GCP for Social/Behavioral Research – Assessment Questions

RESEARCH PROTOCOL

1. True or False: Your study team can begin participant related activities, such as recruitment, before a protocol is approved by the IRB.
    A. True
    B. False

2. The coordinator for a study just realized that not all participants are being asked the same questions during an intervention. What is the first thing she should do?
    A. Disregard all previous answers from participants and start again
    B. Record the deviation, report it (per IRB's procedures), and talk to the study team about the proper protocol
    C. Gather all participants as soon as possible and ensure consistency by asking any questions that were missed
    D. Continue the current process as is, but document the issue in log notes

3. True or False: All deviations are avoidable if you plan ahead
    A. True
    B. False

4. A PI is struggling to set a timeframe for follow up study visits. She thinks a check-in one month after initial visit is appropriate, but her coordinator recommends that the follow up occur at two months. What should be written down in the IRB protocol to accommodate both opinions?
    A. One month – the IRB will require exact specifications
    B. One month plus or minus one week – a range like this will minimize later deviations but include enough specificity with the IRB protocol.
    C. 3 months – it is beneficial to "pad" the estimate, so it will never run over the time listed in the IRB protocol

5. What is the importance of an SOP?
    A. SOPs ensure team members know what, when, how, and why something must be done
    B. SOPs ensure that every participant answers in the exact same way
    C. SOPs detail the background and significance of the science behind a study
    D. SOPs are submitted to grant-making institution before a study is funded

RECRUITMENT AND RETENTION

6. True or False: To make sure that enough participants are enrolled in your study, it is appropriate to persuade a participant after he/she has said he/she does not want to participate.
    A. True
    B. False

7. How can a study team member build trust with participants? Choose all that apply.
    A. Communicate openly with them
    B. Answer any questions honestly
    C. Deviate from standard questions to personalize conversations
    D. Keep commitments made to participants

8. Unfortunately, a participant has decided to leave the study. What is the first step you should take?
    A. Ask the participant to help find a replacement
    B. Refer to your clinical protocol to review the process for participants who are withdrawing
    C. There is no action required – the study will be fine without one participant

9. True or False: The best recruiting efforts usually include multiple recruitment methods.
    A. True
    B. False

10. Which of the following is a best practice when it comes to contacting participants? Choose all that apply.
    A. Asking if it is okay to leave a voicemail
    B. Gathering several pieces of contact information from participants
    C. Calling participants in the evening when you have more time
    D. Asking participants how they prefer to be contacted

11. True or False: Participants are more likely to leave a study if they find involvement to be a hassle.
    A. True
    B. False

12. Your recruitment plan and materials are ready. What is the final step you should take before you begin recruiting participants?
    A. Print 100 copies of your flyer so that they're ready for posting
    B. Have the materials and plan approved by the IRB
    C. Turn on your online search engine ad
    D. Start gathering contact information for potential participants

INFORMED CONSENT COMMUNICATION

13. Which of the following is likely to be a required element of an informed consent document? Choose all that apply.
    A. Study purpose
    B. Study theories or hypotheses
    C. Qualifications to participate (eligibility and exclusion criteria)
    D. Possible risks and discomforts
    E. Compensation
    F. None of the above

14. True or False: The use of other strategies beyond the consent form (such as videos and comprehension checks) can help enhance understanding of what study participation will involve.
    A. True
    B. False

15. A PI has added an additional physical test to her study. The new test involves slightly different risks to her study participants. What is her best course of action?
    A. Call each participant immediately and explain the new test and any possible risk, then obtain their verbal consent to continue participation in the study.
    B. To ensure that all participants receive the same verbiage, she must mail a revised consent to each participant with the new information highlighted.
    C. She must revise the consent form, then review the new form with each participant in a face-to-face conversation.
    D. She must submit a revised consent, highlighting the new test and any associated risk, to her IRB, and continue to use the same methods previously used.

