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MHS-017

POST GRADUATE DIPLOMA IN BIOETHICS (PGDBE)

Term-End Examination

00288

December, 2016

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 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. Double blind trial

(1) Refers to the study subject(s) and/or investigator(s) are unaware of the treatment assigned but monitor and data analyst(s) are aware of the treatment assigned.

(2) Refers to the study subject(s) and/or investigator(s) and monitor are unaware of the treatment assigned but data analyst(s) are aware of the treatment assigned.

(3) Refers to the study subject(s) and/or investigator(s), monitor and data analyst(s) are unaware of the treatment assigned.

(4) Refers to the study subject(s) and/or investigator(s) and data analyst(s) are unaware of the treatment assigned. Monitors are aware of the assignments.

2. The objective of phase-II trials is to determine

(1) The maximum tolerated dose in humans, pharmacodynamic effect and adverse effects

(2) The minimum tolerated dose in humans, pharmacodynamic effect and adverse effects

(3) The maximum tolerated dose in humans and pharmacodynamic effect

(4) The effect of the drug on the disease condition

3. The first Helsinki Declaration was in the year

(1) 1948

(2) 1954

(3) 1958

(4) 1964

4. Principle of privacy and confidentiality upholds which of the following ethical principles ?

(1) Beneficence

(2) Non-malfeasance

(3) Autonomy

(4) Justice

5. Principle of professional competence is

(1) Beneficence

(2) Non-malfeasance

(3) Autonomy

(4) Justice

6. All these are responsibilities of an IEC *except*

(1) To protect the dignity and rights of the investigator

(2) To protect the dignity, rights and well-being of the potential research participants

(3) To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs

(4) To assist in the development and the education of a research community responsive to local health care requirements

7. As per revised Schedule Y of the Drugs and Cosmetics Act, 1940, amended in 2005, the Ethics Committee approving drug trials should have in the quorum at least one representative from the following groups *except*

(1) One basic medical scientist (preferably one pharmacologist)

(2) One clinician

(3) One legal expert or retired judge

(4) One institutional representative

8. Expedited Review is

(1) The researcher needs to hurry the proposal

(2) Proposals presenting not more than minimal risk to research participants

(3) Proposals which present less than minimal risk fall

(4) All research presenting with more than minimal risk

9. The decision taken by the IEC on the proposal is based on

(1) Chairman's decision

(2) Majority vote

(3) A broad consensus after the quorum requirements are fulfilled

(4) Institutional policy

10. IECs may waive off the requirement for informed consent in the following instances *except*

(1) Study on disease burden of HIV/AIDS

(2) Review of guidelines

(3) Discarded blood after the lab test has been performed

(4) Newly discovered drug

11. The investigator can obtain informed consent by using

(1) Deception

(2) Only after the prospective participant is adequately informed

(3) Seek consent from the prospective participant before fully disclosing the purpose of the study

(4) Verbal consent

12. Ancillary care means

(1) Subject is provided treatment for complaints other than the one being studied

(2) Subject is provided treatment for the adverse effects of the treatment

(3) Subject is provided medical care for lifetime

(4) Subject is provided care only for the permanent disabilities that occur during the period of study

13. The following research is permitted in women *except*

(1) To test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child

(2) Trials for detecting foetal abnormalities

(3) For conditions associated with or aggravated by pregnancy

(4) For an anti-asthmatic drug trial

14. In an international collaborative research

(1) The local institution policy is more important than that of the sponsor or the host country policy

(2) The local sponsor policy is more important than the institution or the host country policy

(3) The host country policy is more important than that of the sponsor or the local institution

(4) The local institution, the sponsor or the host country policy are to be given equal importance for research

15. Phase-IV trials are necessary for

(1) Approval of a new drug

(2) Marketing

(3) May be required by the Licensing Authority for optimizing its use

(4) Pricing of the drug

16. The medical management of the adverse event is the responsibility of

(1) The investigator

(2) The sponsor

(3) The institution

(4) The Government

17. In Cross-Sectional Epidemiological Studies

(1) The available records are examined

(2) The study participants are directly contacted only once

(3) The study participants are directly contacted many times

(4) The study participants are directly contacted at the beginning and at the end of the study

