ACRP
CPI
ACRP Certified Principal Investigator

Latest Version: 6.0

Question: 1

A heart failure site is negotiating a trial agreement for a study combining an investigational device and drug. The sponsor's draft omits any indemnification or clinical-trial insurance clause. The principal investigator must judge how this gap affects the site's exposure if a participant is harmed by the investigational product used according to the protocol.
Why is the absence of an indemnification provision a significant concern for the investigator and site?

A. It blocks enrolled participants from being reimbursed for the routine standard-of-care costs they incur during the trial.
B. It can leave the site bearing liability and legal costs for participant injury from the investigational product used per protocol.
C. It means the IRB/IEC is obligated to reject the protocol on ethical grounds during its initial review of the submission.
D. A missing indemnification clause would legally bar the sponsor from shipping the investigational product to the site until the clause is added.

Answer: B

Question: 2

A participant in a study for hepatic encephalopathy associated with advanced liver disease consented while lucid, but his cognitive state now fluctuates: on some visits he is oriented and engaged, and on others he is confused and unable to follow the discussion. An upcoming visit involves a new, more burdensome procedure. The principal investigator must decide how to proceed regarding consent.
Which approach is most appropriate?

A. Reassess the participant's decision-making capacity at the relevant time, and when capacity is impaired, obtain agreement through a legally acceptable representative while seeking the participant's assent as able.
B. Permanently withdraw the participant from the study at the very first sign of confusion, on the view that a degree of fluctuating decision-making capacity makes his continued participation impossible to justify going forward under the circumstances.
C. Proceed with the new, more burdensome procedure on each visit the participant physically attends, on the reasoning that his voluntary attendance at the visit itself implies his ongoing agreement to take part.
D. Rely on the original consent indefinitely, because a signed form obtained while the participant was fully lucid covers his later procedures throughout the study whatever his cognitive state at the time.

Answer: A

Question: 3

A principal investigator conducting a trial of an investigational monoclonal antibody notes that the product is manufactured under Good Manufacturing Practice. A coordinator asks why the manufacturing quality of the investigational product matters to the trial.
Which explanation best captures its relevance?

A. Good Manufacturing Practice is the principal investigator's personal responsibility to carry out on site, compounding and quality-testing each batch of investigational product at the site pharmacy before use
B. Good Manufacturing Practice is relevant only after a product has been granted marketing authorization and is being sold commercially, and it has no bearing on the quality of the investigational supply that is used during the trial before the product is approved
C. Good Manufacturing Practice mainly exists to ensure that the investigational product can be manufactured as inexpensively as possible once production is scaled up to large commercial volumes
D. Good Manufacturing Practice ensures the investigational product is consistently produced and controlled to defined quality standards, so trial results reflect the intended product and participants are not exposed to quality-related risks

Answer: D

Question: 4

A sponsor proposes lengthening the drug-free washout period in a heart-failure trial to sharpen a secondary efficacy signal. Doing so would keep enrolled participants off guideline-directed therapy longer than is clinically prudent for their condition.
As the principal investigator weighing this request, which principle should govern the response?

A. The well-being of the individual participant takes precedence over the interests of science and society.
B. The sponsor holds protocol-design authority, so once the change is drafted the investigator implements it as written.
C. The scientific value of a cleaner efficacy signal justifies the longer washout, because clearer data benefits future patients and society.
D. Participant well-being and scientific interest carry equal weight, so the washout may proceed if most enrolled participants tolerate it.

Answer: A

Question: 5

At an ophthalmology site running a wet age-related macular degeneration trial, a coordinator enters a best-corrected visual acuity letter score of 500 into the eCRF, and the system immediately displays a

query flagging the value as outside the plausible range before the record is saved. The investigator wants to understand the function this feature serves.
What is the primary purpose of automated edit checks in an electronic data capture system?

