Research Methods The Essential Knowledge Base 2nd edition Trochim Test Bank

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True / False

1. Fundamentally, research ethics are about doing the right thing for all involved.
   a. True
   b. False

ANSWER: True
DIFFICULTY: Easy
REFERENCES: 2.1 Foundations of Ethics in Research
KEYWORDS: Bloom's: Understand

2. Milgram's famous study was inspired by the Nazi defense, "orders are orders."
   a. True
   b. False

ANSWER: True
DIFFICULTY: Easy
REFERENCES: 2.2 Historical Cases of Unethical Research
KEYWORDS: Bloom's: Understand

3. FDA inspector Frances Kelsey refused to approve an application with what she viewed as insufficient safety data, even under pressure from her superiors, and thus, prevented the Thalidomide tragedy from occurring in the United States.
   a. True
   b. False

ANSWER: True
DIFFICULTY: Easy
REFERENCES: 2.2 Historical Cases of Unethical Research
KEYWORDS: Bloom's: Understand

4. Assent means that a child has not stated any objections to participating in a research study.
   a. True
   b. False

ANSWER: False
DIFFICULTY: Moderate
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

5. In a Phase III study, a drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely
   a. True
   b. False

ANSWER: True
DIFFICULTY: Moderate
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

6. At smaller universities, Institutional Review Boards typically review research using both humans and animals.
   a. True

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b. False

ANSWER: False
DIFFICULTY: Moderate
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

7. Current standards do not require that participants in clinical trials be told that they might receive a placebo
a. True
b. False

ANSWER: False
DIFFICULTY: Moderate
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

8. The principle of "respect for persons" means that people are to be treated as independent and autonomous individuals
a. True
b. False

ANSWER: True
DIFFICULTY: Moderate
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

9. Even an accidental error in recording or analyzing data is considered misconduct.
a. True
b. False

ANSWER: False
DIFFICULTY: Easy
REFERENCES: 2.4 Ethics in the Production and Publication of Scholarly Work
KEYWORDS: Bloom's: Understand

10. In the United States, the Department of Health and Human Services has placed responsibility for managing conflicts of interest on investigators, IRBs, and institutions
a. True
b. False

ANSWER: True
DIFFICULTY: Easy
REFERENCES: 2.4 Ethics in the Production and Publication of Scholarly Work
KEYWORDS: Bloom's: Understand

Multiple Choice

11. The 10 principles that were developed as a frame of reference for judging the conduct of Nazi physicians accused of atrocities became the ____.
a. Nuremberg Code
b. Milgram Code
c. Belmont Report

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d. Tuskegee Report

ANSWER: a

DIFFICULTY: Easy

REFERENCES: 2.2 Historical Cases of Unethical Research

KEYWORDS: Bloom's: Understand

12. The modern history of human-subject protections began at ____.

a. Nuremberg

b. Stanford

c. Belmont

d. Tuskegee

ANSWER: a

DIFFICULTY: Easy

REFERENCES: 2.2 Historical Cases of Unethical Research

KEYWORDS: Bloom's: Understand

13. Which researcher conducted studies of obedience that suggested ordinary people would do things they knew would cause harm to others simply because they were told to do so?

a. Zajonc

b. Milgram

c. Kohlberg

d. Zimbardo

ANSWER: b

DIFFICULTY: Easy

REFERENCES: 2.2 Historical Cases of Unethical Research

KEYWORDS: Bloom's: Understand

14. The classic “obedience study” is believed to have been the first study in which the term ____ was used.

a. debriefing

b. placebo

c. control group

d. confederate

ANSWER: a

DIFFICULTY: Easy

REFERENCES: 2.2 Historical Cases of Unethical Research

KEYWORDS: Bloom's: Understand

15. After the Thalidomide tragedy, the ____ Amendments were passed, which requires drug manufacturers to prove the safety of their drugs before marketing them.

a. Milgram

b. Belmont

c. Tuskegee

d. Kefauver-Harris

ANSWER: d

DIFFICULTY: Easy

REFERENCES: 2.2 Historical Cases of Unethical Research

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KEYWORDS: Bloom's: Understand

