

POST GRADUATE DIPLOMA IN BIOETHICS (PGDBE)**Term-End Examination****December, 2016**

00203

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 choice from the given choices for each of the following questions. Write your answers in the Answer Sheet provided to you.*

50×1=50

1. Forms of scientific misconduct includes
 - (1) Non-disclosure of conflict of interest
 - (2) Duplicate publication
 - (3) Redundant publication
 - (4) All of the above
2. The strongest evidence of casualty comes from which of the following research methods ?
 - (1) Experimental
 - (2) Casual-comparative
 - (3) Correlational
 - (4) Ethnography
3. Which of the following conditions should credit authorship ?
 - (1) Substantial contribution to conception and design, acquisition of data or analysis and interpretation of data
 - (2) Drafting the article or revising it critically for important intellectual content
 - (3) Final approval of the version to be published
 - (4) All of the above

4. Minimum _____ members constitute the Institutional Ethics Committee.
- (1) 5
 - (2) 12
 - (3) 15
 - (4) 8
5. For International Collaboration in Biomedical and Health Research in India, ICMR operates in close co-operation 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
6. Informed consent needs to be taken even during Internet research.
- (1) True
 - (2) False
 - (3) Partly True
 - (4) Partly False
7. The animal used for research in Rabies vaccine is
- (1) Cattle
 - (2) Swine
 - (3) Rabbit
 - (4) Frog
8. A person who takes responsibility for the integrity of the work as a whole, from inception to published article, and publishes that information is termed as
- (1) Author
 - (2) Guarantor
 - (3) Investigator
 - (4) Researcher

9. "Email exchange of personal data is considered public in social media." is
- (1) True
 - (2) False
 - (3) Partly True
 - (4) Partly False
10. Possible Improvement Techniques for Informed consent include
- (1) Conducting a demographic analysis of the research project's 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
11. Insulin for diabetes was discovered in
- (1) 1920s
 - (2) 1930s
 - (3) 1940s
 - (4) 1950s
12. Method of Euthanasia **not** acceptable for any species is
- (1) Stunning
 - (2) Electrocution
 - (3) Decapitation
 - (4) CO₂ inhalation
13. Concerning "authorship" in educational research, intellectual ownership is predominantly a function of a/an
- (1) Effort expended
 - (2) Creative contribution
 - (3) Professional position
 - (4) Level of higher education

14. In which year was the Indian Research Fund Association (IRFA) established ?
- (1) 1911
 - (2) 1949
 - (3) 1955
 - (4) 1936
15. In phase-III of clinical trials, minimum _____ participants are required.
- (1) 10
 - (2) 100
 - (3) 1000
 - (4) 500
16. 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
17. ICMJE stands for
- (1) Indian Committee of Medical Journal Editors
 - (2) International Committee of Medical Journal Editors
 - (3) Indian Commission of Medical Journal Editors
 - (4) International Commission of Medical Journal Editors
18. What are the spin-off concepts that have emerged over the past one to two decades to address the issues of equity in international collaboration in medical/health research ?
- (1) Free/Differential Pricing
 - (2) Responsiveness to health needs of the host country
 - (3) Use of placebo
 - (4) All of the above

19. The concept of a person's thinking on objects or events as abstract or concrete based on the distance from the object or event is termed as
- (1) Psychological distance
 - (2) Physiological distance
 - (3) Psychological space
 - (4) Physiological space
20. Who started the 3R Principle ?
- (1) Tom Regan
 - (2) Russell and Burch
 - (3) Robert Koch
 - (4) Louis Pasteur
21. Conflict of interest is **not** applicable to
- (1) Author
 - (2) Editor
 - (3) Reviewer
 - (4) Reader
22. Which of the following is most commonly used for research involving tuberculosis ?
- (1) Rat
 - (2) Guinea Pig
 - (3) Mice
 - (4) Monkey
23. 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 of the above

24. In which of the following phases of clinical trials of drugs, is ethical clearance **not** required ?
- (1) Phase I
 - (2) Phase II
 - (3) Phase III
 - (4) Phase IV
25. Which of the following is the correct ethical practice by an editor ?
- (1) Accepting or rejecting a paper is not based on the paper's importance, originality or clarity
 - (2) Excluding studies reporting negative results
 - (3) No necessity of taking into account possible bias or conflict of interest before publishing the study
 - (4) None of the above
26. 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
27. The basic principles of bioethics are
- (1) Autonomy, Beneficence, Non-maleficence and Equity
 - (2) Anonymity, Beneficence, Non-maleficence and Equity
 - (3) Anonymity, Benevolence, Non-maleficence and Equity
 - (4) Autonomy, Beneficence, Non-maleficence and Equivalence
28. Which of the following are termed as academic frauds in an e-Learning environment ?
- (1) Inappropriate assistance on examinations
 - (2) Misuse of sources on papers and projects
 - (3) Lack of adherence to copyright and copy-protection
 - (4) All of the above

