Informed Consent in HIV Cure Research Assessment Questions

1. What led to the creation of the National Research Act in July of 1974?
   a. The Baltimore Lead Study
   b. Kitty Genovese Case
   c. Tuskegee Syphilis Experiment
   d. Nuremberg Trials

2. IRBs stand for:
   a. Internal Review Boards
   b. Institutional Review Bureau
   c. Institute of Research Briefs
   d. Institutional Review Boards

3. Which one of these options is NOT a required element of informed consent?
   a. Reasonably foreseeable risks/discomforts
   b. Assurance of safety and efficacy of product
   c. Confidentiality of records identifying the subject
   d. Whom to contact for answers to questions
   e. The study involves research; explanation of study purpose, procedures and duration

4. Please select the ethical issue(s) associated with HIV cure research (not HIV treatment or prevention):
   a. Potentially significant risks
   b. No prospect of medical benefit
   c. Existence of known effective treatment
   d. All of the above

5. Which one of these is NOT a suggested study to be undertaken to investigate whether consent is truly informed?
   a. Baseline data, prior to recruitment
   b. At-home survey involving partners and family
   c. Interviewing both joiners and decliners
   d. Over time

6. Many early phase, exploratory trials describe their main objectives as safety and tolerability and their “benefit” sections generally state there is no or very little prospect of direct medical benefit HOWEVER:
   a. These are often in long complicated paragraphs that participants skip over
   b. Participants underestimate these claims and ignore them
   c. Long-term aims are often presented in lofty terms that may be interpreted as possible
   d. None of the above
7. Which of the following is a concern for HIV “cure” studies in South Africa?
   a. Conducting early phase trials among populations that are particularly vulnerable require larger financial commitments and are therefore more difficult to be approved
   b. Studies show that people join trials to get health care, often not a voluntary choice
   c. Despite legal focus on informed consent, well-structured documents are readable by ordinary people
   d. Shortcomings in understanding elements of informed consent make the participant’s liable, not the researchers.

8. Acquiring knowledge to be “informed” can happen before, during or after a trial.
   a. True
   b. False

9. All but ONE of the below list is considered a vulnerable population in the US
   a. Fetuses
   b. Men Who Have Sex with Men
   c. Pregnant Women
   d. Prisoners

10. Remission, which implies HIV may return, is the goal of early phase HIV cure trials.
    a. True
    b. False
Answer Key
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