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MHS-018

POST GRADUATE DIPLOMA IN BIOETHICS (PGDBE)

Term-End Examination

00405

June, 2016

MHS-018 : SPECIAL ISSUES IN RESEARCH ETHICS

Time : 2 hours *Maximum Marks : 70*

PART - A

Attempt **all** questions. Each question carries **one (1)** mark. Select the most appropriate answer from the given alternatives for each of the following questions. Write the answers in Answer Sheet provided. **1x50=50**

1. Minimum _____ members constitute Institutional ethics committee.
   (1) 5 (2) 12 (3) 15 (4) 8

2. The purpose of agreements between ICMR with International Organizations/Institutions regarding International Collaboration in Biomedical and Health Research in India has been for :
   (1) Exchange of scientific information
   (2) Exchange of scientists / technicians for training under the projects
   (3) Joint execution of scientific projects including support in the procurement of scientific equipments.
   (4) All of the above

3. Wrong appropriation of another authors language, thoughts, ideas and expression as ones original work is :
   (1) Fabrication (2) Plagiarism
   (3) Selective omission of data (4) None of the above

4. For International Collaboration in Biomedical and Health Research in Indian ICMR operates in close cooperation with the :
   (1) Indian Ministry of Health and Family Welfare
   (2) Ministry of Science and Technology
   (3) Ministry of External Affairs
   (4) All of the above

5. Ideally, the research participant's identity is not known to the researcher. This is called :
   (1) Anonymity (2) Confidentiality
   (3) Deception (4) Desensitizing

6. Researchers can ensure confidentiality by :
   (1) Using identification numbers or pseudonyms for participants
   (2) Not discussing participants in any data gathering with others
   (3) Keeping any identifying information separate from the data
   (4) All of the above

7. How often does the Health Ministry Screening Committee (HMSC) meet ?
   (1) 1 month (2) 3 months (3) 6 months (4) 12 months

8. Basic principles of ethical research include all except :
   (1) Right to withdraw (2) Deceptive practices
   (3) Informed consent (4) Anonymity

9. Components of ethically valid informed consent for research includes :
   (1) Disclosure (2) Understanding
   (3) Competence (4) All of the above

10. The strongest evidence for causality comes from which of the following research methods ?
   (1) Experimental (2) Causal - comparative
   (3) Correlational (4) Ethnography

11. Possible Improvements Techniques for Informed Consent includes :
   (1) Conducting a demographic analysis of the research projects geographical location
   (2) Hiring professionals to translate all the information related to the experiment
   (3) Taking extra time to fully explain the informed consent form
   (4) All of the above

12. International Clinical Trial Day is being held on _____ every year.
(1) 24 January (2) 07 October (3) 28 June (4) 20 May

13. Which of the following is best form of research ?
(1) Single blind clinical trial (2) Double blind clinical trial
(3) Randomized controlled trial (4) Meta analysis

14. Phase O of clinical trial is related to :
(1) Micro - dosing (2) Animal experimentation
(3) Pharmacovigilance (4) Pharmaeconomical analysis

15. Which of the following is most commonly used animal for research purpose ?
(1) Guinea pigs (2) Rat (3) Frog (4) Dog

16. Transgenic animals are used :
(1) To study the biological functions of specific genes
(2) To develop animal models for diseases of humans or animals
(3) To produce therapeutic products
(4) All of the above

17. Research participants must give _____ before they can participate in a study.
(1) Guidelines (2) A commitment
(3) Informed consent (4) Private information

18. The Euthanasia for experimental animals should meet the following requirements **except** :
(1) Minimum physiological and psychological disturbances
(2) Compatibility with the purpose of study and minimum emotional effect on the observer and operator
(3) Should be done in animal rooms and free from environmental contaminations
(4) Method should be reliable, reproducible and safe to the personnel involved

19. Following are the Non - living in vitro systems can be used to reduce / replace animals in experimentation except :
(1) Mechanical models (2) Computer simulation
(3) DNA recombinant technology (4) Organ bath

20. Identify the term that refers to a post-study-interview in which all aspects of the study are revealed, reasons for the use of deception are given, and the participants' questions are answered.

