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MHS-016

00359

POST GRADUATE DIPLOMA IN BIOETHICS (PGDBE)

Term-End Examination

December, 2015

MHS-016 : RESEARCH ETHICS - I

Time : 2 hours *Maximum Marks : 70*

PART - A

Attempt **all** questions. Each carries **one** mark. Select the most appropriate **choices** from the given choices for each of the following questions and write on the answer sheet provided. **1x50=50**

1. Research involving human participants is based on four ethical principles :

(1) Autonomy, Beneficence, Justice, Non - maleficence

(2) Autonomy, Justice, Confidentiality, Beneficence

(3) Beneficence, Non - maleficence, Autonomy, Confidentiality

(4) None of the above

2. What should the Patient Information Sheet contain ?

(1) No loss of benefits on withdrawal

(2) Benefit sharing on the event of commercialization

(3) Contact details of chairman of Institutional Ethics Committee (IEC)

(4) All of the above

3. Drug trials involving an illiterate person should have :

(1) Thumb impression of the participant along with the thumb impression of a relative or legal custodian

(2) Thumb impression of the participant alone

(3) Signature of unrelated witness along with the thumb impression of the participant

(4) Such participants are not included in the study

4. An investigator conducting the study can :

(1) Continue with the same consent of participants who lose consciousness during the study

(2) Choose not to provide entitled benefits to participants who do not consent to the study

(3) Obtain verbal consent through audio/video if participant does not sign or give thumb impression

(4) None of the above

5. The research participant :

(1) Has right to avail entitled benefits if he/she withdraws from study

(2) Can avail free treatment for injuries related to research

(3) Cannot claim insurance coverage, if any

(4) Cannot avail free ancillary care for complaints other than the one being studied

6. In research ethics, professional judgement should be concerning which of the following ?

(1) Welfare of the patient

(2) Both the primary and secondary interest

(3) Academic and Financial benefits

(4) None of the above

7. Conflict of interest should be informed to :

(1) Research participants

(2) Scientific journals

(3) Institutional Ethics Committee (IEC)

(4) All of the above

8. Pregnant women who wish to terminate their pregnancy can participate in research, according to :

(1) ICMR guidelines, 2006

(2) MTP Act GOI, 1971

(3) Regulation and Prevention of Misuse Act, GOI, 1994

(4) No such act

9. When can the confidentiality of individual participants be disclosed ?
   (1) In a court of law or if there is a risk to public health
   (2) Institutional Ethics Committee
   (3) Both
   (4) Can never be disclosed under any circumstance

10. What is the compensation that is provided to the participants ?
   (1) Ancillary care
   (2) Free medication
   (3) Treatment for physical injury related to the study
   (4) (1) and (3)

11. How can a post - trial access benefit the community ?
   (1) Providing education and health centres
   (2) Improving living conditions
   (3) Maintaining good health practices
   (4) All of the above

12. While conducting international collaborative research, it is essential to address special concerns such as :
   (1) Scientific and ethical conduct of research
   (2) Involvement of community representatives through the study
   (3) Not divulge the magnitude and future risks due to participation in the study
   (4) (1) and (2)

13. ICMR updated its guidelines in the year :

(1) 2000

(2) 1998

(3) 2001

(4) 2005

14. What constitutes as misconduct in research ?

(1) Fragmentation of data and republishing several articles

(2) Giving honorary authorship

(3) Taking credit for other's work

(4) All of the above

15. Which is the latest Helsinki Declaration involving post - trial access and registration of clinical trials ?

(1) 6^{th} Declaration, 2008

(2) 5^{th} Declaration, 2007

(3) 8^{th} Declaration, 2010

(4) 10^{th} Declaration, 2012

16. General principles laid down by ICMR 2006 revision include :

(1) HIV/AIDS and Genetics

(2) STDs, HIV and Molecular Studies

(3) STDs and Genetics

(4) Cancer and Genetics

17. Which principle applies 'mutatis mutandis' which means 'change only what needs to be changed' ?

(1) Principle of voluntariness, Informed consent and Community agreement

(2) Principle of Essentiality

(3) Principle of precaution and Risk minimization

(4) All of the above

18. How many times were the ICMR guidelines revised after 1980 ?

(1) Twice - 2000 and 2006

(2) Thrice - 2000, 2006 and 2010

(3) Once - 2006

(4) Several times

19. Which ICMR principle states that research should be conducted in a fair, honest, impartial and transparent manner ?

(1) Principle of Compliance

(2) Principle of Accountability and Transparency

(3) Principle of Non - Exploitation

(4) Principle of Professional Competence

20. When did CIOMS release the 'Proposed International Ethical Guidelines for Biomedical Research involving Human Subjects' ?

(1) 1993

(2) 1991

(3) 1982

(4) 1990

21. Which organization revised its guidelines in 2002, focusing on ethics concerning different socio-cultural patterns to protect interests of research participants ?

(1) ICMR, CIOMS

(2) National Advisory Board on Bioethics

(3) CIOMS, Nuffield Council of Bioethics

(4) All of the above

22. Right after Nuremberg code formulation, which international declaration was made in 1948, pertaining to essentiality of voluntariness in informed consent ?