18. Community participation in an epidemiological research should be

(1) From the design of the study

(2) From the beginning of the investigation

(3) Involved only when the results can affect the community

(4) Throughout the study

19. In pedigree studies

(1) Family members need to know the diagnosis of the subject

(2) Family members need not know the diagnosis of the subject

(3) Only close relatives need to know the diagnosis of the subject

(4) Only the spouse of the subject needs to know the diagnosis

20. In pedigree studies, the following problems could arise *except*

(1) Revealing who else in the family has agreed to participate may lead to breach of confidentiality

(2) Recruitment of the subject through advertisements in the media

(3) If a proband is used, out of personal interest s/he may put undue pressure on relatives to enrol in the study

(4) Direct recruitment by telephone calls, etc. may be seen as an invasion of privacy by the family members

21. To maintain confidentiality in a genetic study

(1) The sample must be anonymised and analysed

(2) The results of the sample must be linked to the patient

(3) The results of the sample may be linked to the patient, if it directly benefits the patient

(4) The results of the sample must be delinked from the patient

22. Ethically, the results of the positive genetic testing can be informed

(1) By the investigator to all the persons likely to be affected by the gene

(2) By the investigators to the Government

(3) By the patient to whomsoever s/he wants

(4) The benefit to the other members of the family overrules the need for confidentiality of the patient

23. Screening of a newborn should be done when

(1) A test is available for testing the condition

(2) A test is available and no treatment is available for treatment

(3) A test is available and an effective treatment is available

(4) As part of the Governmental programme

24. Screening of children for genetic disease must be undertaken

(1) When parents wish for it

(2) Only with the assent of the child

(3) As a programme for improving the community health

(4) At the request of the orphanage head

25. Somatic cell gene therapy

(1) May be permissible for the purpose of preventing or treating a serious disease when it is the only therapeutic option

(2) May be permissible for the purpose of preventing or treating a common disease even when there is an effective treatment

(3) May be permissible for the purpose of preventing a serious disease

(4) Is never permissible

26. To prepare a 'gene construct' the permission must be obtained from

(1) ICMR and IEC

(2) Central Ethics Committee of ICMR

(3) Health Ministry and DCGI

(4) National Bioethics Committee of the DBT

27. Repository activities involve all of these *except*

(1) The collectors of tissue samples

(2) The repository storage and data management centre

(3) The recipient investigators

(4) Dissemination of information on the samples stored

28. The identity of the Repository from which the samples were obtained

(1) Must be revealed in all reports, patents or copyrights arising out of the samples

(2) Must not be revealed in all reports, patents or copyrights arising out of the samples

(3) Only when patents are obtained

(4) Only when copyrights arising out of the samples are involved

29. Ownership of the biological specimen rests with

(1) The community

(2) The donor

(3) The family of the donor

(4) With the donor and the family, if the donor is deceased

30. Prenatal diagnosis should be available

(1) To parents who request it and plan for an abortion

(2) To parents who request it but oppose abortion

(3) To parents who have a genetically affected child

(4) To parents who want a perfect child

31. In which of the following conditions may prenatal diagnosis be performed to protect the health of the mother ?

(1) Morbid anxiety in the mother

(2) Genetic disease in the mother

(3) Systemic lupus erythematosis (SLE)

(4) Eclampsia

32. All these are features of brain death *except*

(1) The presence of deep coma

(2) The absence of any spontaneous respiration

(3) The presence of low body temperature

(4) The absence of pupil reactions and eye movements

33. Donation from a live donor should be restricted in

(1) Bone marrow

(2) Liver

(3) Kidney

(4) Eye

34. The responsibility of providing the information to the donor involved in research involving transplant, and of making sure that s/he understands fully the implications of what is to be done and what he or she consents to, rests entirely on the

(1) Director of the research project

(2) Investigators at the site

(3) Institutional head

(4) Head of the Ethics Committee

35. In all these countries a "Living Will" or advance directives is accepted *except* in

(1) Australia

(2) India

(3) England

(4) Ireland

36. The tissue/organ from the following source should ***not*** be used for transplantation :

(1) Embryo

(2) Live born foetus

(3) Dead born foetus

(4) Blastocyst

37. The final authority on Research on Foetal Tissue or Organs for Transplantation is

(1) National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT)

