

00362 **POST GRADUATE DIPLOMA IN BIOETHICS  
(PGDBE)**

**Term-End Examination**

**December, 2015**

**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 alternatives for each of the following questions. Write answer in your Answer Sheet :

1. The statement of Hippocratic Oath is :
  - (1) "I will give no deadly medicine to anyone if asked, nor suggest any such counsel".
  - (2) "I will maintain the utmost respect for human life".
  - (3) A physician shall always bear in mind the obligation to respect human life".
  - (4) All of these.
2. Physician - assisted suicide is :
  - (1) euthanasia
  - (2) mercy killing
  - (3) at the request and with the consent of the patient
  - (4) at the request and without consent of the patient

3. Which of the following term is coined by Fritz Jahr ?
  - (1) Bioethics
  - (2) Euthanasia
  - (3) Assisted suicide
  - (4) Biopiracy
  
4. The Indian Council of Medical Research is funded by :
  - (1) Ministry of Health and Family Welfare
  - (2) Ministry of Science and Technology
  - (3) Directly by Government of India
  - (4) None of the above
  
5. The Indian Council of Medical Research (ICMR) is located in :
  - (1) New Delhi
  - (2) Hyderabad
  - (3) Pune
  - (4) Ahmedabad
  
6. Indian Council Medical Research (ICMR) was redesigned in :
  - (1) 1949
  - (2) 1965
  - (3) 1956
  - (4) 1975
  
7. The Health Ministry's Screening Committee (HMSC) takes decision on :
  - (1) National research proposals
  - (2) State research proposals
  - (3) International research proposals
  - (4) All the above

8. Declaration of Helsinki is a set of ethical principles regarding :
- (1) Animal experimentation
  - (2) Biotechnology experimentation
  - (3) Microbiology experimentation
  - (4) Human experimentation
9. Belmont Report explains three Fundamental ethical principles except :
- (1) Respect for persons
  - (2) Beneficence
  - (3) Justice
  - (4) Insurance of participants
10. Which of the following phase of clinical trials is associated with screening of safety ?
- (1) Phase I
  - (2) Phase II
  - (3) Phase III
  - (4) Phase IV
11. The valid informed consent for research includes :
- (1) Disclosure
  - (2) Understanding
  - (3) Competence
  - (4) All of the above
12. An Institutional Review Board (IRB) designated to approve, monitor, and review :
- (1) Biomedical and behavioural research involving humans
  - (2) Biomedical and behavioural research involving animal subjects
  - (3) Biomedical research involving microorganisms
  - (4) All of these

13. Conflict of interest is not applicable to :
- (1) Authors
  - (2) Editor
  - (3) Reviewer
  - (4) Readers
14. The responsibilities of an Institutional Ethics Committee includes which of the following :
- (1) To protect the dignity, rights and well being of the potential research participants.
  - (2) To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
  - (3) To assist in the development and the education of a research community responsive to local health care requirements.
  - (4) All the above.
15. The number of persons on an ethics committee should be :
- (1) 4 - 5
  - (2) 8 - 12 members
  - (3) 15 - 20
  - (4) 20 - 30
16. Minimum persons required to form the quorum of ethics committee without which a decision regarding the research should not be taken is :
- (1) 3
  - (2) 5
  - (3) 7
  - (4) 10

17. The composition of Institutional Ethics Committee includes :
- (1) One legal expert or retired judge
  - (2) One philosopher/ethicist/theologian
  - (3) One lay person from the community
  - (4) All the above
18. Drugs and Cosmetics Act was passed in the year :
- (1) 1930
  - (2) 1940
  - (3) 1950
  - (4) 1960
19. Fresh or re-consent is taken in the following conditions :
- (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 a change in the treatment modality, procedures, site visits.
  - (4) All of the above
20. Essential information for prospective research participants is :
- (1) The aims and methods of the research.
  - (2) The expected duration of participation.
  - (3) The benefits that might reasonably be expected as an outcome of research to the participant, community or others.
  - (4) All of these.

21. The historically first international guideline pertaining to research involving human participants was the :
- (1) Declaration of Helsinki
  - (2) Declaration of Japan
  - (3) Nuremberg Code
  - (4) WHO Ethical Guideline
22. The term 'misconduct in research' includes :
- (1) Fabrication
  - (2) Plagiarism
  - (3) Selective omission of data
  - (4) All of these
23. Informed consent is important because :
- (1) It enables the participant to understand vital information on the proposed trial.
  - (2) It provides the participant with all the information regarding remote risks.
  - (3) It enables the investigator to recruit participants of his choice.
  - (4) It promotes clinical research.
24. Informed consent refers to :
- (1) Principle of autonomy.
  - (2) Voluntary but uninformed decision-making.
  - (3) A voluntary decision to participate in research, by a competent individual who has received and understood the necessary information.
  - (4) Permission to participate in research.
25. Principles of Nuffield Council of Bioethics includes the following except :
- (1) Sensitivity to cultural differences
  - (2) Alleviation of suffering
  - (3) Exploitation of vulnerable
  - (4) Showing respect

