

POST GRADUATE DIPLOMA IN BIOETHICS (PGDBE)

Term-End Examination

June, 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 given alternatives for each of the following questions.

Write answer in your answer-sheet.

50×1=50

1. Who coined the term BIOETHICS ?

- (1) Fritz Jahr
- (2) Van Rensselaer Potter
- (3) H. Tristram Engelhardt
- (4) Joseph Fins

2. Assisted suicide is illegal in all these countries *except*

- (1) Australia
- (2) Denmark
- (3) Canada
- (4) Netherlands

3. All these organisations are in support of assisted suicide *except*

- (1) Compassion and Choices
- (2) Dignitary
- (3) Exit
- (4) ADAPT

4. Agricultural diversity can be divided into
- (1) Interspecific Diversity
 - (2) Intraspecific Diversity
 - (3) Both of the above
 - (4) None of the above
5. 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 the Earth.
 - (4) It is the richest in the tropics.
6. For International collaboration in Biomedical and Health Research in India, ICMR operates closely with the Indian
- (1) Ministry of Health and Family Welfare
 - (2) Ministry of Science and Technology
 - (3) Ministry of External Affairs
 - (4) All of the above
7. The purpose of Agreement between ICMR with International Organisations/Institutions regarding International collaboration in Biomedical and Health Research in India has been for
- (1) Exchange of scientific information
 - (2) Exchange of scientists for training under the projects
 - (3) Joint execution of scientific projects including support in the procurement of scientific equipments
 - (4) All of the above
8. Who has the authority for approving Indo-US collaborative projects in India ?
- (1) Ministry of Health and Family Welfare
 - (2) Ministry of Science and Technology
 - (3) Both of the above
 - (4) None of the above

9. How often does the HMSC meet ?

- (1) 1 – 2 months
- (2) 3 – 4 months
- (3) 6 – 7 months
- (4) 11 – 12 months

10. What is the decision-making process of HMSC during review ?

- (1) HMSC may approve the project.
- (2) HMSC does not approve and ask additional information.
- (3) HMSC may disapprove/reject the project.
- (4) All of the above

11. The consequent Belmont Report draws upon the existing Helsinki Declaration and highlighted three principles *except*

- (1) Autonomy
- (2) Beneficence
- (3) Justice
- (4) Maleficence

12. Basic principles of Ethical Research include all *except*

- (1) Right to withdraw
- (2) Deceptive practices
- (3) Informed consent
- (4) Anonymity

13. Components of ethically valid Informed Consent for research includes

- (1) Disclosure
- (2) Understanding
- (3) Competence
- (4) All of the above

- 14.** Moral values relevant to current and new Biofuels include all *except*
- (1) Human Rights
 - (2) Solidarity
 - (3) Unsustainability
 - (4) Stewardship
- 15.** The Nuffield Council of Bioethics sets out the following ethical principles that policy makers should use to evaluate Biofuel technologies and guide policy development *except*
- (1) Biofuels development should not be at the expense of people's essential rights.
 - (2) Biofuels should be environmentally sustainable.
 - (3) Biofuels should contribute to a net reduction of total Greenhouse gas emissions and exacerbate global climate change.
 - (4) Costs and Benefits of Biofuels should be distributed in an equitable way.
- 16.** Guidelines for research with the developing countries were formulated by
- (1) Swiss Commission
 - (2) Health Ministry Screening Commission
 - (3) Nuffield Council
 - (4) US-FDA
- 17.** Covert communication inefficiencies in informed consent includes
- (1) Language Barriers
 - (2) Religious Influence
 - (3) False Expectations
 - (4) All of the above
- 18.** 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

19. Researchers should consider the following acts when considering the issues related to informed consent *except*
- (1) Mental capacity
 - (2) Medicines for Human Use Regulations
 - (3) Data protection
 - (4) MTP
20. In all of the following situations delayed consent can be taken *except*
- (1) At the road side in the event of an accident
 - (2) At a cardiac arrest
 - (3) During the early stages of a patient emergency admission to an accident and emergency department
 - (4) Lung disease
21. Participation in research can have a number of perceived benefits for patient including
- (1) Access to experimental treatment may give better outcomes than standard treatment
 - (2) Increased access to members of the multidisciplinary teams
 - (3) Extra Investigations
 - (4) All of the above
22. Which one is *not* true ?
- (1) The informed consent given by a legal representative for an incapacitated adult in a clinical trial should represent that adult's presumed will.
 - (2) The interest of science and society will always prevail over those of patient.
 - (3) The clinical trial is designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the cognitive abilities of the patient.
 - (4) The risk threshold and the degree of distress are specially defined and constantly monitored.
23. 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) None of the above

