Essential Element 4: Quiz

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1. Individuals who enroll as participants in clinical studies are always exposed to risk and inconvenience that they would not otherwise experience.

    - ○ True
    - ○ False

2. Which of the following statements are NOT true about the fair selection of research participants?
(Check all that apply)

    - ☐ The Belmont Report demands the fair distribution of burdens and benefits of research.
    - ☐ The selection of research participants must be equitable to ensure fair distribution of risks and burdens.
    - ☐ Fair selection of research participants does not apply to vulnerable populations such as children, prisoners, pregnant women, mentally disabled, or economically or educationally disadvantaged persons.
    - ☐ Selection criteria should ensure that research participants adequately represent the population that may benefit from the research.
    - ☐ The fair distribution of burdens and benefits applies to the selection and recruitment of study participants, but not to the study design or conduct of the research.

3. Which of the following questions should be considered for selecting the target population?

    - ○ What is the scientific basis for targeting the specific study population
    - ○ Are healthy participants to be studied?
    - ○ Is the participant population being exposed for the first time?
    - ○ All of the above.

4. A protocol for research involving a potentially vulnerable population should contain information about:
(Check all that apply.)

    - ☐ Scientific justification for including the vulnerable group
    - ☐ Inclusion and exclusion criteria
    - ☐ How the inclusion of the vulnerable group is necessary for answering the scientific question
    - ☐ Relationship between Principal Investigator and vulnerable population
    - ☐ Steps taken to protect individuals who may have diminished capacity to consent

5. Ease of participant recruitment is considered an ethical justification for selection of a population, country or region.

    - ○ True
    - ○ False

6. Research is sometimes conducted with participants who are not competent to give informed consent. Considerations include:
(Check all that apply.)

    - ☐ If the research is not expected to directly benefit participants then risks should be minimal (such as those no greater that would normally be posed by routine medical or

psychological examination of such persons)
- ☐ If the research poses more than minimal risk, there must be a justification for why the research is being conducted in this population
- ☐ A significant amount of risk may be acceptable, even if research that is not expected to directly benefit participants, if the expected benefits to society in terms of generalizable knowledge are sufficient, and if the legal guardian agrees
- ☐ If the research is expected to directly benefit the participants, a minor increase above minimal risk may be considered acceptable by the IEC/IRB

7. How can first use of a new drug or therapy in humans be justified?

   - ○ a) Animal studies and toxicology studies indicate good reason to move to human trials and exposure has been well thought through.
   - ○ b) International guidelines have been used to calculate the dose and escalating the dose.
   - ○ c) Rules for stopping and use of monitoring committees have been defined.
   - ○ d) When appropriate, tolerability of the dose has been shown in healthy participants before giving it to participants with the disease.
   - ○ e) All of the above.
   - ○ f) A, B and C only.

8. How can a first use of a new drug or therapy in women be justified, considering the possibility of pregnancy and the potential risk to the unborn child?

   - ○ a) Ask women of childbearing potential to use a double-barrier method of birth control.
   - ○ b) Involve surgically sterile women.
   - ○ c) Involve postmenopausal women.
   - ○ d) Do never involve women in studies of new drugs and therapies.
   - ○ e) All of the above.
   - ○ f) A, B and C only.

9. Populations at special risk because of underlying disease or other issues (e.g., pacemakers):

   - ○ Should be identified in the study protocol, together with measures identified to make their participation safe.
   - ○ Should be encouraged to participate in clinical trials as they may benefit particularly from the therapy.

10. For healthy participants and participants with significant medical problems, the ethical consideration of a drug study protocol should:

    - ○ Include the Curriculum Vitae of the Principal Investigator.
    - ○ Recognize the potential risks and indicate why it is important and acceptable for these participants to be studied.
    - ○ Describe how the drug has been tested in animals prior to the current study.
    - ○ All of the above.
    - ○ None of the above.

11. Overprotection or underrepresentation of study populations (e.g., men, elderly) can result in misleading conclusions of studies.

    - ○ True
    - ○ False

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