16. A research assistant (RA) is meeting with the potential study participant at the first visit to conduct informed consent. The participant is eager to begin, has read the informed consent at home, and is ready to sign their name and begin the first study assessment. What should the RA do?
    A. Since the participant has read the correct version of the form, the participant may sign the form and proceed with the study.
    B. The RA should ask several comprehension questions to ensure that the participant understood what they read at home.
    C. The RA must walk through each section of the consent form during the initial visit, confirming the participant's comprehension along the way.
    D. The RA must give the participant the printed consent form, then leave the room to allow him/her to read it again in private.

17. Which of the following are methods used to ensure participant comprehension? Choose all that apply.
    A. Sending a copy of the consent form ahead of time for the participant to review
    B. Using a 6th to 8th grade reading level when writing consent
    C. Asking the participant to summarize or explain certain elements in their own words
    D. Asking a family member to be present in order to give consent on behalf of the participant

18. True or False: To appropriately obtain an informed consent, the only people allowed in the room are the study team member and the potential participant.
    A. True
    B. False

19. True or False: A consent form is a legal document that can be signed by an adult 18 years and older; whereas an assent form allows minors to convey their own independent decision about participation.
    A. True
    B. False

20. Why might a participant need to re-consent?
    A. The study procedures/assessments have changed
    B. A significant amount of time has passed between visits
    C. There are new participant risks to consider
    D. All of the above

PRIVACY AND CONFIDENTIALITY

21. What is a Certificate of Confidentiality?
    A. A form issued by the NIH to protect identifiable information from being subpoenaed
    B. A form issued by the NIH, waiving confidentiality rights for participants
    C. A form issued by the IRB, allowing study teams to review the medical records of potential participants

22. What are some ways to securely store study data files? Choose all that apply.
    A. Store backup files on a portable storage device in a locked office
    B. Store files on a secure data server
    C. Keep all physical files in a locked file cabinet in a locked office
    D. Keep all electronic study data in password-protected computer files

23. IT departments can be a great resource at your institution. What topics should you contact your IT department about?
    A. Whether or not to film participants during a focus group
    B. To discuss online search engines for participant recruitment
    C. Setting up database access permissions for study team members
    D. The standard operating procedure for using a pedometer

24. Which of the following is a best practice when conducting a focus group?
    A. Conduct the focus group in an open, public setting so that participants don't feel as if they are "being watched"
    B. Remind participants that what is said within a group setting should not be shared outside of the group in order to protect everyone's privacy, although privacy cannot be guaranteed
    C. Call participants by name during the session to build rapport. Ask everyone to state their first and last name when speaking so you can have a record for your transcript of who said what

25. Which of the following scenarios should be reported as a privacy or confidentiality breach? Choose all that apply.
    A. You accidentally send a letter with one participant's name on it to another participant.
    B. Video recording of participants are backed up on a password-protected university server.
    C. A study team member stores study data on their personal home computer.
    D. The institution's network (used to house all data files) has been hacked, and participant data has been compromised.

26. True or False: Privacy considerations vary from culture to culture.
    A. True
    B. False

27. You have left your laptop (with files including personal information about participants) at the location of a focus group meeting. Upon returning to the site, you see that the laptop is no longer there. After you call the police, what is your next step?
    A. Put a sign on the front door and hope someone returns the laptop
    B. Call a friend to help you look for the laptop

C. Immediately call your IRB to report what happened and get their guidance on how to proceed
D. Wait 24 hours, then report the incident to your IRB

28. Which of the following is an appropriate way to contact participants?
    A. Emailing all of you participants in one main message
    B. Leaving a voicemail detailing study information on a home phone
    C. Mailing information in an envelope addressed to the participant that is not specifically branded to the study
    D. Driving to the participant's home to speak face-to-face

29. True or False: Enrolling a participant in a study and collecting data from him/her – prior to his/her completion of the consent process – is an invasion of privacy.
    A. True
    B. False

30. Kate, a new RA, couldn't find a private place and is talking loudly with potential participants with other people nearby. Is Kate following good privacy best practices?
    A. Yes
    B. No

