

POST GRADUATE DIPLOMA IN BIOETHICS (PGDBE)

Term-End Examination

December, 2016

00013

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

50×1=50

1. All of the following are the qualifications required for doing an abortion *except*
 - (1) 6 months housemanship in obstetrics and gynaecology
 - (2) A post-graduate qualification in OBG
 - (3) 2 years of practice in OBG for those doctors registered before the 1971 MTP Act was passed
 - (4) 1 year of practice in OBG for those doctors registered on or after the date of commencement of the Act
2. Punishment under the PNDDT Act is
 - (1) Five-years in jail
 - (2) Ten-years in jail
 - (3) Seven-years in jail
 - (4) Three-years in jail
3. Which of the following is concerned with Article 21 of the Constitution of India ?
 - (1) Right to Education
 - (2) Right to Information
 - (3) Right to Freedom
 - (4) Right to Life

4. 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 the consent of the patient
5. The first international code for research with human beings was
 - (1) Nuremberg Code
 - (2) Vancouver Code
 - (3) Helsinki Code
 - (4) Washington Code
6. Which of the following terms is coined by Fritz Jahr ?
 - (1) Bioethics
 - (2) Euthanasia
 - (3) Assisted suicide
 - (4) Biopiracy
7. The declaration of Helsinki is a set of ethical principles regarding
 - (1) Animal experimentation
 - (2) Biotechnology experimentation
 - (3) Microbiology experimentation
 - (4) Human experimentation
8. Belmont Report explains three fundamental ethical principles *except*
 - (1) Respect for persons
 - (2) Beneficence
 - (3) Justice
 - (4) Insurance of participants
9. An Institutional Review Board (IRB) is 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 the above

10. Conflict of interest is **not** applicable to
- (1) Authors
 - (2) Editor
 - (3) Reviewers
 - (4) Readers
11. The following kinds or types of information is exempted from disclosure under the RTI Act, 2005 *except*
- (1) Information, disclosure of which would prejudicially affect the sovereignty and integrity of India, the security, strategic, scientific or economic interests of the State
 - (2) Information which has been expressly forbidden to be published by any court of law
 - (3) Information which would cause a breach of privilege of the Parliament or the State Legislature
 - (4) Information which is related to personal issues
12. National Rural Health Mission was launched in the year
- (1) 1990
 - (2) 2009
 - (3) 2005
 - (4) 2011
13. Which of the following Acts was passed in the year 1916 ?
- (1) Indian Medical Degrees Act
 - (2) Indian Drugs and Cosmetics Act
 - (3) Indian Medical Council Act
 - (4) Employee State Insurance Act
14. The responsibilities of an Institutional Ethics 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 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

15. 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
16. The principle underpinning voluntary and informed consent is
- (1) Beneficence
 - (2) Autonomy
 - (3) Non-maleficence
 - (4) Respect
17. The 74th amendment passed in pursuance of Article 40 of the Constitution of India is concerned with
- (1) Panchayats
 - (2) Municipalities
 - (3) Finance Department
 - (4) Drugs and Cosmetics Act
18. 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
19. The different methods used in detecting the status of inbred strains for their homogeneity include
- (1) Histocompatibility or Skin grafting
 - (2) Electrophoresis or Biochemical Markers
 - (3) Immunological Markers
 - (4) All of the above

- 20.** During all of the following situations 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 the emergency department
 - (4) Chronic lung disease patient
- 21.** Participation in research can have a number of perceived benefits for 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
- 22.** Any research using 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
- 23.** Human Rights Day is observed by the international community every year on
- (1) 10th December
 - (2) 25th March
 - (3) 15th September
 - (4) 8th July
- 24.** Which type of container is used for disposal of biomedical wastes of category 1 ?
- (1) Red
 - (2) Blue
 - (3) Yellow
 - (4) Black

25. 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, is known as
- (1) Standard Operating Procedures (SOPs)
 - (2) Validation
 - (3) Verification
 - (4) Monitoring
26. 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
27. The Chairperson of the National Human Rights Commission is
- (1) The President
 - (2) The 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) The member who is or has been the Chief Justice of a High Court
28. For living donation, all can donate human organs without any legal formalities *except*
- (1) Father
 - (2) Brothers
 - (3) Spouse
 - (4) Cousins
29. Who is responsible in relation to health hazards in a factory ?
- (1) Employee
 - (2) State
 - (3) Occupier
 - (4) Appraisal Committee

- 30. Indian Penal Code 268 is concerned with**
- (1) Public nuisance
 - (2) Fouling water of public spring or reservoir
 - (3) Making atmosphere noxious to health
 - (4) Chemical injury
- 31. Which type of euthanasia is legal in India ?**
- (1) Active euthanasia
 - (2) Passive euthanasia
 - (3) Both of the above
 - (4) None of the above
- 32. The basic principle to be followed while conducting clinical trials is**
- (1) Autonomy
 - (2) Beneficence
 - (3) Justice
 - (4) Economic beneficence
- 33. Which of the following acts was passed in the year 1969 ?**
- (1) Registration of Birth and Death Act
 - (2) Indian Evidence Act
 - (3) Drugs and Cosmetics Act
 - (4) Transplant of Human Organ Act
- 34. Which of the following is accepted as documentary evidence without oral evidence ?**
- (1) Dying declaration
 - (2) Medical certificates
 - (3) Evidence of injury recorded by the doctor
 - (4) All of the above
- 35. Chemical waste is included in which of the following categories of biomedical wastes ?**
- (1) Category 1
 - (2) Category 3
 - (3) Category 7
 - (4) Category 10

36. A 25-year-old person sustained injury in the right eye. He developed right corneal opacity following the injury. Left eye already had poor vision. Corneoplasty of the right eye was done and vision was restored. Medicolegally such injury is labelled as
- (1) Grievous
 - (2) Simple
 - (3) Dangerous
 - (4) Serious
37. The Drugs and Cosmetics Act was passed in the year
- (1) 1930
 - (2) 1940
 - (3) 1950
 - (4) 1960
38. Essential information for prospective research participants is
- (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
39. Historically the 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 Guidelines
40. Which chapter of the Drugs and Cosmetics Act of India is concerned with the distribution and sale of drugs ?
- (1) Chapter IV
 - (2) Chapter I
 - (3) Chapter II
 - (4) Chapter V

41. Informed consent is important because
- (1) It enables the participant to understand vital information on the proposed trial
 - (2) It provides the participant all the information regarding remote risks
 - (3) It enables the investigator to recruit participants of his choice
 - (4) It promotes clinical research
42. Informed consent refers to
- (1) Principle of autonomy
 - (2) Voluntary but uniformed 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
43. 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
44. Forest Conservation Act was passed in the year
- (1) 1984
 - (2) 1980
 - (3) 1988
 - (4) 1996
45. 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

46. 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
47. 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
48. Researchers have a duty to avoid, prevent or minimise risk to the study participants. This is based on the principle of
- (1) Non-maleficence
 - (2) Beneficence
 - (3) Human rights
 - (4) Justice
49. 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
50. 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

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. Ethical Issues in Biomedical Waste Management
52. Clinical Trial Registry of India
53. Local Self Governance in India
54. Genetically Modified Foods
55. Research Ethics
56. Plagiarism