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MHS-016

POST GRADUATE DIPLOMA IN BIOETHICS (PGDBE)

Term-End Examination

June, 2016

MHS-016 : RESEARCH ETHICS-I

Time : 2 hours *Maximum Marks : 70*

PART - A

Attempt **all** questions. Each question 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. When a participant withdraws from the study due to medical reasons he/she receives :

(1) Benefit for full participation

(2) Amount equal to the amount of participation

(3) No compensation

(4) None of the above

2. Conflict of interest is :

(1) A disagreement between the investigators conducting the study

(2) Business interest with a company developing the product

(3) Both of the above

(4) None of the above

3. Non-Vulnerable study group includes :

(1) economically disadvantaged people

(2) pregnant mothers

(3) geriatric population

(4) lactating mothers

4. Helsinki declaration stated about post trial access in the following years :
(1) 2000, 2004, 2008
(2) 2001, 2005, 2007
(3) 2000, 2008, 2006
(4) None of the above

5. Informed consent refers to :
(1) voluntary but uninformed decision making
(2) principle of autonomy
(3) voluntary decision made by competent individuals after understanding the information
(4) none of the above

6. Re-consent is obtained from participants when :
(1) study extensions are planned
(2) change in the method of treatment
(3) both of the above
(4) none of the above

7. Conflict of interest should be informed to :
(1) Journals
(2) Research participants
(3) IEC
(4) All of the above

8. In Research ethics, professional judgement should be concerning which of the following ?
(1) Welfare of the patient
(2) Academic and financial benefits
(3) Primary and secondary interest
(4) None of the above

9. Latest Helsinki declaration is :
(1) 6^{th} declaration - 2008
(2) 5^{th} declaration - 2007
(3) 8^{th} declaration - 2010
(4) 10^{th} declaration - 2012

10. ICMR updated its guidelines in the year :
(1) 2000 (2) 1998 (3) 2001 (4) 2005

11. The number of principles laid down by ICMR for ethical guidelines for "Biomedical research with human participants" is :
(1) 16 (2) 14 (3) 12 (4) 10

12. Experimental research should be conducted in a :
(1) Fair, honest, partial and transparent manner
(2) Biased, honest, impartial and transparent manner
(3) Fair, honest, impartial and transparent manner
(4) Biased, dishonest, partial and selective manner

13. Along with investigators and sponsors who should own responsibility of a study about all issues concerning it :
(1) IEC and institution
(2) Participants
(3) Institution and participants
(4) None of the above

14. When was Nuremberg code formulated ?
(1) 1948
(2) 1943
(3) 1957
(4) 1947

15. Participants rights and dignity is protected by :
(1) Distributive justice
(2) Confidentiality
(3) Informed consent
(4) All of the above

16. The four ethical principles for research involving human participants are :
(1) Autonomy, Beneficence, Justice, Non-maleficence
(2) Confidentiality, Beneficence, Justice and Autonomy
(3) Non-maleficence, Anonymity, Justice and Confidentiality
(4) None of the above

17. ICMR 2006 revisions include :
(1) HIV/AIDS and genetics
(2) Molecular studies, HIV and STD
(3) Cancer and genetics
(4) STDs and genetics

18. Misconduct in Research is :
(1) Plagiarism
(2) Taking credit for other's work
(3) Fragmentation of data and republishing it as several articles
(4) All of the above

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

20. The principle which states that research should be conducted in a "fair, honest, impartial and transparent manner" is :
(1) Principle of Accountability and Transparency
(2) Non-exploitation
(3) Professional competence
(4) Compliance

21. Declaration made in 1948 pertaining to essentiality of volunteers in informed consent :
(1) UNESCO
(2) Helsinki declaration
(3) Universal declaration of Human Research
(4) International convenant on civil and political rights

22. CIOMS released the proposed International ethical guidelines for Biomedical Research involving Human subjects in the year :
(1) 1993 (2) 1991 (3) 1982 (4) 1990

23. Mature minor is a person :
(1) Around 16 years of age
(2) Takes independent decisions
(3) Can reject or choose health care treatment
(4) All of the above

24. A child has the right to express his/her way freely in all matters affecting the child. Which article in UN convention states this ?
(1) Article 12 (2) Article 22 (3) Article 14 (4) Article 11

25. Proxy consent from guardian can be obtained :
(1) Prisoners, Terminally ill
(2) Pregnant women, Nursing women, geriatric population
(3) All of the above
(4) None of the above

26. The advantages of informed consent include :
(1) Protection of Research group and institution
(2) Privacy and confidentiality
(3) Protection of right of participant
(4) (2) and (3)