(1) Universal Declaration of Human Rights

(2) UNESCO

(3) Helsinki Declaration

(4) International Convenant on Civil and Political Rights

23. Which of the following obstructs the right of a participant to decline from the study ?

(1) Unrealistic promises of benefits

(2) Deception

(3) Deprivation of essential information

(4) All of the above

24. The Belmont report states that :

(1) Subjects should be given the opportunity to choose what shall or shall not happen to them

(2) Subjects should be given the opportunity to choose only if they are not economically disadvantaged

(3) Subjects should be given the opportunity to choose only what shall not happen to them

(4) Subjects have no right of choice

25. Legally Authorized/Acceptable representative broadly includes :

(1) Village Head, School teacher, Warden

(2) Health care providers, Partners, NGOs

(3) Unrelated witness, Research members

(4) Any adult person

26. Which article of UN convention states that a child has the right to express his/her view freely in all matters affecting the child ?

(1) Article 20

(2) Article 10

(3) Article 12

(4) Article 14

27. Who is a mature minor ?

(1) Around 16 years of age

(2) Can reject or choose healthcare treatment

(3) Take independent decisions

(4) All of the above

28. Proxy consent can be obtained from a guardian of :

(1) Prisoners, terminally ill patients, children

(2) Pregnant and lactating women, geriatric population

(3) None of the above

(4) All of the above

29. The advantages of informed consent include :

(1) Protection of rights of participant

(2) Privacy and Confidentiality

(3) Protection of research group and Institution

(4) (1) and (2)

30. When is the investigator not allowed to disclose all the information to the participant ?

(1) When a detailed justification is provided and peer review and ethical approval is obtained

(2) When a participant might refuse to give consent if all the information is revealed

(3) Investigator cannot withhold any information from participant

(4) None of the above

31. Which of the following statements is **true** ?

(1) Gatekeeper permission should not be substituted for consent from participants

(2) Informed consent is not a one time event

(3) Informed consent not only explains risks and dangers but also recognizes uncertainities

(4) All of the above

32. What are the responsibilities of Institutional Ethics Committee ?

(1) Protect rights, dignity and well-being of participants

(2) Ensure maximum benefit for scientific/ research community

(3) Ensure ethical values and scientific standards are upheld

(4) All of the above

33. When was the revised schedule Y of Drugs and Cosmetics Act, 1940, amended ?

(1) 2003

(2) 2005

(3) 2001

(4) 2006

34. What is the role of subject experts in an IEC ?

(1) Ensure maintenance of standards and ethical values

(2) Offer opinions/views which are documented

(3) Take decisions on approval of research study

(4) Have no role

35. An IEC member is qualified only after training in :

(1) Universal ethical guidelines and laws

(2) Genetics and HIV/AIDS

(3) Biotechnology

(4) None of the above

36. Ethical review of a research proposal involves :

(1) Evaluating possible risks to participants

(2) Assessing expected benefits

(3) Ensure documentation for confidentiality and justice of participants

(4) All of the above

37. Who decides that a proposal can be exempted from review ?

(1) Investigator

(2) IEC

(3) ICMR

(4) Legal expert

38. What is the full form of DSMB ?

(1) Data Safety Monitoring Board

(2) Documentation Safety Monitoring Board

(3) Digital Services and Monitoring Board

(4) None of the above

39. Prospective collection of biological specimens for research purposes should be by :

(1) Invasive means

(2) Co - ercive means

(3) Non - invasine means

(4) Disfiguring means

40. How many items does the ICMR guidelines give which are to be included in the research study application ?

(1) 20

(2) 21

(3) 19

(4) 22

41. What is the full form of SIDCER ?

(1) Strategic Initiative for Development of Committees for Ethical Review

(2) Society for International Development Code of Ethics and Research

(3) Social Institute for Development of Committees for Ethical Reasons

(4) None of the above

42. For how long can an IEC decision be kept pending ?

(1) 1 year

(2) No time limit

(3) Not more than 3 - 6 months

(4) Less than a month

43. Which type of review involves re-examination of a proposal already examined by IEC, which should be brought to IEC's attention ?

(1) Continuing review

(2) Interim review

(3) Periodic review

(4) Partial review

44. What is the full form of AAHRPP ?

(1) Academic Alliance for Healthcare providers Research Proposal Program

(2) Association for Accreditation of Human Research Participant Protection

(3) Association for Accreditation of Human Research Protection Program

(4) None of the above

45. The composition of an IEC should be :

(1) Multi - disciplinary

(2) Multi - sectoral

(3) (1) and (2)

(4) None of the above

46. IEC members should be up to date with all National and International development in Ethics through :

(1) Training in ethics related to human protection

(2) Orientation causes on all Life Science Subjects

(3) Good clinical practice for clinical trial review

(4) None of the above

47. Any IEC member with conflict of interest in a project should submit conflict of interest declaration in writing to :
(1) Secretary
(2) Legal Expert
(3) Chairperson
(4) Subject expert

48. Kasturba Hospital, Manipal is accredited by :
(1) SIDCER
(2) AAHRPP
(3) Both
(4) Neither

49. A disaster includes :
(1) Sudden occurrence of calamities event at any time
(2) Creating vulnerable groups
(3) Disruption of functioning of society
(4) All of the above

50. From the following, which of the methods are used for monitoring by IEC :
(a) Actual site visits
(b) Periodic status reports
(c) Sponsor monitoring reports
(d) Review of SOP reports
(e) ICMR recommendations
(1) (a), (b) and (c)
(2) (a), (b) and (d)
(3) (a), (b) and (e)
(4) (b), (c) and (e)

PART - B

Write short notes on the following. Each carries **five** marks. **4x5=20**

51. Records to be maintained by IEC and their methods of monitoring.

52. Need and concerns for international collaborations.

53. General principles laid out by ICMR for biomedical research on human participants.

54. Points for consideration IEC for decision making regarding a proposal.