A. To assign standardized MedDRA dictionary codes to reported adverse-event terms as they are entered by the site
B. To detect implausible, missing, or inconsistent entries at the point of data entry so they can be resolved early
C. To lock and freeze the study database on its own as soon as the expected case-report-form fields have been entered
D. To take the place of the monitor's on-site source-data review, so routine monitoring visits are dropped from the site's plan

Answer: B

Question: 6

During an outbreak of a severe emerging infectious disease, a trial of an investigational therapeutic enrolls acutely ill patients, some of whom arrive obtunded and without an available representative. The protocol includes ethics-committee-approved provisions for research in emergency settings where prospective consent is not possible. A newly qualified sub-investigator wants to know how consent is handled for such a patient.
Which approach is most consistent with approved emergency-research provisions?

A. Under the approved provisions, enrollment may proceed without prospective consent, and consent is then sought from the participant or their representative as soon as reasonably possible (deferred consent).
B. Any acutely ill patient may be enrolled without consent whenever the treating investigator personally believes the experimental therapy could help, with no further conditions and no later consent obligations attached.
C. Enrollment must always be postponed until the patient personally regains decision-making capacity and can consent, even if the narrow therapeutic window for the intervention closes in the meantime.
D. A member of the treating clinical team may consent on the obtunded patient's behalf permanently, so that once enrollment occurs no later consent from the patient or a representative is ever required.

Answer: A

Question: 7

In a Phase III respiratory trial enrolling children with asthma, a 10-year-old gave assent at enrollment. At a later visit, after his parents have again confirmed their permission, the child says he no longer wants to undergo the study inhalation procedure.
What is the MOST appropriate action for the investigator?

A. Continue the procedure, because valid parental permission overrides a minor's refusal in all cases.
B. Ask the study sponsor to decide whether the child should be permitted to decline the study procedure.
C. Withdraw the child from the study at once and record it as the participant's own formal withdrawal decision.
D. Pause and reassess assent with the family, since a child's sustained dissent should be respected.

Answer: D

Question: 8

Midway through a trial of an investigational agent for metabolic dysfunction-associated steatohepatitis, the sponsor issues an updated Investigator's Brochure that adds a newly identified hepatic adverse reaction to the product's safety profile.
What should the principal investigator do on receiving the updated brochure?

A. File the updated brochure in the site's trial master file but keep applying the prior safety information until the current enrolment cohort has completed the study and exited follow-up
B. Discard the previous brochure and treat the newly added adverse reaction as retroactively requiring expedited reporting of past events of that type collected since the trial began
C. Review the revised safety information, consider whether it affects participant risk, ongoing consent, and monitoring, and ensure the site acts on the updated reference safety information
D. Wait for the ethics committee to formally instruct the site in writing before the investigator reads, files, or applies the updated Investigator's Brochure to the ongoing trial

Answer: C

Question: 9

A research coordinator realizes she recorded a participant's blood pressure value on the wrong source worksheet and needs to correct the entry.
Which method of correcting the source record is MOST appropriate?

A. Write the correct value directly over the incorrect one without adding any date, initials, or a brief explanatory reason documenting the change.
B. Draw a single line through the error, write the correct value, and add dated initials with a brief reason, keeping the original readable.
C. Erase the incorrect entry entirely so that only the corrected value remains visible on the worksheet.
D. Cover the incorrect value with correction fluid and then carefully write the correct value directly over the now-concealed original entry.

Answer: B

Question: 10

A candidate with advanced cancer is being considered for the Phase I dose-escalation trial at the academic medical center. The coordinator is preparing the screening visit.
According to good clinical practice, when must the participant's informed consent be obtained?

A. After the first dose is administered but before the second scheduled study visit.
B. At any point during the first treatment cycle, provided the consent is later documented.
C. Once screening laboratory results have confirmed that the participant is eligible.
D. Before any trial procedure or screening assessment is performed on the participant.

Answer: D

Thank You for Trying Our Product

For More Information – Visit link below:

https://www.examsboost.com/

15 USD Discount Coupon Code:

G74JA8UF

FEATURES

- ✓ 90 Days Free Updates
- ✓ Money Back Pass Guarantee
- ✓ Instant Download or Email Attachment
- ✓ 24/7 Live Chat Support
- ✓ PDF file could be used at any Platform
- ✓ 50,000 Happy Customer