29. "Masking the eye region in photographs of patients is adequate protection of anonymity and need not take informed consent." This statement is
- (1) True
 - (2) False
 - (3) Partly True
 - (4) Partly False
30. Which of the following is **not** correct for Housing and Environmental requirement in case of Guinea Pig ?
- (1) Average weight – 400 to 500 gms
 - (2) Temperature – 22 to 24°C
 - (3) Humidity – 30 to 40%
 - (4) Photo cycle [Light : Dark] – 12 : 12
31. 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
32. When should Ethics Committee approval be taken ?
- (1) After the start of the study
 - (2) Before the start of the study
 - (3) At the time of publication of results
 - (4) None of the above
33. Animal ethics is related to the use of animals for
- (1) Household purposes
 - (2) Animal experimentation
 - (3) Animal breeding
 - (4) All of the above

- 34.** What are the barriers of "Digital Divide" ?
- (1) Unable to afford Internet access from home
 - (2) Find e-learning content that is difficult to comprehend or not culturally relevant
 - (3) People with disabilities often confront more barriers in e-learning than others
 - (4) All of the above
- 35.** Which of the following constitutes authorship ?
- (1) Acquisition of funding
 - (2) Collection of data
 - (3) Data analysis and interpretation
 - (4) General supervision of the research group
- 36.** Following are the non-living in vitro systems that can be used to reduce/replace animals in experimentations *except*
- (1) Mechanical methods
 - (2) Computer simulation
 - (3) DNA recombinant technology
 - (4) Organ bath
- 37.** Non-Human Primates are commonly used for research in
- (1) Rabies vaccine
 - (2) Rubella vaccine
 - (3) Small pox vaccine
 - (4) Measles vaccine
- 38.** 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
- 39.** Issues concerning research by developed country scientists/institutions in developing countries have been specified by
- (1) National Bioethics Advisory Commission (NBAC), USA
 - (2) Nuffield Council on Bioethics, UK
 - (3) UNESCO, Universal Declaration on Human Genome and Human Rights
 - (4) Both (1) and (2)

40. The guidelines for animal ethics are issued by
- (1) MOHFW
 - (2) CDSO
 - (3) HMSC
 - (4) None of the above
41. "Digital watermarking" is one of the preventive methods to protect which copyrighted material ?
- (1) Text
 - (2) Audio
 - (3) Pictures
 - (4) Both (1) and (3)
42. 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"
43. The process of introducing an exogenous gene into a living organism so that the organism will exhibit a new property and transmit the property to its offspring is known as
- (1) Xenotransplantation
 - (2) Conventional breeding
 - (3) Cisgenesis
 - (4) Transgenesis
44. The purpose of use of animals in scientific research is
- (1) Preparation of natural products used in medical research and treatment
 - (2) Study of genetic disorders
 - (3) Medical education
 - (4) All of the above

45. 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
46. Phase-IV of clinical trial is mainly concerned with
- (1) Dose ranging
 - (2) Efficacy assessment
 - (3) Pharmacokinetic analysis
 - (4) Post marketing surveillance
47. Fresh or re-consent is taken in the 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 a change in treatment modality, procedures and site visits
 - (4) All of the above
48. It is ethical to submit a manuscript simultaneously to two journals to avoid or reduce time for publication.
- (1) True
 - (2) False
 - (3) Partly True
 - (4) Partly False
49. The word "Plagiarism" is derived from a _____ word.
- (1) French
 - (2) Latin
 - (3) Hebrew
 - (4) Roman
50. Research participants must give _____ before they can participate in a study.
- (1) Guidelines
 - (2) A commitment
 - (3) Informed consent
 - (4) Private information

PART B

Write short notes on any **four** of the following in 200 – 300 words each.
Each carries **five (5)** marks.

4×5=20

51. Nuffield Council of Bioethics
52. Institutional Ethics Committee
53. Helsinki Declaration
54. Internet and E-Learning
55. COPE Guidelines
56. Extent of Use of Animals