- 24.** It is mandatory that all proposals on Biomedical Research involving human participants should be cleared by all *except*
- (1) Institutional Ethics Committee
 - (2) Institutional Review Board
 - (3) Ethics Review Board
 - (4) Indian Council for Medical Research
- 25.** Following are potential alternatives to animal testing *except*
- (1) Microdosing
 - (2) Quantitative Structure Activity Relationship
 - (3) Computer Simulator
 - (4) None of the above
- 26.** Most commonly used animal for research purpose is
- (1) Guinea-Pig
 - (2) Rat
 - (3) Frog
 - (4) Dog
- 27.** Regarding housing and environment of research animals, which of the following is *not* correct ?
- (1) Animal room should occupy about 40 – 50% of the total constructed area.
 - (2) The cages should be made of suitable metal.
 - (3) A change in temperature of 9°C can cause 10-fold alteration in Biological Responses.
 - (4) An effective ventilation system with 10 – 12 air changes per hour of 100% fresh air must be provided.
- 28.** Transgenic animals are used
- (1) To study the biological functions of specific genes.
 - (2) To develop animal models for diseases of humans and animals.
 - (3) To produce therapeutic products.
 - (4) All of the above

29. In the development of transgenic animals the following are correct *except*
- (1) Photoperiod is critical regulator of reproductive behaviour of many species of animals.
 - (2) Pseudopregnant females which receive embryos should be kept in separate room where there is no disturbance.
 - (3) Bedding, feed, water or cage, should be changed immediately after embryo transfer, as at this stage there is high risk of embryo rejection and termination of pregnancy.
 - (4) High protein diet should be given to lactating mother.
30. Regarding nutrition and feeding of research animals, which of the following is *not* correct ?
- (1) A balanced diet should contain proteins, carbohydrates, fats, minerals, vitamins, roughage and water in required proportions for each species of animal.
 - (2) No drug, hormone or antibiotic should be added in the feed as these are likely to disturb the normal metabolism of the animals and produce biased results.
 - (3) The feed should be palatable.
 - (4) Clean, chlorinated water should be available to the animals in limited amount.
31. 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 contamination.
 - (4) Method should be reliable, reproducible and safe to the personnel involved.
32. Following are the non-living in-vitro systems that can be used to reduce animals in experimentation *except*
- (1) Mechanical Models
 - (2) Computer Simulation
 - (3) DNA Recombinant Technology
 - (4) Organ Bath
33. Following are the members of IAEC *except*
- (1) Senior Biological scientist of the Institute
 - (2) A veterinarian
 - (3) Non-scientist socially aware member
 - (4) Dean of the Institute

34. Average life span in years is true for the following *except*
- (1) Mice — 1.5 – 2
 - (2) Guinea-Pig — 5 – 10
 - (3) Monkey — 10 – 15
 - (4) Dog — 10 – 15
35. Which of the following housing and environment requirements for Guinea-pigs is *false* ?
- (1) Average weight — 400 – 500 gms
 - (2) Temperature — 22 – 24°C
 - (3) Humidity — 30 – 40%
 - (4) Photocycle (Dark – light) — 12 : 12
36. 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
37. Methods of Euthanasia *not* acceptable for any species is
- (1) Drowning
 - (2) Electrocutation
 - (3) Decapitation
 - (4) CO₂ inhalation
38. Forms of scientific misconduct includes
- (1) Fabrication
 - (2) Falsification
 - (3) Plagiarism
 - (4) All of the above

- 39. Most common form of conflict of interest is**
- (1) Self-dealing
 - (2) Nepotism
 - (3) Pump and Dump
 - (4) All of the above
- 40. Cornerstone of any research in medical treatment is**
- (1) Selection of participants
 - (2) Informed consent
 - (3) Randomisation
 - (4) Provision of treatment
- 41. 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
- 42. The discovery of protamine sulphate, an antidote of heparin toxicity, was first discovered on**
- (1) Dog
 - (2) Mice
 - (3) Fish
 - (4) Guinea-Pig
- 43. The guidelines of Animal Ethics in India are issued by**
- (1) INSA
 - (2) CDSCO
 - (3) HMSC
 - (4) MOHFW
- 44. Animal Ethics is related to the use of animals for**
- (1) Household purposes
 - (2) Animal experimentation
 - (3) Animal breeding
 - (4) All of the above

- 45.** Conflict of Interest is *not* applicable to
- (1) Author
 - (2) Editor
 - (3) Reviewer
 - (4) Reader
- 46.** Conflict of Interest may
- (1) Not be fully apparent.
 - (2) Not influence the scientific judgement.
 - (3) Mislead the reader.
 - (4) Undermine the credibility.
- 47.** Code of conduct for a peer reviewer includes all *except*
- (1) Speed of review
 - (2) Maintenance of confidentiality
 - (3) Reporting misconduct
 - (4) Use of data of the author
- 48.** All are true regarding e-learning *except*
- (1) Outline education
 - (2) Ham education
 - (3) Distance education
 - (4) Computer based education
- 49.** "Digital Divide" means difference in terms of
- (1) Computer hardware
 - (2) Internet speed
 - (3) Access to internet e-learning material
 - (4) All of the above
- 50.** Global issues in internet based education includes all of the following *except*
- (1) Geographical Diversity
 - (2) Cultural Diversity
 - (3) Learner Diversity
 - (4) Digital Interference

PART B

Write short notes (in about 200 – 300 words) on each of the following.

Each carries five (5) marks.

4×5=20

- 51. Indian Regulations regarding sending of blood samples abroad**
- 52. Role of CPCSEA in animal experiments**
- 53. Use of Internet and Plagiarism**
- 54. 5 Rs of Animal experimentation**