(1) Desensitizing (2) Debriefing (3) Dehoaxing (4) Deploying

21. Which of the following is not correct for Housing and Environmental requirement in case of Guinea Pig ?

(1) Average Weight → 400 - 500 gms

(2) Temperature → 22 - 24°C

(3) Humidity → 30 - 40%

(4) Photocycle (Light : Dark) → 12 : 12

22. Methods of Euthanasia NOT acceptable for any species is :

(1) Stunning (2) Electrocution

(3) Decapitation (4) CO_2 inhalation

23. Forms of scientific misconduct includes :

(1) Fabrication (2) Falsification

(3) Plagiarism (4) All of the above

24. The Health Ministry's Screening Committee (HMSC) takes decision on :

(1) National research proposals (2) State research proposals

(3) International research proposals (4) All of the above

25. Consent process in collaborative research in medicine includes :

(1) Freedom to take part

(2) Freedom to deny participation

(3) Provision of understandable information

(4) All of the above

26. The guidelines of animal ethics in India are issued by :

(1) INSA (2) CDSCO (3) HMSC (4) MOHFW

27. Animal ethics is related to use of animals for :

(1) Household purposes (2) Animal experimentation

(3) Animal breeding (4) All of the above

28. Conflict of interest is NOT applicable to :

(1) Author (2) Editor (3) Reviewer (4) Reader

29. In phase III of clinical trial minimum _____ participants required.

(1) 10 (2) 100 (3) 1000 (4) 500

30. Which of the following is most commonly used for research involving tuberculosis ?

(1) Rat (2) Guinea pig (3) Mice (4) Monkey

31. The composition of Institute Ethic Committee includes :

(1) One legal expert or retired judge

(2) One philosopher/ethicist/theologian

(3) One lay person from the community

(4) All of the above

32. In which of the following phases of clinical trials of drugs, ethical clearance is not required ?

(1) Phase I (2) Phase II (3) Phase III (4) Phase IV

33. Which of the following need(s) to be obtained when doing research with children ?

(1) Informed consent from the parent or guardian

(2) Assent from the child if he or she is capable

(3) Informed consent from the child

(4) Both (1) and (2)

34. Good Clinical Practice (GCP) is not required in :

(1) Pre - clinical phase (2) Phase I

(3) Phase II (4) Phase IV

35. In which year, Indian Research Funds Association (IRFA) was established ?

(1) 1911 (2) 1949 (3) 1955 (4) 1936

36. In which animal model pre - clinical trial of antiemetic drugs cannot be performed ?
(1) Monkey (2) Mouse (3) Guinea Pig (4) Dog

37. The valid informed consent for research includes :
(1) Disclosure (2) Understanding
(3) Competence (4) All of the above

38. Randomised Control Trials (RCTs) :
(1) Are not required to be based on the concept of equipoise
(2) Always have a control arm that uses placebo
(3) Are considered to be the 'gold standard' for determining efficacy and safety in clinical research
(4) Are always "double blinded"

39. The process of introducing an exogenous geneinto a living organism so that the organism will exhibit a new property and transmit that property to its offspring is known as :
(1) Xenotransplantation (2) Conventional breeding
(3) Cingenesis (4) Transgenesis

40. The act of publishing the same data and results in more than one journal or publication refers to which of the following professional issues ?
(1) Partial publication (2) Duplicate publication
(3) Deception (4) Full publication

41. Who is responsible for the trial and for the rights, health and welfare of the subjects in the trial ?
(1) Subject (2) Investigator
(3) Institute (4) Government

42. Phase IV of clinical trial is mainly concerned with :
(1) Dose ranging (2) Efficacy assessment
(3) Pharmacokinetic analysis (4) Post marketing surveillance

43. Fresh or re-consent is taken in following conditions **except** :
(1) Availability of new information which would necessitate deviation of protocol
(2) When long term follow-up or study extension is planned later
(3) When there is change in treatment modality, procedures, site visits
(4) All of the above

44. Which of the following is necessary in obtaining informed consent ?

(1) A description of the statistical analyses that will be carried out

(2) A description of the purpose of the research

(3) A description of the reliability and validity of test instruments

(4) A list of publications that the researcher has had in the last ten years

45. _____ means that the participant's identity, although known to the researcher is not revealed to anyone outside of the researcher and his or her staff.

(1) Anonymity (2) Confidentiality

(3) Falsification (4) Plagiarism

46. Which of the following is **not** true ?

(1) Misrepresenting and creating fraudulent data is dishonesty

(2) Misrepresenting data is very easy to detect

(3) Misrepresenting data can be difficult to detect

(4) Breaking confidentiality is not a problem

47. Which term refers to publishing several articles from the data collected in one large study ?

(1) Duplicate publication (2) Partial publication

(3) Triplicate publication (4) None of these

48. Which of the following is a right of each participant in a clinical trial or study involving human subjects ?

(1) Deception (2) Utilitarianism

(3) Freedom to withdraw (4) Participants have no rights

49. Concerning "authorship" in educational research, intellectual ownership is predominantly a function of a :

(1) Effort expended (2) Creative contribution

(3) Professional position (4) Level of higher education

50. Which of the following approaches says that ethical issues should be judged on the basis of some universal code ?

(1) Deontological (2) Ethical skepticism

(3) Utilitarianism (4) All of the above

PART - B

Write short notes on **any four** of the following in about **200 - 300** words : **5x4=20**

51. Drugs and Cosmetics Act.

52. Digital Divide.

53. Nuffield Council of Bioethics.

54. Misconduct in Research.

55. Institutional Ethics Committee.

56. Helisnki Declaration.