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MHS-017

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POST GRADUATE DIPLOMA IN BIOETHICS (PGDBE)

Term-End Examination

December, 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 the answers in the answer-sheet provided.* *50×1=50*

1. Audit of a Trial means

(1) A systematic verification of the study, carried out by persons directly involved in the study.

(2) A systematic verification of the study, carried out by persons not directly involved in the study.

(3) A random verification of the study, carried out by the financial department.

(4) A systematic verification of the study, carried out by the financial department.

2. Double blind trial refers to

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

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

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

(4) The study subject(s) and/or investigator(s), and data analyst(s) being unaware of the treatment assigned, monitors are aware of the treatment assigned.

3. The objective of Phase-I of trials is to determine

(1) the maximum tolerated dose in humans; pharmacodynamic effect and adverse effects

(2) the maximum tolerated dose in animals; pharmacodynamic effect and adverse effects

(3) the minimum tolerated dose in humans; pharmacodynamic effect and adverse effects

(4) the maximum tolerated dose in humans; and pharmacodynamic effect

4. The selection of clinicians for monitoring and supply of drug to them

(1) will need approval of the Ethics Committee

(2) will need approval of the CRO

(3) will need approval of the institutional head

(4) will need approval of the licensing authority

5. Principles of essentiality means

(1) Research is necessary for the advancement of knowledge and for the benefit of all members of the human species and for the ecological and environmental well-being of the planet.

(2) Research is necessary for the advancement of knowledge and for the benefit of all members of the scientific community and for the ecological and environmental well-being of the planet.

(3) Research is necessary for the advancement of knowledge and for the benefit of members of the developed countries and for the ecological and environmental well-being of the planet.

(4) Research is necessary for the advancement of knowledge and for the benefit of all members of the developing countries and for the ecological and environmental well-being of the planet.

6. Principles of totality of responsibility have to be followed by

(1) The researchers

(2) The funding agencies

(3) The institution where research is being conducted

(4) All the persons and agencies involved in research

7. The minimum number of persons required to compose a quorum of an Ethics Committee is

(1) 3 (2) 5

(3) 7 (4) 9

8. The Chairperson of the Ethics Committee should preferably

(1) Be the head of the institution

(2) Be a representative of the institution

(3) Be from outside of the institution

(4) Be from outside of the institution with a legal background

9. In case of a Non-Therapeutic Study, the consent

(1) Must always be given by the subject

(2) Is not required

(3) Can be given by the institution on behalf of the subject

(4) May be given by the legal representative

10. In case of severe adverse event, the Ethics Committee should inform the licensing authority about the event and the action is to be taken within

(1) 30 days (2) 60 days

(3) 90 days (4) 120 days

11. A subject who suffers from an injury during clinical trial

(1) Should be given free treatment for life

(2) Should be given free treatment till the condition resolves

(3) Should be given free treatment only if the injury is a result of clinical trial

(4) Should not be given free treatment as the patient willingly agrees for the trial knowing the risks and benefits

12. Abbreviated drug trials are allowed in the following situation :

(1) Generics and biological approved in other countries as soon as the approval is obtained

(2) Generics and biological approved in other countries are never allowed in our country

(3) For new drugs that are vital to the country

(4) Generics and biological that have been in use for more than 4 years in other countries

13. Compensation to a trial participant should be paid

(1) For any injury that occurs during the time of trial

(2) For any injury that occurs after the trial has ended, if the injury is caused by the participation in the trial

(3) Only for death that occurs after the trial has ended, if the death is caused by the participation in the trial

(4) Only for death that occurs during the trial

14. Compensation for death is based on

(1) Motor Vehicle Accident Act

(2) ESI Act

(3) Workmen's Compensation Act

(4) The Companies Act

15. The first ethics guideline was issued by ICMR in the year

(1) 1970 (2) 1980

(3) 1990 (4) 2000

16. The guideline to be followed for animal experimentation is

(1) The Indian National Science Academy (INSA) guidelines

(2) ICMR guidelines

(3) PETA guidelines

(4) SPCA guidelines

17. ICH GCP Guideline is to provide a unified standard for the following regions :

(1) All countries doing drug trials

(2) European Union (EU), Japan and the United States

(3) Developing countries

(4) The United States and Canada only

18. New drug that is being introduced should be approved by

(1) Institutional Ethics Committee

(2) DCGI

(3) DCGI and Institutional Ethics Committee

(4) DCGI, Government of India and Institutional Ethics Committee

19. More than minimal manipulation of stem cells is

(1) No major alterations in cell population or function

(2) Defined as alterations in cell population, which is expected to result in alteration of function

