

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

Term-End Examination

00195

June, 2016

MHS-019 : BIOETHICS AND LAW

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 the answer sheet provided.

1x50=50

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 the above.

2. Which of the following is concerned with article 21 of Constitution of India ?
 - (1) Right to Education
 - (2) Right to Information
 - (3) Right to Freedom
 - (4) Right to Life

3. 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

4. Which of the following term is coined by Fritz Jahr ?
 - (1) Bioethics
 - (2) Euthanasia
 - (3) Assisted Suicide
 - (4) Biopiracy

5. Indian Council of Medical Research (ICMR) was redesignated in the year :
- (1) 1949 (2) 1965 (3) 1956 (4) 1975
6. Declaration of Helsinki is a set of ethical principles regarding :
- (1) Animal experimentation (2) Biotechnology experimentation
(3) Microbiology experimentation (4) Human experimentation
7. Belmont Report explains three Fundamental ethical principles **except** :
- (1) Respect for persons (2) Beneficence
(3) Justice (4) Insurance of participants
8. 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 micro-organisms
(4) All of these
9. Conflict of interest is not applicable to :
- (1) Authors (2) Editor (3) Reviewers (4) Readers
10. Which schedule of Drugs and Cosmetics Act gives a list of poisonous substances under Ayurvedic, Siddha and Unani Systems of medicines ?
- (1) Schedule - C1 (2) Schedule - F1
(3) Schedule - E1 (4) Schedule - M1
11. Which of the following act was passed in year 1916 ?
- (1) Indian medical degree act (2) Indian drug and cosmetic act
(3) Indian medical council act (4) Employee state insurance act
12. The responsibilities of an Institute Ethic Committee can be defined as follows :
- (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 of the above.

13. Drugs and Cosmetics Act was passed in the year :
- (1) 1930 (2) 1940 (3) 1950 (4) 1960
14. Essential information for prospective research participants :
- (1) the aims and methods of the research
(2) the expected duration of the participation
(3) the benefits that might reasonably be expected as an outcome of research to the participant or community or to others
(4) All of the above
15. 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
16. The Information Technology Act was passed in the year :
- (1) 1995 (2) 2007 (3) 2015 (4) 2000
17. Informed consent is important because :
- (1) It enables the participants 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
18. 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
19. Capacity to consent to trial participation may not be diminished by :
- (1) Poverty (2) Source of research funding
(3) Lack of understanding (4) Cultural barriers

20. Who cannot consent to trial participation ?
- (1) Healthy but poverty stricken volunteers
 - (2) Healthy volunteers below the age of 18
 - (3) Mentally stable but sick adults
 - (4) Medical students
21. Plagiarism refers to which of the following ?
- (1) Copying verbatim and 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
22. Can the requirement for informed consent be waived ?
- (1) Yes, at the discretion of the investigator
 - (2) No, unless a designated ethics review committee approves
 - (3) Never
 - (4) Yes, with the consent of the participant
23. Researchers have a duty to avoid, prevent or minimise risk to study participants. This is based on the principle of :
- (1) Non - maleficence
 - (2) Beneficence
 - (3) Human rights
 - (4) Justice
24. 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
25. 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

33. 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
34. 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
35. Human Rights Day is observed by the international community every year on :
- (1) 10 December
 - (2) 25 March
 - (3) 15 September
 - (4) 8 July
36. Which type of container is used for disposal of bio-medical wastes of category 1 ?
- (1) Red
 - (2) Blue
 - (3) Yellow
 - (4) Black
37. The Declaration was originally adopted in Helsinki, Finland in the year :
- (1) 1964
 - (2) 1947
 - (3) 1985
 - (4) 1955
38. Action of proving, in accordance with the principles of Good Clinical Practice, that any procedure, process, equipment material, activity or system actually leads to the expected results :
- (1) Standard Operating Procedures (SOP)
 - (2) Validation
 - (3) Verification
 - (4) Monitoring
39. Declaration of MALTA adopted by World Medical Association is related to :
- (1) Death Sentence
 - (2) Hunger Strike
 - (3) Human rights in clinical trials
 - (4) Good Clinical Practice
40. The chairperson of a National Human Rights Commission is :
- (1) The President
 - (2) Member who is or has been, a Judge of the Supreme Court
 - (3) The person who has been a Chief Justice of the Supreme Court
 - (4) Member who is, or has been, the Chief Justice of a High Court
41. For living donation; all can donate human organs without any legal formalities **except** :
- (1) Father
 - (2) Brothers
 - (3) Spouse
 - (4) Cousins

42. Who is responsible in relation to health hazards in a Factory ?
(1) Employee (2) State
(3) Occupier (4) Appraisal Committee
43. The recent amendment in Indian Factory Act was done in the year :
(1) 2008 (2) 2005 (3) 2011 (4) 2014
44. Bhopal Gas Tragedy occurred in the year :
(1) 1980 (2) 1984 (3) 1990 (4) 1976
45. Which type of euthanasia is legal in India ?
(1) Active euthanasia (2) Passive euthanasia
(3) Both (4) None
46. Which of the following act was passed in the year 1969 ?
(1) Registration of birth and death act
(2) Indian evidence act
(3) Drug and cosmetic act
(4) Transplant of human organ act
47. Which of the following is accepted as documentary evidence without oral evidence ?
(1) Dying declaration
(2) Medical certificates
(3) Evidence of injury recorded by doctor
(4) All of the above
48. In which year the Bio-Medical Waste (Management and Handling) Rules, were framed ?
(1) 1985 (2) 1998 (3) 2004 (4) 2011
49. Chemical waste is included in which of the following category of biomedical waste :
(1) Category 1 (2) Category 3
(3) Category 7 (4) Category 10
50. A 25 year old person sustained injury in right eye. He developed right corneal opacity following the injury. Left eye was already having poor vision. Corneoplasty of right eye was done and vision was restored. Medicolegally such injury is labelled as :
(1) Grievous (2) Simple (3) Dangerous (4) Serious

PART - B

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

5x4=20

51. Research Ethics.
 52. Indian Council of Medical Research (ICMR).
 53. Types of Consent
 54. Plagiarism
 55. Euthanasia
 56. Issues in Internet based education.
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