COPD FOUNDATION

BRIDGE Patient to Investigator Training Module 7
Protections for Research Participants Review Questions and Answer Key

Questions:

Match the historical moment in research protections with the correct description below:

1. Nazi Experimentation (early 1940s)
2. Nuremberg Code (1947)
3. Willowbrook Study (1963-1966)
4. Declaration of Helsinki (1964)
5. Tuskegee Syphilis Study (Ended 1972)
6. National Research Act (1974)
7. Belmont Report (1979)

a. A congressional act which did two major things to stop unethical research on people:
- It required the U.S. government to create rules to protect people in research studies.
- It created a national committee to develop guidelines for ethical research

b. A home for children with mental disabilities in New York City. Researchers deliberately injected children with hepatitis to learn about the disease. Risk not fully explained to parents.

c. After the Nuremberg Trials, the judges listed important principles of acceptable medical experiments.
- Research participation must be voluntary.
- Research participation cannot put people at high risk for disability or death.
- Participants can quit a study at any time.

d. A report that defined three basic principles for the ethical treatment of individuals participating in research:
- *Respect*: People must have a choice about what happens to them.
- *Beneficence : "Doing good"* The risks of a study cannot outweigh the possible benefits.
- *Justice*: The benefits and risks of research should be fairly shared across society.

e. The World Medical Association, meeting in Finland, approved principles for ethical research:
- Research plans should be reviewed by an independent committee, such as an institutional review board (IRB).
- Research participants must give their "informed consent" to be in a study.
- Risks of being in a study should not outweigh benefits.

f. Doctors in Nazi concentration camps forced prisoners to take part in dangerous experiments. Examples of unethical experiments were forcing prisoners to be sterilized and be infected with diseases.

g. African-American men in Alabama with syphilis were not given available treatments because doctors wanted to study long- term effects of the disease. Dozens of men died of syphilis or its complications. The study did not end until 1972 when details about it became public.

8. Please select the answer below that is NOT a role of the institutional review board

a. Reviews and approves all research before the study begins.
b. Ensures that people joining studies will be protected from unknown harm or risks.
c. Weighs risks versus benefits, looks at what protections are in place and if people in the study are informed about the study before they decide to join.
d. Conducts yearly reviews of all studies.
e. Any unexpected or serious study issues must be reported to the IRB.
f. Serves as a place for individuals participating in the study to share their concerns or complaints about the study.
g. Implements the study and reports the results.

9. True or false: The informed consent document explains what will happen in the study and what is being asked of people who join the study.

a. True
b. False

10. True or false: The informed consent document is a binding contract and once participants begin a study they must continue it until the study is complete

a. True
b. False

Which of the descriptions below is about Privacy (P) and which is about Confidentiality (C)?	**P or C**
11. An understanding that information an individual shares will not be shared with others without their permission.	
12. Involves a person's identifiable information and the security/procedures in place to ensure that only authorized individuals see the information.	
13. Applies to the person	
14. Applies to the information	

15. Which of the answers below best describes the Health Insurance Portability and Accountability Act (HIPAA)?

a. It protects health care insurance coverage for individuals when they lose or change jobs.
b. It addresses fraud, abuse and waste in health care insurance and the delivery of health care.
c. It ensures the security and confidentiality of patient information.
d. All of the above

Answers:

1. f
2. c
3. b
4. e
5. g
6. a
7. d
Explanation: See slides 5-8 for a review of these important historical milestones in Research Protections

8. g
Explanation: An institutional review board is *not* involved with the implementation or results reporting of a study, but rather serves as an independent group that reviews the study plans, ensures that participants' will be protected from harm, weighs risks versus benefit and serves as a place for reporting serious issues or concerns and complaints about the study.

9. a-True
Explanation: The informed consent document explains in clear language to study participants what will happen in the study, what is being asked of them, potential risks, their individual rights and contact information for the study team and the institutional review board.

10. b-false
Explanation: The informed consent document is a *voluntary agreement* between the participant and the study team—it is not a contract and a participant has the right to *stop participating in a study at any time.*

11. P (privacy)
12. C (confidentiality)
13. P
14. C
Explanation: See slide 13 for a review of privacy and confidentiality

15. d
Explanation: All of these answers describe the Health Insurance Portability and Accountability Act.