(3) Long-term culture of cells through multiple passages

(4) Induction of genetic alteration by insertion of gene/siRNA

20. All these researches are prohibited *except*

(1) Studies on chimeras

(2) Human germ line genetic engineering

(3) Reproductive cloning

(4) Implantation of human embryo into uterus after in-vitro manipulation, at any stage of development, in humans or primates

21. In a living related donor, all these ethical principles are fulfilled *except*

(1) Autonomy

(2) Beneficence

(3) Non-malfeasance

(4) Justice

22. Embryonic stem cells are derived from

(1) Spare blastocysts

(2) The inner cell mass (ICM) of blastocysts

(3) Genetic reprogramming of somatic cells

(4) Hematopoietic stem cells

23. Data Safety Monitoring Board (DSMB) for stem cell research

(1) Shall comprise members associated with IC-SCR/NAC-SCR

(2) Shall comprise independent members not associated with IC-SCR/NAC-SCR

(3) Shall be constituted by IC-SCR/NAC-SCR

(4) Shall be constituted by the institution irrespective of funding

24. Cord Blood Stem Cell Banking

(1) Requires registration and license from the DCGI

(2) Does not require any license

(3) Requires license from the local body

(4) Requires license from the State Health Department

25. All these are ethical issues involved in the use of stored umbilical cord blood *except*

(1) Concern about ownership

(2) Risk of transmission of potential genetic disorders

(3) Autonomy

(4) Justice

26. The following is true in case of termination of pregnancy for formation of stem cells :

(1) It is banned.

(2) It can be done for financial gain.

(3) The donor cannot specify the use of the foetal tissue.

(4) The person doing the abortion and the person using the foetal tissue must be same.

27. The following is true about the consent for donation of supernumerary embryos after clinical care :

(1) Consent should be obtained 48 hours before the actual donation

(2) Once the consent is given it cannot be withdrawn

(3) The donor has the right to withdraw the consent until the blastocysts are actually used in cell line derivation

(4) Consent should be obtained just before the embryo is used for forming embryonic stem cells

28. The benefits of the commercial returns from the products of stem cell should be shared with the

(1) Institution obtaining the tissue

(2) Government

(3) Donor of the embryo even if it is not mentioned in the consent form

(4) Community

29. Exemption from review is granted

(1) To research on educational practices

(2) To research strategies that involve public behaviour and can identify the human participant directly

(3) When interviews involve direct approach or access to private papers

(4) In emergency situations

30. A physician may use new intervention as investigational intervention to provide emergency medical care to his/her patients in life threatening conditions *except*

(1) When the consent of patient/responsible relative is not possible to obtain

(2) When the intervention has undergone testing for safety prior to its use in emergency situations and there is prior approval of DCGI

(3) When the local IEC reviews the protocol and approves it before emergency

(4) When there is no Data Safety Monitoring Board to access the effectiveness of the treatment

31. All of these are essential for research on disaster management *except*

(1) Research planned to be conducted after a disaster should be essentially culturally sensitive and specific in nature with possible application in future disaster situations.

(2) Disaster-affected community participation is not essential and its representative or advocate must be identified.

(3) Extra care must be taken to protect the privacy and confidentiality of participants and communities.

(4) Protection must be ensured so that only minimal additional risk is imposed.

32. The amount of blood that is permitted to be drawn by ICMR from healthy adults and non-pregnant women who weigh normal for their age is

(1) Not more than 500 ml blood drawn in an 8-week period and the frequency of collection is not more than 2 times per week

(2) Not more than 500 ml blood drawn in a 4-week period and the frequency of collection is not more than 3 times per week

(3) Not more than 300 ml blood drawn in an 8-week period and the frequency of collection is not more than 2 times per week

(4) Not more than 800 ml blood drawn in an 8-week period and the frequency of collection is not more than 2 times per week

33. In all these conditions fresh consent or re-consent is taken *except*

(1) When a research participant regains consciousness from unconscious state

(2) When long-term follow-up or study extension is planned later

(3) On availability of new information which would necessitate deviation of protocol

(4) On availability of new information which does not necessitate deviation of protocol

34. Waiver of the requirement for informed consent can be granted in all these conditions *except*

(1) When it is impractical to conduct research

(2) When the research is on publicly available information

(3) When the research is on anonymized biological samples

(4) In emergency situations when no surrogate consents can be taken

35. Conflict of interest is

(1) A set of conditions in which professional judgement concerning a primary interest such as the validity of research tends to be unduly influenced by financial gain.