16. What did the 1980s activist poster that read “Stop Protecting Us to Death” refer to?

a. The HIPAA’s requirements to obtain patient data
b. The IRB’s monitoring of compliance with research protocols
c. The FDA’s cautious approach to approving new drugs
d. The NIH’s lack of funding due to conflict of interest

ANSWER: c
DIFFICULTY: Moderate
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

17. The ____, passed in 1974, represents one of the first serious attempts to build a comprehensive system of research ethics in the United States.

a. National Research Act
b. Declaration of Helsinki
c. Tuskegee Code
d. Kefauver-Harris Amendments

ANSWER: a
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

18. The principle of ____ means that people are to be treated as independent and autonomous individuals.

a. respect for persons
b. beneficence
c. justice
d. non-maleficence

ANSWER: a
DIFFICULTY: Moderate
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

19. The principle of ____ means that researchers should attempt to maximize the benefits of participation and take steps to identify and limit the potential for harm.

a. respect for persons
b. beneficence
c. justice
d. non-maleficence

ANSWER: b
DIFFICULTY: Moderate
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

20. The principle of ____ means that participation should be based on fairness and not on circumstances that give researchers access to or control of a population based on status.

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a. respect for persons
b. beneficence
c. justice
d. non-maleficence

ANSWER: c
DIFFICULTY: Moderate
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

21. When ____ is used, either misleading or incomplete information is given to participants in the informed consent process.

a. deception
b. debriefing
c. de-identification
d. duplicity

ANSWER: a
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

22. Sondra has just finished participating in an experiment that involved deception and is now being told the whole truth about what was done and why. Sondra is undergoing ____.

a. deception
b. debriefing
c. post-hoc consenting
d. post-hoc analysis

ANSWER: b
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Apply

Narrative 2-1
The Homeless Shelter

Carlos, a psychologist at a local shelter for homeless individuals, makes determinations about who should get special privileges. He is working on his doctorate at the same time, and naturally considers dissertation topics that would involve people who are homeless.

23. Should Carlos decide to recruit participants from the shelter at which he works, his institutional review board is likely to be concerned about ____.

a. respect for persons
b. beneficence
c. justice
d. non-maleficence

ANSWER: c
DIFFICULTY: Difficult
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics

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PREFACE NAME: Narrative 2-1
KEYWORDS: Bloom's: Apply

24. Carlos is well aware that even a small amount of money can be a powerful incentive. He is struggling with how much he can pay participants without being coercive. This issue relates most strongly to ____.

a. respect for persons
b. beneficence
c. justice
d. assent

ANSWER: a
DIFFICULTY: Difficult
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
PREFACE NAME: Narrative 2-1
KEYWORDS: Bloom's: Apply

25. Carlos wants to make sure that any information from participant surveys is not shared with the shelter's administration to avoid potential consequences. This issue relates most strongly to ____.

a. deception
b. beneficence
c. justice
d. confidentiality

ANSWER: d
DIFFICULTY: Difficult
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
PREFACE NAME: Narrative 2-1
KEYWORDS: Bloom's: Apply

26. Carlos is thinking about including children in his study. Although the children cannot enter into a legal agreement to participate, he feels it is important that they still agree to participate. By doing so, Carlos is seeking the children's ____.

a. assent
b. confidence
c. willing participation
d. consent

ANSWER: a
DIFFICULTY: Difficult
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
PREFACE NAME: Narrative 2-1
KEYWORDS: Bloom's: Apply

27. Carlos decides to focus on individuals who are at high risk of becoming homeless, specifically, individuals with severe, persistent mental illness who are being released from state hospitals. He is aware that many of his potential research participants have low literacy levels and takes this into consideration when preparing his informed consent materials. In terms of the Belmont Report's conceptualization of informed consent, Carlos is addressing ____.

a. assent
b. comprehension
c. information
d. voluntariness

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ANSWER: b
DIFFICULTY: Difficult
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
PREFACE NAME: Narrative 2-1
KEYWORDS: Bloom's: Apply

28. Carlos decides to focus on individuals who are at high risk of becoming homeless, specifically, individuals with severe, persistent mental illness who are being released from state hospitals. He is extremely careful, in his consent materials, to be clear that people do not have to participate, that their decision to participate or not participate will in no way impact their treatment at the hospital or thereafter, and that, even if they agree to participate, they can withdraw their consent without penalty. In terms of the Belmont Report's conceptualization of informed consent, Carlos is addressing ____.

a. assent
b. comprehension
c. information
d. voluntariness

ANSWER: d
DIFFICULTY: Difficult
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
PREFACE NAME: Narrative 2-1
KEYWORDS: Bloom's: Apply

Narrative 2-2
Brain Imaging

Katherine is a researcher studying the neurophysiology of schizophrenia. In order to do so, she compares fMRI imaging when individuals are on effective medication and when they have been off their medication long enough that it is no longer detectible in their blood.