27. Who decides that proposal can be exempted from review ?
(1) IEC (2) ICMR
(3) Legal expert (4) Investigator

28. Collection of Biological specimens for Research purpose for prospective study should be by :
(1) Invasive means (2) Co-ercive means
(3) Disfiguring means (4) Non-invasive means

29. AAHRPP stands for :
(1) Acadamic Alliance for Healthcare Providers and Research Protection Program
(2) Association of Accreditation of Human Research Protection Program
(3) Accreditation Association of Human Research Participation Program
(4) None of the above

30. Undue compensation is :
(1) Free Medication
(2) Insurance for unrelated condition
(3) Free Transport for any investigations unrelated to the study
(4) All of the above

31. CIOMS stands for :
(1) Council for International Organisations of Medical Science
(2) Council for International Organisation of Molecular Science
(3) Council of Indian Organisations of Medical Science
(4) None of the above

32. An example for unethical practice is :
(1) Unethical to coerce children to participate in research without parental approval
(2) You cannot participate in a study as you are a student of a university
(3) If few results in a research are different you can delete the different ones
(4) It is okay to conduct research of students under the age of 18 years but first obtain parental approval

33. Which of the following is unethical when conducting research with humans ?
(1) Getting consent from participant
(2) Telling participants that they must continue till the study has been completed
(3) Maintaining anonymity of the participants
(4) Telling them that they can withdraw at any time

34. The theory of _____ would state that if an act produces more good than bad that act is ethically correct.
(1) Justice (2) Autonomy
(3) Beneficence (4) Rightfulness

35. Helsinki declaration is a document of :
(1) American Medical Association (2) World Medical Association
(3) World Health Organisation (4) Helsinki Medical Association

36. IEC is an acronym for :
(1) Institutional Ethics Committee
(2) Informational and Educational Committee
(3) Internal Ethics Committee
(4) All of the above

37. Helsinki declaration has been revised :
(1) 5 (2) 7 (3) 10 (4) 8

38. SIDCER stands for :
(1) Society of International Development Code for Ethics and Research
(2) Strategic Initiative for Developing Capacity in Ethical Review
(3) Social Initiative for Development of Codes in Ethical Research
(4) None of the above

39. Composition of IEC should be :
(1) Multi-disciplinary (2) Multi-sectoral
(3) Both of the above (4) None of the above

40. A review which involves re-examination of a proposal already examined by IEC which should be brought to IEC's attention ?
(1) Interim review (2) Periodical review
(3) Partial review (4) Continuing review

41. IEC decisions can be kept pending for :
(1) 12 months (2) < 1 month
(3) 3 - 6 months (4) No time limit

42. DSMB stands for :
(1) Data Safety Monitoring Board
(2) Documentation Safety Monitoring Board
(3) Digital Services and Monitoring Board
(4) None of the above

43. IEC members should be upto date with all National and International developments in Ethics :
(1) Training in Ethics related to human protection
(2) Orientation Causes on all life science
(3) Good Clinical practice for clinical trial
(4) All of the above

44. Principal investigator should :

(1) Observant of right and welfare of the participants

(2) Comply with scientific, legal and ethical requirements of study

(3) Be competent in Biomedical research methodology

(4) All of the above

45. Any study testing a new drug in children should be conducted after :

(1) Animal trials (2) Phase I trials in humans

(3) Phase II trials in animals (4) Phase III in humans

46. A legally acceptable/authorized representative can be :

(1) Relative/Caretaker (2) Research member

(3) Unrelated witness (4) None of the above

47. Components of Informed consent :

(1) Information, Comprehension, Voluntariness

(2) Comprehension, Non-exploitation, Compensation

(3) Compensation, Information, Autonomy

(4) None of the above

48. When is research children are justified as study subject ?

(1) With minimal risk

(2) Direct benefit to the child in case of greater risk

(3) Research devised only for children

(4) All of the above

49. Emancipated Minor refers to :

(1) < 14 years (2) Working teenager

(3) Married (4) (2) and (3)

50. Proposals are categorised into :

(1) Exemption from review, expedited, full review

(2) High risk, full review, expedited

(3) Partial, high risk, full review

(4) Expedited, partial, high risk

PART - B

Write short notes on **any four** of the following in **200** to **300** words. Each question carries 5 marks. **5x4=20**

(a) Informal Consent

(b) Third Party Reproduction

(c) Expedited Review

(d) IEC and its Role in Research

(e) Ethical Principles in Human Participant Research

(f) Helsinki Declaration