

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

**Term-End Examination**

**June, 2015**

**MHS-017 : RESEARCH ETHICS-II**

*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. The basic ethic principles for conducting a clinical trial are
  - (1) Autonomy or respect of study participants
  - (2) Beneficence or do good
  - (3) Non-maleficence or do no harm
  - (4) All of the above
  
2. In a clinical trial of drugs, DCGI clearance is required for
  - (1) Phase-I
  - (2) Phase-II
  - (3) Both Phase-I and Phase-II
  - (4) Phase-I, Phase-II and Phase-III
  
3. Deviation in the protocol of a clinical trial should be intimated to
  - (1) Ministry of Health
  - (2) Ethical Committee
  - (3) Licensing Authority
  - (4) Ethical Committee and Licensing Authority

4. In the threatening or serious disease or disease specific to India, the toxicological and clinical data requirement is decided by
- (1) Pharmaceutical Society of India
  - (2) Ministry of Health
  - (3) Licensing Authority
  - (4) Ethical Committee
5. The medical devices in India are supervised by
- (1) Indian Standards Institute
  - (2) Bureau of Indian Standards
  - (3) Drug Controller General of India
  - (4) All of the above
6. Cross-sectoral study (survey) is primarily
- (1) Hospital based
  - (2) Clinic based
  - (3) Population based
  - (4) All of the above
7. Case control studies have to be
- (1) Prospective
  - (2) Retrospective
  - (3) Both of the above
  - (4) None of the above
8. Cohort studies require
- (1) Small number of participants for short time
  - (2) Large number of participants for long time
  - (3) Both of the above
  - (4) None of the above
9. The pre-natal test conducted for diagnosing genetic defects include
- (1) Amniocentesis
  - (2) Chorionic Villus sampling
  - (3) Cord Blood sampling
  - (4) All of the above

- 10. The different types of gene therapy are**
- (1) Somatic cell
  - (2) Germ line
  - (3) Designer babies or gene therapy enhancement
  - (4) All of the above
- 11. The human genome project was completed in**
- (1) 1990
  - (2) 1997
  - (3) 2003
  - (4) 2005
- 12. In an organ donation programme**
- (1) Interest of the recipient is paramount
  - (2) Interest of the donor is paramount
  - (3) Interest of the institute is paramount
  - (4) Interest of the doctor is paramount
- 13. Cord blood banks have to register with**
- (1) State Health Department
  - (2) Central Health Department
  - (3) Drug Controller General of India
  - (4) Medical Council of India
- 14. The ICMR guidelines on live donor transplant suggest**
- (1) All tissues or organs can be donated by volunteers
  - (2) Restrict donation only to renewable tissue
  - (3) Restrict donation only to renewable tissue and paired organs
  - (4) No live donor transplant to be done
- 15. In a cadaver donation programme**
- (1) Any organ can be harvested
  - (2) Harvest only the organ for which consent has been given
  - (3) Both of the above
  - (4) Cadaver donation programme should be discouraged

- 16.** The use of embryonic cells or foetal tissue for research or transplantation has to be approved by
- (1) Institute Committee for Stem Cells Research and Therapy
  - (2) Ethics Committee
  - (3) National Ethics Committee for Stem Cells Research and Therapy
  - (4) All of the above
- 17.** Xeno transplantation is
- (1) Transplantation from another human being
  - (2) Transplantation of animal organ or tissue
  - (3) Transplantation from laboratory grown organs
  - (4) All of the above
- 18.** The risk of Xeno transplantation is
- (1) Ethical objection, exploitation of animals
  - (2) Risk of transmission of disease from animal to man
  - (3) Immune rejection
  - (4) All of the above
- 19.** The ICMR Guidelines on Xeno transplantation state
- (1) Institutional scientific and ethical committee approval
  - (2) An advisory committee must oversee all these transplants
  - (3) Animal to man transplant is not permitted at present knowledge
  - (4) All of the above
- 20.** The prohibited area of research includes
- (1) Germ line genetic engineering
  - (2) Reproductive cloning
  - (3) In vitro fertilisation and embryo transfer
  - (4) Both (1) and (2)

- 21. Research using foetal tissues is permitted under the following circumstances :**
- (1) Consent to have termination of pregnancy, donation of foetal material for the purpose of research or therapy should be taken separately.
  - (2) Termination of pregnancy is sought with a view to donate foetal tissue, for financial or possible therapeutic use.
  - (3) The identity of the donor or recipient may be known to each other.
  - (4) The medical person doing the termination may also be using foetal tissue.
- 22. In research using umbilical cord blood stem cells**
- (1) Collecting as much blood as possible is the priority
  - (2) Safety of the new-born is the priority
  - (3) Registering with the Drug Controller General of India is essential
  - (4) Both (2) and (3)
- 23. In international collaborative research**
- (1) The guidelines of the sponsoring agency should be followed
  - (2) National guidelines of respective country should be followed
  - (3) If there is conflict between international and national guidelines, the national guidelines will prevail
  - (4) Both (2) and (3)
- 24. Export of cell lines will be covered under Government of India guidelines for**
- (1) Intellectual Property Rights
  - (2) Trade and restrictive practices
  - (3) Transfer of biological materials
  - (4) Medical practice guidelines
- 25. Foetal tissue transplantation is being researched in**
- (1) Infertility
  - (2) Huntington's Chorea
  - (3) Alzheimer's Disease
  - (4) HIV-Acquired Immuno Deficiency Syndrome

