRB/IEC approval and an FDA IDE

D. IRB/IEC and manufacturer approval

ANSWER: C

Explanation:

IRB/IEC approval and an FDA IDE are required because the proposed investigation studies a legally marketed stent for a new, unapproved indication: placement in the carotid artery. A marketed-device investigation may be exempt from IDE requirements only when, among other conditions, the device is used according to its approved labeling and the investigation is not intended to support a new indication or other labeling change. Those conditions are not met when the research evaluates carotid use outside the device's approved indication. The IDE framework permits FDA-regulated clinical investigation of an investigational device use and requires protection of participants through prospective IRB review. For a study of this nature, the sponsor-investigator must submit the IDE to FDA and obtain FDA approval before beginning the significant-risk investigation; the IRB must also approve the protocol before subjects are enrolled. The physician's status as the treating clinician does not eliminate these research oversight obligations when the activity is a prospective clinical investigation. FDA's IDE regulation is available at 21 CFR Part 812, and FDA explains IDE responsibilities in its IDE Application resource.

QUESTION NO: 9

An IND application must contain all EXCEPT:

A. A cover sheet

B. Chemistry, manufacturing, and control information

C. Investigator's brochure

D. Financial disclosure information

ANSWER: D

Explanation:

Financial disclosure information is the correct exception because it is not a required component of the initial investigational new drug application content specified by FDA regulation. An IND is intended to provide FDA with sufficient information to determine whether proposed human studies may proceed safely. Its required submission components include a cover sheet, chemistry, manufacturing, and controls information describing the investigational product, an investigator's brochure, clinical protocols and investigator information, pharmacology and toxicology data, and relevant prior human experience. These materials allow FDA to assess product quality, nonclinical safety, the scientific rationale for clinical investigation, and protections for study participants.

Financial disclosure is governed separately under FDA's financial disclosure regulations for clinical investigators. These requirements are generally associated with marketing applications, where an applicant must submit specified investigator financial-interest information or certifications for covered clinical studies used to support product approval. Sponsors should still collect, maintain, and manage financial-interest information appropriately throughout a study, consistent with applicable regulations and institutional requirements, but that information is not listed as a standard required section of an IND submission under 21 CFR 312.23. See 21 CFR 312.23 and FDA's Financial Disclosure by Clinical Investigators guidance.

QUESTION NO: 10

The sponsor of a multi-institutional clinical trial provided a site with information regarding a newly identified unanticipated adverse event attributed to study drug administration. The site's investigator has a subject actively receiving this study drug. Which of the following is the site investigator's responsibility to the subject?

A. To discontinue the subject's study drug

B. To submit this safety update to the regulatory authority

C. To provide the subject with information regarding the significant new findings

D. To give the subject's contact information to the sponsor in order to allow the sponsor to contact the subject

ANSWER: C

Explanation:

To provide the subject with information regarding the significant new findings is the investigator's responsibility. An unanticipated adverse event attributed to the investigational drug is potentially important new safety information, particularly for a participant who is actively receiving that drug. The investigator must ensure that the participant is told about information that could reasonably affect the decision to remain in the study. This communication should occur promptly, be understandable to the participant, and be documented according to the site's procedures and institutional review board requirements. When the information requires a revision to the informed-consent form, the investigator should use the IRB-approved revised form and obtain the participant's re-consent before further study procedures or continued participation, when applicable. The investigator must also assess the participant's clinical status and discuss any appropriate care considerations in light of the newly recognized risk. This duty supports ongoing informed consent: consent is a continuing process rather than a one-time signature. ICH Good Clinical Practice states that when new information may be relevant to a subject's willingness to continue, the consent form should be revised and the subject informed in a timely manner. FDA consent regulations likewise require provision of significant new findings that may relate to willingness to continue. See ICH E6(R2), section 4.8.2 and 21 CFR 50.25(b)(5).

QUESTION NO: 11

During an audit of a sponsor, the following documents and activities were reviewed: the protocol, applicable regulatory requirements, and compliance with Good Clinical Practice (GCP). What additional documents must be reviewed during the sponsor audit?

A. Standard Operating Procedures (SOPs)

B. Personnel records

C. Financial reports

D. Audit reports

ANSWER: D

Explanation:

Audit reports are the appropriate additional documents because they are the formal, contemporaneous record of prior independent quality-assurance audit work, including the scope of the audit, observations, findings, conclusions, and follow-up actions. Reviewing these reports allows the sponsor audit to assess whether previously identified compliance issues were documented, evaluated, corrected, and prevented from recurring. This creates an auditable trail demonstrating that the sponsor's quality-management and oversight processes are functioning effectively.

ICH E6(R2), section 5.19, requires sponsors to implement quality assurance through audits that are independent of routine monitoring and states that audit observations and findings must be documented. Audit reports therefore provide essential evidence of the sponsor's audit activities and of the status of corrective and preventive action. Their review supports a meaningful assessment of GCP compliance beyond reviewing the protocol and applicable regulatory requirements alone. The relevant ICH standard is available in the ICH E6(R2) Integrated Addendum. FDA also recognizes this standard in its ICH E6(R2) Good Clinical Practice guidance.

