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MHS-017

POST GRADUATE DIPLOMA IN BIOETHICS (PGDBE)

Term-End Examination

00091

June, 2016

MHS-017 : RESEARCH ETHICS - II

Time : 2 hours *Maximum Marks : 70*

PART - A

Attempt **all** questions. Each question carries **one** mark. Select the most appropriate **choice** given for each of these questions. Write the answers in answer sheet provided. **1x50=50**

1. Research ethics is to :
   (1) Responsible conduct of research of high ethical standard
   (2) Educate and monitor the scientists
   (3) Both of the above
   (4) None of the above

2. Voluntary participation was initiated in :
   (1) Nuremberg code
   (2) Helsinki declaration, 1964
   (3) Helsinki declaration 2000
   (4) None of the above

3. Informed consent indirectly stresses the need of inclusion of literate participants only.
   (1) True
   (2) False

4. Informed consent form should contain only the list of names of *investigators* whom a study participant can contact at any time during the trial.
   (1) Yes
   (2) No

5. It is ethical to permit at times the renumeration for the participants.
   (1) Yes
   (2) No

6. Informed consent is necessary for the :
   (1) Statistical analysis
   (2) Purpose of research
   (3) Validity of test instruments
   (4) All the above

7. For qualitative studies informed consent form may not be possible.
   (1) Yes
   (2) No

8. In ethics deontological approach is :
   (1) Ethical standards are not universal, but are particular to culture and time
   (2) Comparison of cost and benefit
   (3) Identification and use of universal code
   (4) None of the above

9. "Anonymity" means participants' identity is not revealed to others, though the researcher knew the identity.
   (1) True
   (2) False

10. Before initiating any form of study procedure the researcher must obtain :
   (1) A commitment from the participant
   (2) General information from the participant
   (3) Informed consent
   (4) None of the above

11. Choose the odd in ethical issues.
   (1) Utilitaranism
   (2) Ethical skepticism
   (3) Deontology
   (4) Ontology

12. *Desensitizing* means a post study interview in which all aspects of the study are revealed, participants questions are answered and reasons for deception if any are given to participants.
   (1) True
   (2) False

13. Some amount of deception is permitted to conduct a scientifically valid study.
   (1) True
   (2) False

14. The main ethical issues in conducting research in internet platform is :
   (1) Informed consent
   (2) Privacy
   (3) Debriefing
   (4) None of the above

15. Exempt studies are decided by :
    (1) Independent Ethics Committee
    (2) Institutional Review Board
    (3) Researcher
    (4) None of the above

16. Any study can be reviewed as "expedited" by Institutional Review Board.
    (1) True
    (2) False

17. Under certain conditions waiver of consent form is possible.
    (1) True
    (2) False

18. The main drawback of offering financial incentive for participation is :
    (1) Study is more expensive
    (2) Invite selective bias
    (3) It is a form of coercive
    (4) None of the above

19. *Plagiarism* refers to fabrication of data and results.
    (1) True
    (2) False

20. Children's participation presents different problem for researchers than adults because :
    (1) It is difficult to get informed consent
    (2) Difficult to analyse children's data
    (3) There will be more dropouts
    (4) None of the above

21. Researchers are not given the right of privileged communication offered by law.
    (1) True
    (2) False

22. Informed consent :
    (1) Promotes Clinical Research
    (2) Offers choice to choose the participant
    (3) Provides participants' will
    (4) Provides vital information of the study to trial participant

23. Informed consent should include aim, method and possible conflict of interest.
    (1) True
    (2) False

24. Control arm of a clinical trial should be :
(1) Historical control
(2) Best locally available method
(3) Best currently available method
(4) Any established method

25. According to WHO guidelines, ethical committee should be :
(1) Competent
(2) Independent
(3) Pluralism
(4) Transparent

26. Choose the odd in the review process of Institutional Review Board.
(1) Express review
(2) Expedited review
(3) Full review
(4) Exempt

27. In a prenatal testing, detection of a faulty gene or a chromosonal abnormality shall provide all the information about the future quality of life or severity of a particular condition.
(1) True
(2) False

28. Cloning of genes in the laboratory may be the ultimate treatment for genetic disorder.
(1) True
(2) False

29. First living kidney transplant was performed in :
(1) 1967
(2) 1962
(3) 1952
(4) 1983

30. A physician who declared that the donor had died can be involved directly for subsequent transplantation.
(1) True
(2) False

31. Recommended age of an organ donor should be :
(1) Any age
(2) Children
(3) Young adults
(4) Below 80 years

32. Choose the odd in "Tissue transplantation".
(1) Skin
(2) Tendons
(3) Kidney
(4) Heart valves

33. In ethics, device is :
(1) in vitro agent
(2) an instrument
(3) a component
(4) all of the above

34. A compound formulation made from the components of originally used traditional system should be considered as new substance.
(1) True
(2) False

35. To evaluate the efficacy of a substance mentioned in the traditional system of medicine, the starting trial phase is :
(1) Phase I
(2) Phase II
(3) Phase III
(4) Phase IV

36. If predefined parameters in a defined population over a specified period of time are recorded, then it is :
(1) Cross sectional study
(2) Case control study
(3) Cohort study
(4) All of the above

37. For program evaluation and surveillance in Epidemiology, IEC (Independent Ethics Committee) approval is not necessary.
(1) True
(2) False

38. If clinical trial is over, and found effective then it is *mandatory* that the sponsoring agency should provide the drug to the patient till it is marketed.

(1) True

(2) False

39. For evaluation in India, any new substance discovered abroad need not undergo phase I trial if sufficient information and data are made available.

(1) True

(2) False

40. If unexpected number of adverse events were found in phase IV study :

(1) The drug should be withdrawn from market immediately

(2) The drug should undergo again phase III with more sample size

(3) Phase IV continued for some more time

(4) None of the above

41. For medical devices the followings are not necessary.

(1) Phase I

(2) Phase II

(3) Phase III

(4) All of the above

42. Prevention of pre-conceptual diagnostic technique for pre-selection of sex was introduced in the year _____ (fill) by the Government of India.

(1) 1994

(2) 2006

(3) 2003

(4) None of the above

43. Randomized control trial will not create ethical problem if :

(1) Placebo is a control

(2) Standard drug is a control

(3) Trial is open

(4) Sample size is large

44. Choose the odd in observational Epidemiology.
(1) Cross sectional study
(2) Cohort study
(3) Case control study
(4) Randomized study

45. Genetic test :
(1) Often does not identify the condition
(2) Exactly identifies the risk, but that may not happen in future
(3) Exactly identifies the risk that does happen later
(4) None of the above

46. Genetic screening and testing need to be accompanied by Counselling and Education.
(1) True
(2) False

47. Pharmacogenomics aims to :
(1) Reduce the cost of treatment
(2) Understand the differential response to treatment
(3) Have Tailor made treatment regimen
(4) All of the above

48. Suggested duration of time interval between two trials on the same volunteer will be :
(1) 3 days
(2) 3 months
(3) 6 months
(4) Same volunteer should not be used again

49. Children born due to failure of contraceptive trials should be :
(1) Taken care off by the sponsor
(2) Followed for any abnormality
(3) Keep them in registered orphanages
(4) None of the above

50. In human reproduction ART stands for :
(1) Artificial Reproductive Technology
(2) Assisted Reproductive Technology
(3) Artificial Reproductive Therapy
(4) Assisted Reproductive Therapy

PART - B

Write short notes on (**200 - 300** words) attempt **all** : **4x5=20**

51. Observational studies.

52. Major approaches to Ethics.

53. Important considerations for designing an ethical study.

54. Consent form.

55. Genomics.