26. Who cannot consent to trial participation ?
- (1) Healthy but poverty stricken volunteers.
  - (2) Healthy volunteers below the age of 18 years.
  - (3) Mentally stable but sick adults.
  - (4) Medical students.
27. Plagiarism refers to which of the following :
- (1) Copying verbatim without citing the source.
  - (2) Stealing the intellectual property of someone else without citing the source.
  - (3) Using the examples from another paper but mixing up the order so it is unrecognisable.
  - (4) All of the above.
28. The golden rule of plagiarism is that all sources shall be :
- (1) Enclosed
  - (2) Closed
  - (3) Embedded
  - (4) Disclosed
29. Researchers have a duty to avoid, prevent or minimise the risk to study participants. This is based on the principle of :
- (1) Non - maleficence
  - (2) Beneficence
  - (3) Human rights
  - (4) Justice

30. Which of the following is correct if a participant wishes to withdraw from a study ?
- (1) Participation is voluntary and they can withdraw at any time.
  - (2) They must continue to participate as they have signed the consent form.
  - (3) Withdrawal from the study has to occur through the ethics committee.
  - (4) They may be able to withdraw if they negotiate with the research team.
31. Researchers must seek approval from a Human Research Ethics Committee if they intend to :
- (1) Collect data from people by Interview or Survey.
  - (2) Collect data by observation of people.
  - (3) Perform an intervention/treatment.
  - (4) All of the above.
32. The principle underpinning voluntary and informed consent is :
- (1) Beneficence
  - (2) Autonomy
  - (3) Non-maleficence
  - (4) Respect
33. 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

34. 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
35. Ideally, the research participant's identity is not known to the researcher. This is as known :
- (1) Anonymity
  - (2) Confidentiality
  - (3) Deception
  - (4) Desensitizing
36. Assisted suicide is illegal in all except :
- (1) Australia
  - (2) Denmark
  - (3) Canada
  - (4) Netherland
37. All are true regarding Biodiversity except :
- (1) It is a measure of the variety of organisms present in different ecosystems.
  - (2) Terrestrial biodiversity tends to be highest near the equator.
  - (3) Biodiversity is distributed evenly on Earth.
  - (4) It is the richest in the tropics.
38. Following are the Non-Living in vitro systems that can be used to reduce/replace animals in :
- (1) Mechanical Models.
  - (2) Computer Simulation.
  - (3) DNA Recombinant Technology.
  - (4) Organ Bath

39. Average life span in years is false for which of the following :
- (1) Mice → 1.5 - 2
  - (2) Guinea pig → 5 - 10
  - (3) Monkey → 10 - 15
  - (4) Dog → 10 - 15
40. The different methods, used in detecting the status of inbred strains for their homogeneity includes :
- (1) Histocompatibility or Skin Grafting.
  - (2) Electrophoresis or Biochemical Markers.
  - (3) Immunological Markers.
  - (4) All of the above.
41. Methods of Euthanasia **not** acceptable for any species is :
- (1) Stunning
  - (2) Electrocution
  - (3) Decapitation
  - (4) CO<sub>2</sub> inhalation
42. Animal ethics is related to use of animals for :
- (1) Household purposes
  - (2) Animal experimentation
  - (3) Animal breeding
  - (4) All of the above
43. Convert communication. In efficiencies in informed consent includes :
- (1) Language Barriers
  - (2) Religious influence
  - (3) False expectations
  - (4) All of the above

44. Researchers should consider the following issues related to informed consent except :
- (1) Mental Capacity Act (2005)
  - (2) Medicines for Human use (clinical trials) Regulation (2004)
  - (3) Data Protection Act (1998)
  - (4) MTP Act (1971)
45. 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.
46. How often does the Health Ministry's Screening Committee (HMSC) meet ?
- (1) 1 - 2 months
  - (2) 3 - 4 months
  - (3) 6 - 7 months
  - (4) 11 - 12 months
47. All of the following are the situations where delayed consent may be needed except :
- (1) At the roadside in the event of an accident.
  - (2) At a cardiac arrest.
  - (3) During the early stages of a patient's emergency admission to an accident and emergency department.
  - (4) Chronic Lung Disease Patient.

48. Participation in research can have a number of perceived benefits for patients including :
- (1) Access to experimental treatments that may give better outcomes than standard treatments.
  - (2) Increased access to members of the multidisciplinary team.
  - (3) Extra investigations
  - (4) All of the above
49. Any research using the human beings as participants shall follow the principles given below except :
- (1) Principle of Essentiality.
  - (2) Principle of Compliance.
  - (3) Principle of Non-exploitation.
  - (4) All of the above.
50. 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.

### **PART - B**

Write short notes (in about 200-300 words) on  
any four of the following : **5×4=20**

51. Global issues in internet based education.
  52. Euthanasia
  53. Covert Communications
  54. Informed Consent
  55. Principles of Ethical Research
  56. Plagiarism
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