Questions: Human Subjects and Clinical Trials

1. Which of the following is not a basic underlying ethical principle in the protection of human subjects?
    a. Justice
    b. Respect for Persons
    c. Beneficence
    d. Cure

2. Membership in the IRB must include.
    a. member of the sponsored programs office
    b. member of the clergy
    c. member with primary concern in non-scientific area
    d. the PI

3. Which of the following is not an approval level for Human Subjects.
    a. Expedited
    b. Exempt
    c. Full
    d. Partial

4. For which of the following population groups are there special guidelines for their protection as research subjects?
    a. prisoners
    b. the elderly
    c. college students
    d. persons diagnosed as HIV positive

5. A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
    a. Human subjects research
    b. Drug study
    c. Devise study
    d. Clinical Trial

6. Assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by HHS.
    a. Federalwide Assurance
    b. Worldwide assurance
    c. Human subjects compliance
    d. Institutional assurance

7. A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information.
    a. Graduate student
    b. Clinical trial subject
    c. Human subject
    d. Survey participant

8. Resulted from criminal proceedings against German physicians and scientists for their part in crimes against humanity for their experiments that killed or permanently crippled their subjects.
    a. Nuremburg Code
    b. Belmont Report
    c. Declaration of Helsinki
    d. National Research Act

9. This document provides the basis for Common Rule's criteria for approval followed by IRB's and established the three guiding principles (1) Respect for Persons, (2) Beneficence, and (3) Justice.
    a. Nuremburg Code
    b. Belmont Report
    c. Declaration of Helsinki
    d. National Research Act

10. Maximize benefits and minimize risk of harm refers to
    a. Justice
    b. Respect for persons
    c. Beneficence
    d. None of the above

11. DHHS 45 CFR 46 was formally adopted by more than a dozen of the other federal departments and agencies is known as
    a. 21stCentury Cures Act
    b. Public Welfare Act
    c. The Common Rule
    d. The Belmont report

12. Clinical trials are registered on
    a. ClinicalTrials.gov
    b. Grants.gov
    c. Government Register of Clinical Trials
    d. NIH eCommons

13. An agreement between the institution and the Federal government certifying that all research supported by federal funds will be reviewed and approved by Institutional Review Board registered with OHRP.
    a. IRB protocol
    b. HIPPA privacy agreement
    c. Federal-wide Assurance
    d. Institutional Certificate of Compliance

14. A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
    a. Clinical Trial
    b. Surveys
    c. Intervention
    d. Research

15. Clinical trial phase characteristic of first use with human–usually very small number of healthy subjects; looking at how absorbed, distributed, metabolized
    a. Phase I
    b. Phase II
    c. Phase III
    d. Phase IV

16. Interviews, Focus groups and surveys would most commonly be found in
    a. Biomedical research
    b. Clinical trial
    c. Investigational new drug application
    d. Social & Behavioral Research

17. Membership in the IRB must include at least one member
    a. of the sponsored programs office
    b. of the clergy
    c. who is not affiliated with the institution
    d. the faculty

18. Research with greater than minimal risk require what type of review?
    a. Full
    b. Expedited
    c. Exempt
    d. Continuing

19. A clinical trial that involved post-marketing studies would be conducted in which Phase?
    a. Phase I
    b. Phase II
    c. Phase III
    d. Phase IV

20. The IRB reviews projects that meet the following criteria
    a. Research
    b. Human Subjects
    c. More than minimal risk
    d. Answers a&b

21. Governs international ethics and rules for research combined with clinical care and non-therapeutic research. It is the basis for Good Clinical Practices (GCP).
    a. Nuremburg Code
    b. Belmont Report
    c. Pure Food and Drug Act
    d. Declaration of Helsinki

22. Created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in response to the Tuskegee Syphilis Study.
    a. Nuremburg Code
    b. Belmont Report
    c. National Research Act
    d. Declaration of Helsinki

23. Principle that selection of subjects is equitable so that benefits and risk are distributed fairly.
    a. Justice
    b. Respect for persons
    c. Beneficence
    d. Principle of natural selection

24. The Common Rule provides additional protections for which populations?
    a. Pregnant women, human fetuses and neonates
    b. Prisoners
    c. Children
    d. All of the above

25. A gold standard recognizing adherence to a rigorous set of human subjects protection standards that go beyond federal and state requirements.
    a. Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)
    b. DHHS ORP regulations
    c. FDA Regulations
    d. None of the above

26. The main mission of the Institutional Review Boards is to protect the rights, safety and welfare of research subjects. The IRB is given authority through federal regulations to:

a. approve, modify or disapprove research
b. conduct continuing review of already approved research
c. suspend or terminate approval of research
d. All of the above

27. Serves to document that the subject agreed to participate in the study and also serves for the subject's future reference.
    a. Consent form
    b. Research protocol
    c. Recruitment plan
    d. Payment receipts

28. Investigational device exemption (IDE)
    a. Allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data.
    b. Covers the procedures for the conduct of clinical studies with medical devices including application, responsibilities of sponsors and investigators, labeling, records, and reports.
    c. Permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements of the Food, Drug, and Cosmetic Act.
    d. All of the above

29. To test a drug in clinical trials in multiple state locations the researcher would need to obtain.
    a. A signed consent form
    b. A valid protocol
    c. Approval of the IRB
    d. Exemption from the FDA

30. Responsible for protecting the public health by assuring safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
    a. Public Health Service
    b. NIH
    c. Office for Human Research Protections (OHRP)
    d. Food and Drug Administration

Answers

1 d	16 d
2 c	17 c
3 d	18 a
4 a	19 d
5 d	20 d
6 a	21 d
7 c	22 c
8 a	23 a
9 b	24 d
10 c	25 a
11 c	26 d
12 a	27 a
13 c	28 d
14 d	29 d
15 a	30 d