QUESTION NO: 12

An investigator is working with a new sponsor to submit a cardiovascular trial to the IRB/IEC. In accordance with the ICH GCP Guidelines, which parties should sign the protocol to confirm agreement that the trial will be conducted as agreed?

A. The investigator/institution and the sponsor

B. The investigator/institution and the delegated site staff

C. The sponsor and the IRB/IEC

D. The sponsor and the FDA

ANSWER: A

Explanation:

The investigator/institution and the sponsor should sign the protocol to document their agreement on how the clinical trial will be conducted. ICH GCP identifies the signed protocol and any amendments as essential trial documents and specifies that the sponsor and investigator/institution sign them to confirm their agreement. This signature process establishes that the parties responsible for designing, managing, and conducting the study have accepted the protocol's scientific procedures, participant-safety measures, data-collection requirements, and operational responsibilities.

The investigator is responsible for conducting the trial in compliance with the protocol agreed to by the sponsor and for ensuring appropriate oversight at the investigational site. The sponsor is responsible for the trial's design, management, quality assurance, and provision of the protocol. Where an institution is involved in the agreement, the investigator/institution designation recognizes that the institution may have applicable site-level responsibilities and authorization requirements. The executed protocol therefore serves as clear documentation of the shared agreement underpinning compliant trial conduct before and throughout the study. See ICH E6(R2), section 8.2.2, in the ICH E6(R2) Addendum, and the ICH guideline resource page at ICH Efficacy Guidelines.

QUESTION NO: 13

A sponsor-investigator implemented a protocol deviation in a device trial to eliminate an immediate hazard. Before applying this change to all subjects, what must occur?

A. Obtain IRB/IEC approval

B. Inform all subjects

C. Train sub-investigators

D. Document change in study file

ANSWER: A

Explanation:

Obtain IRB/IEC approval is correct because an emergency deviation may be implemented immediately when necessary to protect a subject from an imminent hazard, but that emergency authority does not authorize routine or prospective use of the change for the remaining study population. Once the immediate hazard has been addressed, the sponsor-investigator must submit the revised investigational plan or protocol change to the reviewing IRB/IEC and obtain its approval before implementing it as an ongoing study procedure for all subjects. This review ensures that the revised procedures continue to protect participants' rights, safety, and welfare and that the risk-benefit assessment remains acceptable.

For a U.S. investigational device exemption study, FDA regulations permit deviations needed to protect the life or physical well-being of a subject in an emergency, with required reporting after the event. A substantive planned change to the investigational plan is then subject to the applicable IDE requirements, including IRB review and, where required, FDA approval before broader implementation. The sponsor-investigator should also maintain complete regulatory documentation and fulfill all required reports. See 21 CFR 812.150 and 21 CFR 812.35.

QUESTION NO: 14

An investigator discovered a new serious unanticipated adverse device effect. Who must they notify?

A. FDA

B. Sponsor

C. Research pharmacist

D. OHRP

ANSWER: B

Explanation:

The investigator must notify the **Sponsor**. Under the investigational-device-exemption regulations, an unanticipated adverse device effect is any serious adverse effect on health or safety, or any life-threatening problem or death, associated with a device when the effect was not previously identified in nature, severity, or incidence in the investigational plan or application. It also includes other unanticipated serious problems associated with a device that relate to the rights, safety, or welfare of participants. The investigator's direct regulatory reporting obligation is to promptly report the event to the sponsor, and the report must be made no later than 10 working days after the investigator first learns of the effect. The sponsor then evaluates the report and has the responsibility to notify FDA and all reviewing institutional review boards and participating investigators within 10 working days of receiving the report. This reporting pathway ensures that the entity responsible for the overall device investigation can assess whether changes to the investigational plan, informed consent, risk controls, or study conduct are necessary. See 21 CFR 812.150 and FDA's IDE reporting requirements guidance.

QUESTION NO: 15

In accordance with the CFR, the IRB/IEC membership must have:

A. At least seven individuals

B. A majority of individuals whose primary area of expertise is nonscientific

C. At least one cleric

D. At least one individual who is not affiliated with the institution

ANSWER: D

Explanation:

At least one individual who is not affiliated with the institution is correct because FDA regulations require an IRB to include an independent perspective. Under 21 CFR 56.107(d), each IRB must have at least one member who is not otherwise affiliated with the institution and who is not an immediate family member of a person affiliated with the institution. This membership requirement is intended to support independent review of proposed research and to help protect the rights and welfare of human subjects by ensuring that IRB deliberations are not solely influenced by institutional interests.

The unaffiliated member is a specific regulatory safeguard within the required composition of an FDA-regulated IRB. In practice, the institution should document the member's status and ensure that this person participates as part of a properly constituted IRB when actions requiring a convened meeting are taken. The governing FDA provision is available in the Electronic Code of Federal Regulations, 21 CFR 56.107. FDA also summarizes IRB membership and operational expectations in its Institutional Review Boards Frequently Asked Questions.