PARTICIPANT SAFETY AND ADVERSE EVENT, UNANTICIPATED PROBLEM REPORTING, AND PROTOCOL NON-COMPLIANCE

31. An adverse event is:
    A. Always an unexpected event
    B. Always an event that happens as a result of participation in a study
    C. Any untoward medical event that occurs during a study, but may or may not be caused by a study

32. In general, what should be included in an adverse event report? Choose all that apply.
    A. Event date
    B. Steps taken to address the event
    C. The name of the participant involved
    D. Whether or not the event was expected

33. True or False: Not all adverse events are always classified as serious.
    A. True
    B. False

34. True or False: Sonya has identified an adverse event that she believes is unexpected, not related to the research and not serious. She should report it to the IRB right away.
    A. True
    B. False

35. A participant in a study assessing the effect of relaxation techniques on overall mood has come to you with feelings of depression. The study began two weeks ago, but the participant has reported feeling depressed for the last several months. Because your team has defined a study-specific adverse event reporting plan, you know that depressive thoughts are a possibility for participants. How would you classify this event?
    A. Related, expected, non-serious
    B. Unrelated, unexpected, non-serious
    C. Related, unexpected, serious
    D. Unrelated, expected, non-serious

36. Who is responsible for reporting an adverse event to the IRB?
    A. PI
    B. Research assistant
    C. Coordinator
    D. Data manager

37. Carla, a new coordinator, is having trouble keeping up with all the adverse event reports she need so give her IRB. How could she have made this situation easier on herself?
    A. There's nothing she could have done
    B. She should have outlined a study-specific adverse event reporting plan.
    C. She should have waited to report these events after her annual review.

38. True or False: All participants in a study are expected to experience the study in the same way. Therefore, an adverse event in one sub-population is always an adverse event in another.
    A. True
    B. False

39. What is the most common risk that participants in social and behavior trials might experience?
    A. Legal
    B. Psychological
    C. Physical

QUALITY CONTROL AND ASSURANCE

40. Choose the correct statement below regarding study priorities.
    A. The highest priority in a study is placed on the safety of a participant followed by the collection of good data.
    B. The highest priority in a study is placed on the collection of good data followed by the safety of a participant.
    C. The safety of a participant and the collection of good data are equally important.

41. A discrepancy in the data entered during a study has been detected. Who should decide what value is correct? Choose all that apply.
    A. The person inputting the data
    B. The PI or Data Manager
    C. The person who is NOT entering the data

42. Which of the following is a best practice for ensuring data quality?
    A. Collect as much data during a participant visit as possible, regardless of their safety.
    B. Make an executive decision on missing data so the PI doesn't need to get involved.
    C. Check participant files at the end of a study to ensure completeness.
    D. Use a checklist to ensure that assessments and interventions are carried out according to the protocol.

43. It has just been brought to the attention of a coordinator that a scale has not been functioning properly for all the initial study visits. What type of error is this?
    A. Systematic
    B. Random
    C. Unplanned
    D. Standard

44. A data management plan should include guidance on how to handle:
    A. Data that is out of range
    B. Discrepancies in double data entry
    C. Transcription errors and typos
    D. All of the above

45. One survey question asked by a research assistant is resulting in a variety of answers by participants. Some are stating that their feeling of fatigue is high, while others report they are not lethargic at all. It is discovered that participants are interpreting this question in different ways. Some are reporting on their feelings at the moment of the interview while others are considering how they felt in the last month. What type of bias is this?
    A. Measurement bias
    B. Systematic bias
    C. Memory bias

46. True or False: Electronic surveys help avoid transcription errors.
    A. True
    B. False

47. Annalise is a research nurse responsible for collecting blood samples from all participants one week after they begin a diet which minimizes sugars. Unfortunately, Annalise has misinterpreted the protocol and is submitting these samples for the wrong type of analysis by the university lab. What type of error has occurred?
    A. Random error
    B. Systematic error