(2) Institutional Committee for Stem Cell Research and Therapy (IC-SCRT)

(3) Institutional Committee for Stem Cell Research and Therapy (IC-SCRT) and IEC

(4) Health Ministry

38. In termination of pregnancy

(1) Mother can terminate her pregnancy as she wants to donate foetal tissue for her older child

(2) In a spontaneous abortion consent of the mother is essential for use in transplantation research

(3) In a spontaneous abortion consent of the father is essential for use in transplantation research

(4) The aborted foetus cannot be used for research

39. When collecting umbilical cord blood for bio-banking, to protect the blood, it should be collected

(1) When the cord is seen in the vagina

(2) As soon as the baby is born

(3) On normal clamping of the cord

(4) After the cord is cut

40. Transplantation of organs from the animals to humans is banned because of the fear of/that

(1) Transplanted person may get the psychological character of the transplanted animal

(2) Transmitting disease from the animals to humans

(3) Increased chances of rejection

(4) Organ may not be sufficient to support the human body

41. The transfer of an adult cell nucleus into an egg that has had its nucleus removed to asexually create an embryo without the fusion of sperm and egg is known as

(1) Cloning

(2) Reproductive Cloning

(3) Therapeutic Cloning

(4) Cell Nuclear Replacement

42. All these are permissible areas of research in stem cells *except*

(1) In vitro studies on established cell lines from any type of stem cells

(2) In vivo studies with established cell lines from any type of stem cells

(3) In vivo studies on experimental animals (other than primates) using foetal/adult somatic stem cells

(4) Creation of a zygote by IVF, SCNT or any other method with the specific aim of deriving a hES cell line for any purpose

43. Reproductive cloning

(1) Is a prohibited area for research

(2) Can be undertaken at the request of the couple

(3) Can be undertaken with permission from the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT)

(4) Can be undertaken with permission from the Institutional Committee for Stem Cell Research and Therapy (IC-SCRT)

44. In assisted reproductive procedures, informed signed consent has to be obtained from the

(1) Mother

(2) Father

(3) Donor of the sperm or ovum

(4) All of the above

45. The semen bank assumes the responsibility in selection of the suitable donor on the following terms :

(1) The blood group of the donor and the recipient should match

(2) The donor should be healthy with reasonable expectation of good quality of sperms and need not have proven fertility

(3) The physical characteristic and mental make-up of the donor should match as closely as possible to that of the spouse of the recipient

(4) Donated semen must be used immediately to prevent transmission of infections

46. An embryo shall be stored

(1) Indefinitely

(2) For not more than five years

(3) For not more than three years

(4) For not more than one year

47. A child born through assisted reproductive technique is presumed to be the legitimate child of

(1) The Ovum donor

(2) The Sperm donor

(3) The couple who are married and consented for therapy

(4) The couple who are not married and consented for therapy

48. In case of a child conceived by surrogate motherhood

(1) Adopting parents have an obligation to inform the child of its biological parents

(2) The child has a right to seek information on the identity of genetic parent(s) or surrogate mother

(3) The child does not have any legal rights on the adopting parents

(4) Adopting parents have no obligation to inform the child of its biological parents

49. The Chairman to deliberate and work out the formula to be followed to determine the quantum of compensation in case of clinical trial related injury other than death was

(1) R.K. Jain

(2) A.K. Agarwal

(3) Y.K. Gupta

(4) Mira Shiva

50. The base amount in case of injury or death is determined by

(1) The minimum wages of the skilled workers

(2) The minimum wages of the unskilled workers

(3) The minimum wages earned by the victim

(4) The maximum wages earned by the subject in his/her lifetime of the unskilled workers

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. Phase-3 Trials

52. Ethical problems in conducting research among mentally challenged

53. The difference between a vaccine trial and a new drug trial

54. Wavier of consent for research proposal

55. Guidelines for unrelated live organ donor