(2) A set of conditions in which professional judgement concerning a primary interest such as the validity of research tends to be or appears to be unduly influenced by a secondary personal interest.

(3) A set of conditions in which professional judgement concerning a primary interest such as the validity of research tends to be or appears to be unduly influenced by a secondary interest or financial gain.

(4) A set of conditions in which professional judgement concerning a primary interest such as the validity of research tends to be or appears to be unduly influenced by a need to achieve academic success.

36. Prenatal Diagnostic Techniques Act, allows for

(1) Sex determination

(2) Identification of genetic disorders

(3) Abortions when foetal anomalies are discovered late in the course of pregnancy

(4) Sex selective abortions

37. Research must be done on

(1) People who are poor so that the rich can benefit

(2) Mentally challenged persons so that the normal people can benefit

(3) Rich and poor people so that all can benefit

(4) Rich so that the poor can benefit

38. In the post study period, one of the following is true :

(1) Sponsor must make arrangements for free drugs to the participants that they received during the study, throughout their life.

(2) Sponsor must make arrangements for the access of the drug to the subjects till the drug is available in the market.

(3) Sponsor must not take any responsibility for post trial access to the drugs found beneficial in the study.

(4) Sponsor may take a decision on post trial access to the medicine after completion of the study.

39. Standard of care for a clinical trial is the

(1) Best available care known to the scientific community

(2) Best available care in the local institution

(3) Best available care that the researcher can give

(4) Best available care that is available nationally

40. Misconduct in research means all these *except*

(1) Reporting data on adverse effect

(2) Fabrication

(3) Falsification

(4) Plagiarism

41. For new drug substances discovered in India

(1) Phase-1 clinical trial is not essential for marketing the drug

(2) Phase-1 and Phase-2 clinical trials are enough for marketing the drug

(3) Phase-1, Phase-2 and Phase-3 clinical trials are a must for marketing the drug

(4) Phase-1, Phase-2, Phase-3 and Phase-4 of the clinical trials are required before the drug can be marketed in India

42. Bioequivalence studies are necessary

(1) For all new drug substances and for new dosage forms administered for systemic absorption which are approved elsewhere in the world.

(2) Only for new drug substances forms administered for systemic absorption which are approved elsewhere in the world.

(3) Only for new dosage forms administered for systemic absorption which are approved elsewhere in the world.

(4) For all new drug substances and for new dosage forms administered for systemic absorption which are to be approved in our country.

43. Active Control Equivalence trial (ACE) is

(1) A non-inferiority trial

(2) A superiority trial

(3) A trial in which placebo can be used

(4) Not indicated

44. Efficacy in vaccine trials means

(1) Information of protective rate conferred on a given population.

(2) It measures the direct and indirect protection to a non-vaccinated person among the defined vaccinated population determined by the vaccine.

(3) It is the correlation between the strains present in the vaccine and that circulating in the area.

(4) Reduction in incidence of the disease after vaccination compared to the incidence that prevailed before vaccination.

45. Bridging studies in vaccine trials are done

(1) When there is a change in vaccine composition

(2) When the vaccine is suspected to be ineffective

(3) Comparing only the sera

(4) Only to show the immunogenicity of the new product

46. Post trial access to the vaccine should be given first

(1) To the family of the individual who participated in the study.

(2) To the community from which the participants were drawn.

(3) To all the persons who are at a high risk from the disease that the vaccine protects.

(4) To the person who can afford to pay for the vaccine.

47. The organisation that certifies and regulates low technology devices in India is

(1) The Drugs Controller General of India (DCGI)

(2) India Standards Institute (ISI)

(3) The Bureau of Indian Standards (BIS)

(4) The Federal Drug Administration (FDA) of the United States of America

48. Category I drug trials are conducted for the following class of AUS drugs :

(1) Substances that have never been in use before

(2) Has not ever been mentioned in ancient literature

(3) Clinically evaluated for a therapeutic effect not originally described in the texts of traditional systems

(4) The substance to be tested is already in use in Indian Systems of Medicine or has been described in their texts

49. In a drug trial conducted on Unani medicine by an allopathic doctor or institution

(1) It is necessary to have a Unani practitioner as a co-investigator

(2) A practitioner of an alternate system of medicine can be a co-investigator

(3) There is no need for a co-investigator

(4) The investigator can incorporate another allopathic doctor trained in Unani and is not registered

50. In an epidemiological study, the consent has to be obtained

(1) Only from the individual

(2) Only from the community

(3) Only from the family

(4) Only from the individual and the community