

# Essential Element 1: Quiz

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### Results

**Score for this question group: 80%**

1. Which elements are necessary for a research study?
  - a) Scientific integrity
  - b) Social value
  - c) Contribution to medical knowledge
  - d) All of the above Your correct answer
  - e) A and B only
2. A relevant study question:
  - Should be formally stated in the objectives and hypotheses in the protocol Your correct answer
  - Need not be stated as it can be assumed to be obvious in studies comparing the efficacy of two drugs.
  - Is not necessary for studies that provide useful, non-trivial information.
  - None of the above.
3. If related elements are already discussed in designated sections of the protocol, it may still be helpful to introduce a special ethical section wi...
  - True Your correct answer
  - False
4. Which of the following queries should be considered for writing relevant study questions? (Check all that apply)
  - What is the unmet need? Your correct answer
  - Does it contribute to a development program or medical knowledge? Your correct answer
  - What is the justification for the study? Your correct answer
  - How does the study recruit and compensate the research participants?
5. Which of the following is/are NOT a good example/s of addressing relevant questions in a research protocol?
  - Drug X offers greater potential advantages than Drug Y for long-term treatment of disease Z. Drug X is a new therapy that is longer acting and does not require refrigeration. This requires less frequent office visits for patients with disease Z who will be participant of this study. A comparison between Drug X and Drug Y is planned to study the ability of both drugs to produce the desired result. Your answer
  - Drug A has shown to have much more serious undesirable effects than Drug B in a prior study on cancer with more than 1,000 participants. Both drugs have the same ability to produce the desired result. A new study of Drugs A and Drug B is proposed to confirm this result. Correct answer
  - Drug D will be given to healthy participants to study how the body processes it (pharmacokinetics) at the current dose. This proposed study will provide valuable information in regard to dosing Drug D for patients with disease E.

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