- 26.** The first and most important principle of medicine is
- (1) Primum non nocere
  - (2) Somehow complete the treatment
  - (3) Protect the interest of the institution
  - (4) Protect medical practitioner's interest
- 27.** In human genetics and genomic research
- (1) Counselling is of no importance
  - (2) Counselling is secondary to research for knowledge
  - (3) Counselling is crucial and should precede any genetic study or research
  - (4) Both (1) and (2)
- 28.** In epidemiological research, it is enough to have
- (1) Consent of the individual
  - (2) Consent of the community
  - (3) Both of the above
  - (4) None of the above
- 29.** The vulnerable group in any research study are
- (1) Young children
  - (2) Imprisoned individuals
  - (3) Sick people
  - (4) All of the above
- 30.** In a youth of 17 years of age, any participant in research requires
- (1) Consent of the individual
  - (2) Consent of the parent/legal guardian
  - (3) Consent of the individual and parent or legal guardian
  - (4) No consent is required
- 31.** In assisted reproduction, doctors and scientists
- (1) Play God
  - (2) Create new life
  - (3) Meddle with nature
  - (4) Bring sperm and egg together to assist reproduction

- 32. Drug trial should not be conducted without the approval of**
- (1) Indian Council of Medical Research
  - (2) Indian Regulatory Authority
  - (3) Medical Council of India
  - (4) Both (1) and (2)
- 33. Phase-II is called as**
- (1) Therapeutic confirmatory trials
  - (2) Therapeutic exploratory trials
  - (3) Both of the above
  - (4) None of the above
- 34. The most important quality control parameter in herbal or herbal mineral formulation is**
- (1) Absence of any adulterants in the final compound
  - (2) Absence of toxic contaminants as such in these compounds
  - (3) Absence of the level of contaminants through herbicides and pesticides in the compound
  - (4) All of the above
- 35. In genetic counselling**
- (1) Learned counsellors should explain natural course of the disorder
  - (2) Confidentiality is the major concern in counselling
  - (3) Written explanation in vernacular language is important
  - (4) All of the above
- 36. Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act was proposed in**
- (1) 1993
  - (2) 1994
  - (3) 1995
  - (4) 1991

**37. Repository activities involve**

- (1) The collection of tissue samples
- (2) The repository storage and data management centre
- (3) The recipient investigators
- (4) All of the above

**38. Which of the following is true about Genomics ?**

- (1) Started in 1970
- (2) Is the study of collective genetic material in an organism
- (3) Was established by Fred Sanger
- (4) All of the above

**39. In epidemiological evaluation**

- (1) No consideration of culture characteristic of the community needs to be given
- (2) Special consideration should be given for culture characteristic of the community that has been studied
- (3) Culture has no bearing on the study
- (4) All of the above

**40. Ethics is defined as the science of**

- (1) Mortality
- (2) Morbidity
- (3) Disease and disability
- (4) Morality

**41. Fertility of a female cancer patient can be preserved by**

- (1) Oocyte freezing
- (2) Embryo freezing
- (3) Ovarian tissue freezing
- (4) All of the above



- 42.** In surrogacy, besides age of the woman, the other important things to be considered are
- (1) Educational status of the patient and the financial status of the patient
  - (2) Physical fitness of the patient
  - (3) Mental fitness of the patient
  - (4) Both (2) and (3)
- 43.** Medical ethics is the principle of correct professional conduct with regard to
- (1) The rights of the physician only
  - (2) The rights of the physician himself and the patient
  - (3) The rights of the physician himself and the fellow practitioners
  - (4) Both (2) and (3)
- 44.** In organ donation programmes, if the donor suffers from serious physical complication, then the responsibilities are borne by the
- (1) Recipient
  - (2) Recipient's family
  - (3) Donor's family
  - (4) Institute in which the procedure is being done
- 45.** If the donor is less than 18 years, one should
- (1) Proceed with parent's consent
  - (2) Proceed with regulatory authority's consent
  - (3) Proceed without any consent
  - (4) Abandon the programme
- 46.** Prophylactic vaccines are
- (1) Given for disease control
  - (2) Given for disease prevention
  - (3) Meant only for adults
  - (4) Meant only for children

**47. Intellectual Property Rights (patents)**

- (1) Is a right of the manufacturing company
- (2) Is a right of the individual who devised the methodology
- (3) Is a right of the participant individual in the study
- (4) Is a right only of the Government authority

**48. Genetic screening helps**

- (1) To identify the particular genetic disease
- (2) To allay the anxiety
- (3) In the birth of healthy children
- (4) All of the above

**49. Wrongful birth is**

- (1) When the child is deformed
- (2) Affected child sues the doctor
- (3) Affected parents sue the doctor
- (4) Both (1) and (2)

**50. Brain death**

- (1) Is actual evidence of death
- (2) Is also associated with organ death
- (3) With evidence of rigor mortis
- (4) None of the above

## **PART B**

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

*Each carries **five (5)** marks.*

**4×5=20**

- 51. Genetic Counselling**
- 52. Ethics in Epidemiological Research**
- 53. Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act**
- 54. Bureau of Indian Standards**
- 55. Clinical Drug Trials**

**SPACE FOR ROUGH WORK**