

Essential Element 11: Quiz

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1. Strategies for managing study-related injuries and impairments:

(Check all that apply)

- Should be developed in advance.
- May be included in informed consent materials, sponsor policies, study protocols.
- Should not be discussed with research participants.
- Should assume that injured participants cover the costs of medical care on their own.

2. What should be addressed in a protocol in terms of study-related injury or impairment?

- What physical, psychological, economic, and/or social conditions qualify
- What injuries will be considered related to the study and who will decide
- How to distinguish between study-related injury and a participant's underlying medical condition
- What time, monetary and other limits may be placed on receiving free care
- All of the above

3. Injury refers to longer-term, not resolvable but potentially manageable harm which may result from participation in a study.

- True
- False

4. Most advisory bodies and international groups agree that:

- as long as risks are adequately explained to and understood by study participants, the possibility of injury is an acceptable sacrifice for participants to endure on their own
- there is an obligation to ensure that participants do not individually bear the costs of medical care directly resulting from their participation in clinical research, regardless of fault
- none of the above

5. Approaches to dealing with study-related injury:

- a) Should be compliant with the local law.
- b) Should be responsive to ethical factors.
- c) Should include a good justification for not providing free care for study-related injury.
- d) All of the above.
- e) A and B only.

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