29. Katherine recognizes that this may create more than minimal risk. In terms of the principles in the Belmont Report, she is concerned about ____.

a. respect for persons
b. beneficence
c. justice
d. voluntariness

ANSWER: b
DIFFICULTY: Difficult
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
PREFACE NAME: Narrative 2-2
KEYWORDS: Bloom's: Apply

30. Katherine is aware that some potential participants may have cognitive impairments and she considers excluding them solely on that basis. At the same time, she is aware that participants may, themselves, benefit from participating in the study, since they will live in at research hospital during the study and will have access to numerous resources while hospitalized. If Katherine decides to exclude persons with cognitive impairments, she is also denying these individuals access to other services, and this bothers her. In terms of the principles in the Belmont Report, she is struggling with issues related to ____.

a. respect for persons
b. beneficence

c. justice
d. voluntariness

ANSWER: c
DIFFICULTY: Difficult
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
PREFACE NAME: Narrative 2-2
KEYWORDS: Bloom's: Apply

31. During the study, participants will stay at a research hospital and be unable to work at their usual jobs, will be aware from friends and families, and have other restrictions on their activities. As a result, Katherine is going to pay her participants. In terms of the principles in the Belmont Report, Katherine's decision about how much to pay participants is most related to ____.

a. comprehension
b. beneficence
c. justice
d. non-maleficence

ANSWER: c
DIFFICULTY: Difficult
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
PREFACE NAME: Narrative 2-2
KEYWORDS: Bloom's: Apply

32. After recent research showed that the caregivers of family members with developmental disabilities showed significant stress reduction when taught simple mindfulness techniques during everyday activities, Liese wonders whether the same might be true of the caregivers of family members with Alzheimer's disease. Liese will recruit participants from a local peer support program for caregivers but, knowing how stressful caregiving can be, worries about how she will create an ethically sound control group. Liese is most concerned with ____.

a. right to service
b. external validity
c. deception
d. non-maleficence

ANSWER: a
DIFFICULTY: Difficult
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Analyze | Bloom's: Apply

33. From the standpoint of an Institutional Review Board, research would include ____.

a. program evaluation required by a funding agency
b. patient satisfaction surveys
c. surveys conducted in order to improve clinic services
d. an examination of which of two treatments are most effective

ANSWER: d
DIFFICULTY: Moderate
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

34. Human subjects are to the Institutional Review Board as animal subjects are to the ____.

a. Board for the Ethical Treatment of Animals
b. Institutional Animal Care and Use Committee
c. Animal Protection Committee
d. Committee for Animals

ANSWER: b
DIFFICULTY: Moderate
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

35. What term refers to an assurance made to study participants that identifying information about them acquired through the study will not be released to anyone outside of the study?
a. privacy
b. anonymity
c. confidentiality
d. de-identification

ANSWER: c
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

36. What term refers to an assurance made to study participants that no one, including the researchers, will be able to link data to a specific individual?
a. privacy
b. anonymity
c. confidentiality
d. de-identification

ANSWER: b
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

37. What term refers to an assurance made to study participants that personal information about participants will be protected?
a. privacy
b. anonymity
c. confidentiality
d. de-identification

ANSWER: a
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

38. The process of removing identifying information from data sets is known as ____.
a. privacy
b. anonymity
c. confidentiality

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d. de-identification

ANSWER: a
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

39. A ____ study is designed to test a new drug or treatment in a small group of people to evaluate its safety, determine a safe dosage range, and identify potential side effects.

