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True/False

1. Any type of research performed can qualify as “regulated research”.

Answer: False
A-Head: Introduction

2. Examples of inhumane treatment for research purposes should include the Nazi Human Experiments during WWII.

Answer: True
A-Heading: Table 2-1

3. The Belmont Princple led to the development of the following requirements: informed consent, assessment of risks and benefits, and participant compensation.

Answer: False
A-Heading: How is Research Approved

4. A study that tested the efficiacy of a new migraine drug in children would likely be exempted from IRB approval.

Answer: False
A-Heading: Can it be Exempted

5. The Common Rule defines research as a systematic study that can include research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Answer: True
A-Heading: Is this Regulated Research

6. For a study to be categorized as regulated research, it must meet the criteria for being defined as systematic and generalizable.

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Answer: True
A-Heading: Is this Regulated Research

7. A study that uses medical chart reviews for information that is both pre-existing and does not trace back to the individual would likely require a convened IRB (i.e., full committee) review.

Answer: False
A-Heading: Can It be Expedited

8. In healthcare research, studies that have significant risk, where the probability of risks outweighs the benefits of participating can still be approved by the IRB.

Answer: False
A-Head: How Will the IRB Review a Regulated Research Project

9. If informed consent cannot be documented (e.g., telephone surveys), the researcher may request a waiver of documentation of informed consent, which must be approved by the IRB.

Answer: True
A-Head: How Will the IRB Review a Regulated Research Project

10. Any and all problems that occur during the study, must be immediately reported to the IRB committee.

Answer: False
A-Head: Tracking Adverse Events and Reporting UPIRSOs

11. Noncompliance is an action by the investigator, or member of the research team, that disregards federal regulations, IRB requirements, or institutional policies and procedures.

Answer: True
A-Head: Reporting Noncompliance

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12. It is the responsibility of the primary investigator (PI), to ensure the study continues to meet the criteria used by the IRB committee for the initial approval.

Answer: True
A-Head: What are the Investigator's Responsibilities?

13. The principle investigator (PI) typically inactivates the study by providing a final status report to the Institutional Review Board (IRB).

Answer: True
A-Head: Inactivation

14. An example of FDA-Regulated research would include the use of a device to evaluate safety or effectiveness of that device.

Answer: True
A-Head: Is this FDA-Regulated Research?

15. The Common Rule requires IRB approval of all human-subjects research.

Answer: True
A-Head: When is IRB Approval Required?

16. The convened IRB (i.e., the full committee) must review regulated research that does not meet criteria as wither exempt or expedited.

Answer: True
A-Head: What if a Research Project is Not Eligible for Expedited Review?

Multiple Choice

17. To highlight the need for IRB regulations in research, a prime example would the case of Harvey Wiley, Chief Chemist of the Department of Agriculture. What did he do that was unethical?

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A. He deliberately withheld penicillin as a treatment from 339 African American males diagnosed with Syphilis to see how the disease progressed.
B. He used a vulnerable group of inmates to study the effects of harsh chemicals on the skin.
C. He recruited 12 unmarried men to eat contaminated food to study which preservatives were toxic to the human body.
D. None of these.

Answer: C
A-Head: Historical Context

18. The Nazi Human Experiments lead to the development of which guideline?
A. The Food, Drug, and Cosmetic Act of 1938
B. Nuremberg Code of 1947
C. Belmont Report
D. National Research Act of 1974

Answer: B
A-Head: Eugenics and Nazi Experiments

19. Can a participant be allowed to leave a study (e.g., stop participating) at any time?
A. Yes
B. No

Answer: A
A-Head: Table 2-3 Elements of Informed Consent

20. Choose the best answer. "According to the IRB, Harm …
A. is defined by physical abuse
B. can be categorized as psychological and/or social abuse
C. includes economic and legal risks and violations of dignity
D. All of these
E. None of these

Answer: D
A-Head: Can It Be Expedited?

21. Which example of research would likely be given expedited review by the IRB?
A. A drug trial on a new medication to treat high blood pressure

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B. The use of a new device that is used by surgeons during cardiac-bypass surgery
C. The use of information or specimens that have already been collected for a purpose.
D. All of these

Answer: C
A-Heading: Can It Be Expedited?

22. The Common Rule requires which aspect as one of the three basic protetions?
A. The confidentiality of records will be maintained
B. Participants in a study is voluntary
C. Individuals with diminished autonomy are entitled protection
D. Informed consent will be sought from each prospective participant

Answer: D
A-Head: How Will the IRB Review Regulated Research Project?

23. Which element of informed consent is not required?
A. The extent to which confidentiality will be maintained.
B. Financial compensation for all individuals is mandatory.
C. An explanation of the purpose of the research.
D. The description of any reasonably foreseeable risks or discomforts

Answer: B
A-Head: Table 2-3 Elements of Informed Consent

24. Which answer makes this sentence a true statement? “When changes to a research study are need,…”
A. IRB approval must first be obtained before any modifications are implemented.
B. the IRB committee can be notified after the study is complete.
C. All of these
D. None of these

Answer: A
A-Head: Modifications

25. What is the main goal of the institutional review board (IRB) approval?
A. Assists the researcher with the design of the study
B. Ensures the protection of study participants

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C. Reviews the final study report for grammatical errors
D. Sends members to investigate possible fraudulent study activities

Answer: B
A-Head: How Is Research Approved?

26. Which of the following is an example of a study modification that does not require IRB approval once the study has been initiated?
A. Enrolling four additional subjects as participants because some initial participants dropped out in the middle of the study
B. An impromptu change in the statistical analysis due to the development of a new software program
C. A change in the delivery method of a medication to eliminate an immediate hazard to study subjects
D. A change in the recruitment posters for the study

Answer: C
A-Head: Modifications

27. Which of the following must be reported immediately to the IRB?
A. A study subject involved in an automobile accident and is in critical condition
B. A study subject complains that the cost of travel to the study site is excessive and demands reimbursement not approved by the IRB
C. A laptop computer with study data goes missing
D. A member of the research team is fired for insubordination

Answer: C
A-Head: Tracking Adverse Events and Reporting UPIRSOs

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