Protecting Human Research Participants: Select Quiz Questions

Codes and Regulations: Section Quiz

1. Identify the most influential event that led to the HHS Policy for Protection of Human Research Subjects:

   A. Nuremberg trials
   B. Syphilis Study at Tuskegee
   C. Jewish Chronic Disease Hospital Study
   D. Willowbrook Study

2. An institutionally designated authority, other than the investigator, should determine that proposed studies are exempt from regulatory requirements.

   A. True
   B. False

3. The Belmont Report is significant because:

   A. It was written by the National Commission for the Protection of Human Subjects.
   B. It articulated ethical principles that formed the basis for the HHS Human Subjects Regulations.
   C. Belmont is another word for individual autonomy and respect.
   D. It was a seminal document about the concept of informed consent.

4. 45 CFR 46 requires Federal Departments and Agencies to rely solely on IRBs to evaluate risks to subjects, protection against these risks, potential benefits of the research and the importance of the knowledge to be gained.

   A. True
   B. False

5. A "systematic investigation designed to develop or contribute to generalizable knowledge" may include:

   A. Evaluation
   B. Research Development
   C. Testing
   D. All of the above

6. An "autonomous person" is someone who:

A. Has reached the legal age to provide informed consent in the State.
B. Is willing to accept certain risks if the research will benefit others in the future.
C. Understands the risks and benefits of his or her participation and is able to make a voluntary decision if adequate information is provided.
D. Meets all eligibility criteria for a study and asks the investigator if she or he may participate.

Respect for Persons: Section Quiz

7. Why might an individual have diminished autonomy?

A. They are a neonate.
B. They are incarcerated or involuntarily confined.
C. They are unconscious.
D. All of the above.

8. In order to participate in research, children must:

A. Provide written informed consent
B. Provide written permission
C. Provide assent, unless the IRB determines that they are too young

9. For research involving pregnant women, participation requires:

A. That women have completed the first trimester.
B. That the study be conducted first in men.
C. Permission of the father.
D. Consideration of risks and potential benefits for the fetus and the pregnant woman.

10. The three fundamental principles of Informed consent are:

A. Voluntariness, Equipoise, Respect
B. Voluntariness, Comprehension, Disclosure
C. Benefits, Comprehension, Privacy
D. Disclosure, Equipoise, Privacy

11. The regulations strongly suggest but do not require that the informed consent process be delivered in a language that is understandable to the subject.

A. True
B. False

12. If informed consent information is presented orally, it must be documented using a short form that states that all the required elements were presented orally.

A. True
B. False

Beneficence: Section Quiz

13. What is an appropriate method for maintaining confidentiality of private information obtained from human subjects?

A. Keeping data in a password-protected database
B. Storing images in a secured cabinet
C. Coding data or specimens and keeping the key to the code in a separate, locked drawer
D. All of the above are ways to maintain confidentiality

14. If a researcher determines that his/her study poses no more than minimal risk as defined in 45 CFR 46, there is no need for the protocol to have IRB review and approval.

A. True
B. False

15. Which of the following most accurately describes clinical equipoise?

A. Scientific uncertainty that one study intervention is superior to another
B. A reasonable balance of risks and benefits to research subjects
C. When the probability and magnitude of harm or discomfort is not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams
D. A double blind controlled trial

16. Because the expedited IRB review process is generally used for certain types of minimal risk research, it is less stringent than review by the full IRB.

A. True
B. False

17. Therapeutic misconception is the tendency for investigators to mislead research participants about the research purpose, procedures or benefits.

A. True
B. False

Justice: Section Quiz

18. In localities where community consent is the norm,

A. A family member's consent for another individual may be sufficient, as long as community consent is given
B. Federal regulations preclude the conduct of PHS-funded research
C. Community consent to participate in the research study is sufficient and no IRB approval is required
D. In addition to the cultural norm, individual informed consent is required

19. NIH has specific policies addressing:

A. Inclusion of children in research
B. Inclusion of women and minorities in research
C. Treatment for research subjects in HIV/AIDS antiretroviral studies following completing of trials in developing countries
D. All of the above

20. IRBs reviewing research in a different geographical location and/or cultural context have a responsibility to:

A. Obtain knowledge of the local context by talking to those who have traveled to the region
B. Defer to an IRB that is in the situated within the local research context
C. Ask specialists with direct knowledge of the local research context to participate in IRB discussions
D. B or C
E. A or C

21. It is ethical to use deceptive methods in research when the scientific goals of the project can be achieved by non-deceptive methods.

A. True
B. False