a. pilot
b. Phase I
c. Phase II
d. Phase III

ANSWER: b
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

40. In a ____ study, the drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.

a. pilot
b. Phase I
c. Phase II
d. Phase III

ANSWER: c
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

41. In a ____ study, the drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

a. pilot
b. Phase I
c. Phase II
d. Phase III

ANSWER: d
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

42. Although the rules surrounding the testing and approval of new drugs were indented to protect the public, these rules can also limit the access to drugs by people who are desperately ill. As a result of demands by ____ activists, the FDA eventually developed an expedited review process as well as a program to expand access to promising drugs.

a. AIDS
b. cancer
c. autism spectrum disorder
d. Alzheimer's disease

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ANSWER: a
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

43. Researcher and couples' therapist ____ hired actors to falsely testify about their involvement with data collection activities related to his research studies and deceived those actors about what they were actually doing.

a. Jan Hendrik Schön
b. William Fals-Stewart
c. Haruko Obokata
d. Bodo-Eckehard Strauer

ANSWER: b
DIFFICULTY: Difficult
REFERENCES: 2.4 Ethics in the Production and Publication of Scholarly Work
KEYWORDS: Bloom's: Understand

44. Physicist ____ was found to have completely made up some of the data on which his astounding discoveries were made.

a. Jan Hendrik Schön
b. William Fals-Stewart
c. Haruko Obokata
d. Bodo-Eckehard Strauer

ANSWER: a
DIFFICULTY: Difficult
REFERENCES: 2.4 Ethics in the Production and Publication of Scholarly Work
KEYWORDS: Bloom's: Understand

45. Research misconduct involving making up data or results and recording or reporting them is classified as ____.

a. plagiarism
b. falsification
c. fabrication
d. deception

ANSWER: c
DIFFICULTY: Difficult
REFERENCES: 2.4 Ethics in the Production and Publication of Scholarly Work
KEYWORDS: Bloom's: Understand

46. Research misconduct involving manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record is classified as ____.

a. plagiarism
b. falsification
c. fabrication
d. deception

ANSWER: b
DIFFICULTY: Difficult
REFERENCES: 2.4 Ethics in the Production and Publication of Scholarly Work

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KEYWORDS: Bloom's: Understand

47. Research misconduct involving the appropriation of another person's ideas, processes, results, or words without giving appropriate credit is classified as ____.

a. plagiarism
b. falsification
c. fabrication
d. deception

ANSWER: a
DIFFICULTY: Difficult
REFERENCES: 2.4 Ethics in the Production and Publication of Scholarly Work
KEYWORDS: Bloom's: Understand

48. Rhonda, a stem cell researcher, is found to have mislabeled graphs and photomicrographs. This can most accurately be described as ____.

a. plagiarism
b. falsification
c. fabrication
d. deception

ANSWER: b
DIFFICULTY: Difficult
REFERENCES: 2.4 Ethics in the Production and Publication of Scholarly Work
KEYWORDS: Bloom's: Apply

49. Ralph, a clinical researcher, is found to have omitted data that are inconsistent with his hypothesis about the causes of autism spectrum disorders. He has engaged in ____.

a. plagiarism
b. falsification
c. fabrication
d. deception

ANSWER: b
DIFFICULTY: Difficult
REFERENCES: 2.4 Ethics in the Production and Publication of Scholarly Work
KEYWORDS: Bloom's: Apply

50. Sergey is lagging behind his proposed research schedule. Desperate to demonstrate that he is making good use of federal grant money, he makes up data to present in a progress report. What behavior is Sergey demonstrating?

a. plagiarism
b. falsification
c. fabrication
d. deception

ANSWER: c
DIFFICULTY: Difficult
REFERENCES: 2.4 Ethics in the Production and Publication of Scholarly Work
KEYWORDS: Bloom's: Understand

Completion

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51. The _____ requires manufacturers to present evidence on the safety and effectiveness of their products to the FDA before marketing them

ANSWER:
Kefauver-Harris amendments
Kefauver Harris amendments

DIFFICULTY: Easy

REFERENCES: 2.2 Historical Cases of Unethical Research

KEYWORDS: Bloom's: Understand

52. The _____ was adopted by the World Medical Association in 1964 in order to provide a set of principles to guide the practice of medical research.

ANSWER: Declaration of Helsinki

DIFFICULTY: Easy

REFERENCES: 2.2 Historical Cases of Unethical Research

KEYWORDS: Bloom's: Understand

53. The _____ involved poor African American sharecroppers with a potentially fatal sexually transmitted infection who were not treated for the infection even after a cure was available.

ANSWER: Tuskegee Syphilis Study

DIFFICULTY: Easy

REFERENCES: 2.2 Historical Cases of Unethical Research

KEYWORDS: Bloom's: Understand

54. The _____ includes basic standards that should underlie the conduct of any biomedical and behavioral research involving human participants.

ANSWER: Belmont Report

DIFFICULTY: Easy

REFERENCES: 2.3 Evolution of a Modern System of Research Ethics

KEYWORDS: Bloom's: Understand

55. In research ethics, groups who may not be fully in control of their decision making are referred to as _____.

ANSWER: vulnerable populations

DIFFICULTY: Moderate

REFERENCES: 2.3 Evolution of a Modern System of Research Ethics

KEYWORDS: Bloom's: Understand

56. A detailed document summarizing the purpose and procedures of a study is referred to as a(n) _____.

ANSWER: protocol

DIFFICULTY: Moderate

REFERENCES: 2.3 Evolution of a Modern System of Research Ethics

KEYWORDS: Bloom's: Understand

57. The phrase "_____" means that the risk of harm is not greater than that experienced in everyday life situations such as typical academic or medical examinations.

ANSWER: no more than minimal risk

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DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

58. The term _____ means that participation should be based on fairness and not on circumstances that give researchers access to or control of a population based on status.
ANSWER: justice
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

59. When a researcher pre-test assessment that identifies those in greatest need and then provides the intervention to them, the researcher is using a _____ design.
ANSWER: Regression-Discontinuity
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

60. A(n) _____ study is designed to test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify potential side effects.
ANSWER: Phase I
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

61. An assurance of _____ made to study participants specifies that identifying information about them acquired through the study will not be released to anyone outside of the study.
ANSWER: confidentiality
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

62. In research, _____ means protection of personal information about participants.
ANSWER: privacy
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

63. The role of a local _____ is to review all proposed research involving human subjects to ensure that subjects are going to be treated ethically and that their rights and welfare will be adequately protected.
ANSWER: IRB
Institutional Review Board
Institutional Review Board (IRB)
DIFFICULTY: Easy
REFERENCES: 2.3 Evolution of a Modern System of Research Ethics
KEYWORDS: Bloom's: Understand

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64. According to the Office of Research Integrity, _____ involves making up data or results and recording or reporting them.

ANSWER: fabrication

DIFFICULTY: Easy

REFERENCES: 2.4 Ethics in the Production and Publication of Scholarly Work

KEYWORDS: Bloom's: Understand

65. According to the Office of Research Integrity, _____ is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

ANSWER: falsification

DIFFICULTY: Easy

REFERENCES: 2.4 Ethics in the Production and Publication of Scholarly Work

KEYWORDS: Bloom's: Understand

Essay

66. What is a conflict of interest and why is it considered to be an ethical issue?

ANSWER: A conflict of interest exists in research when a researcher's primary interest in the integrity of a study is compromised by a secondary interest such as personal gain (e.g., financial profit). Many ethical principles such as those relating to conflict of interest and research misconduct help ensure that researchers who are funded by public money can be held accountable to the public. In other words, funders can be assured that all research they fund adheres to a common set of ethical precepts relating to quality and integrity. Ensuring that all projects abide by these principles also levels the playing field among different researchers. This helps to build broad public support for research in general.

DIFFICULTY: Difficult

REFERENCES: 2.1 Foundations of Ethics in Research

KEYWORDS: Bloom's: Analyze

67. Describe the goals and methods of the Tuskegee Study and the consequences for the participants involved.

ANSWER: The Tuskegee Syphilis Study was an infamous clinical study that lasted for 40 years (1932–1972) and was administered by the U.S. Public Health Service in Alabama. Its main goal was to study the health effects of untreated syphilis, which was a deadly sexually transmitted disease at that time. This study led to considerable physical harm, as it involved not treating research participants for the disease (leading to their subsequent deaths) even when a cure became available. All of the participants were poor African American sharecroppers in the area around Tuskegee, Alabama. None of them had a good understanding of the study and were given the impression that they were receiving good medical care when in fact they were subjected to painful procedures that did nothing to address their condition. Many were not even told that they had the condition. Even worse, they were not given curative treatment—penicillin—when it became available. Thus, a federally sponsored study took advantage of a vulnerable population, was racially motivated, created permanent and serious harm for participants, and left a legacy of ethical misdeeds. As you can imagine, when the media broke the story about Tuskegee, a massive public outrage ensued. If you think about it, during many of the 40 years of the syphilis studies, the Nuremberg Code and the Declaration of Helsinki were in existence. At the time, each of these international standards delineated ethical principles for informed consent and medical care of research subjects. However, both these documents were disregarded in the syphilis studies. For whatever reasons, the U.S. government continued to sponsor research in humans that was not guided by the Nuremberg and Helsinki principles.

DIFFICULTY: Difficult

REFERENCES: 2.2 Historical Cases of Unethical Research

KEYWORDS: Bloom's: Analyze

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68. Explain beneficence and how it relates to research ethics.

ANSWER: Beneficence represents the expected impact on a person's well-being that may result from participation in research. Researchers should attempt to maximize the benefits of participation and take steps to identify and limit the potential for harm. This is typically done when planning a study by a careful risk/benefit assessment. Risk of harm and probability of benefit is assessed most importantly at the level of the individual participant, but researchers are also obliged to consider the impact on families, communities, and society in general. When assessing risk, researchers should try to think about worst-case scenarios—situations with significant potential for harm even if the probability seems low. The term "no greater than minimal risk" has become an important threshold in risk assessment. It means that the risk of harm is not greater than that experienced in everyday life situations such as typical academic or medical examinations. If an outside authority determines that this threshold is exceeded, then a research proposal will receive greater scrutiny in the review process, and specific safeguards must be implemented in the protocol. If the minimal risk threshold appears reasonable, then researchers may obtain a waiver of written informed consent. A very common situation in which a signed consent form may not be necessary is online survey research in which consent is implied by participation.

DIFFICULTY: Difficult

REFERENCES: 2.3 Evolution of a Modern System of Research Ethics

KEYWORDS: Bloom's: Analyze

69. Discuss privacy as it relates to research ethics.

ANSWER: Privacy means that information shared by individual participants will not be shared with others. The most certain way of maintaining privacy is through the provision of anonymity. Anonymity means that there is no personally identifying information in a data set. That is, there is no way that an individual can be identified from the information stored in a researcher's files. When anonymity is possible, it also has a potential benefit in terms of data quality because respondents may be willing to share information more freely.

However, anonymity may not be possible in some research designs. For example, in a longitudinal study, there has to be a way to link records for each measurement occasion at the individual level, necessitating a coding system based on a unique personal identifier.

Alternatively, confidentiality means that the researcher makes a promise that whatever identifying information is shared will be known only by the researcher, unless circumstances dictate exceptions to maintain the well-being of participants. For example, researchers who study sensitive topics such as depression and suicidal thinking may need to maintain a record of the identity of individuals in the event that a "red flag" of significant distress and likelihood of harm appears in the data. In such cases, research protocols spell out the steps that a researcher will take to provide intervention and support to such a person. The informed consent process should always include clear information about what sort of privacy is promised and what exceptions to confidentiality are necessary.

Privacy of participants receives special protection when medical records are part of the study. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 requires that researchers obtain special permission to utilize data kept in medical records. This may include obtaining permission directly from patients. It may also include obtaining a waiver of permission when it is practically impossible to obtain permission, or a process called "de-identification" in which all identifying information is removed from the data prior to the researcher being able to access it.

DIFFICULTY: Difficult

REFERENCES: 2.3 Evolution of a Modern System of Research Ethics

KEYWORDS: Bloom's: Analyze

70. How does the office of research integrity define research misconduct?

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ANSWER: Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
(a) Fabrication is making up data or results and recording or reporting them.
(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
(d) Research misconduct does not include honest error or differences of opinion.

DIFFICULTY: Difficult

REFERENCES: 2.4 Ethics in the Production and Publication of Scholarly Work

KEYWORDS: Bloom's: Analyze

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