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MHS-016

00304

POST GRADUATE DIPLOMA IN BIOETHICS (PGDBE)

Term-End Examination

June, 2015

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 choice from the given choices for each of the following questions and write it on the answer-sheet provided.* *50×1=50*

1. The responsibilities of a principal investigator are

(1) Observance of rights and welfare of research participants

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

(3) Competency in biomedical research methodology

(4) All of the above

2. Informed consent refers to

(1) Principle of autonomy

(2) Voluntary but uninformed decision-making

(3) Permission to participate in research

(4) Voluntary decision made by competent individuals after understanding the information

3. Reconsent is obtained from participants when

(1) Study extensions are planned

(2) Change in the method of treatment

(3) (1) and (2)

(4) None of the above

4. When can the Institutional Ethics Committee (IEC) choose to waiver the consent ?
   (1) For leftover samples after clinical investigations
   (2) If participant privacy may be breached
   (3) In situations with no available surrogate consent
   (4) All of the above

5. What does the participant receive when he/she withdraws from the study ?
   (1) Benefit for full participation
   (2) Amount equal to the amount of participation
   (3) No compensation
   (4) None of the above

6. What is considered as undue compensation ?
   (1) Free medication
   (2) Providing insurance for unrelated conditions
   (3) Free transportation for investigations not included in the study
   (4) All of the above

7. What is conflict of interest ?
   (1) Disagreement between investigators conducting the study
   (2) Business interest with a company developing the product
   (3) (1) and (2)
   (4) None of the above

8. Any study, testing a new drug in children should be conducted after
   (1) Animal trials
   (2) Phase II trials in adults
   (3) Phase III trials in adults
   (4) Only simulation is allowed

9. In which years did the Helsinki Declaration state about post-trial access ?
   (1) 2000, 2004, 2008
   (2) 2001, 2003, 2009
   (3) 2000, 2005, 2008
   (4) 2001, 2004, 2008

10. Vulnerable study groups include

(1) Economically disadvantaged people

(2) Lactating mothers

(3) Pregnant women

(4) Geriatric population

11. What can the investigator inform the media about ?

(1) Preliminary findings

(2) Selective information that might bring about fear in the public

(3) Assure clinical applications for human use

(4) None of the above

12. Experimental research should be conducted in a

(1) Fair, honest, partial and transparent manner

(2) Biased, honest, partial and transparent manner

(3) Fair, honest, partial and selective manner

(4) Fair, honest, impartial and transparent manner

13. What is the full form of CIOMS ?

(1) Council for Indian Organization of Molecular Science

(2) Council for International Organization of Medical Science

(3) Committee for International Offenses in Medical Science

(4) None of the above

14. How many principles were laid down by ICMR in 2006 for 'Ethical Guidelines for Biomedical Research on Human Participants' ?

(1) 12

(2) 10

(3) 14

(4) 8

15. A legally acceptable/authorized representative (LAR) can be

(1) Relative or caretaker

(2) Investigator or research member

(3) Unrelated witness

(4) Any person of legal age

16. The Principle of Voluntariness, Informed Consent and Community Agreement should apply 'mutatis mutandis' which means

(1) Change only what needs to be changed

(2) Do not make any changes

(3) Change what can be changed

(4) None of the above

17. The ICMR code has certain general and specific principles which specifically pertain to

(1) Epidemiology, Clinical trials, Gynaecology and Transplantation

(2) Interventional clinical trials, Epidemiology, Genetics, Transplantation and ART

(3) Transplantation, ART, Genetics, Clinical trials and HIV/AIDS

(4) None of the above

18. What is the opinion of Supreme Court in India about confidentiality regarding HIV/AIDS ?

(1) Individual with HIV should tell his/her partner

(2) Individual's wish whether or not to disclose HIV status to his/her partner

(3) No regulations related to confidentiality regarding HIV/AIDS

(4) None of the above

19. Who should undertake the professional and moral responsibility of the study ?

(1) Investigators, Institutional Ethics Committee (IEC), Participants

(2) Investigators, Sponsors, Institution, IEC

(3) Investigators, Participants and Sponsors

(4) Investigator alone

20. Which ICMR general principle states that all research procedures and data should be duly protected and preserved ?

(1) Principle of Institutional Arrangements

(2) Principle of Professional Competence

(3) Principle of Totality of Responsibility

(4) Principle of Essentiality

21. When was the Nuremberg code formulated ?

(1) 1948

(2) 1942

(3) 1947

(4) 1945

22. Which ICMR principle highlights autonomy ?

(1) Principle of Voluntariness, Informed Consent and Community Agreement

(2) Principle of Maximization of Public Interest and Distributive Justice

(3) Principle of Non-Exploitation

(4) None of the above

23. The rights and dignity of the participant can be protected by

(1) Informed Consent

(2) Confidentiality

(3) Distributive Justice

(4) All of the above

24. What are the four basic ethical decrees that form the pillars of research involving humans ?

(1) Autonomy, beneficence, non-maleficence, justice

(2) Autonomy, confidentiality, justice, non-exploitation

(3) Beneficence, non-maleficence, confidentiality, responsibility

(4) All of the above

25. What are the three components of Informed consent ?

(1) Information, comprehension, voluntariness

(2) Comprehension, compensation, confidentiality

(3) Comprehension, voluntariness, non-exploitation

(4) Autonomy, confidentiality, comprehension

26. When is research on children justified ?

(1) Minimal risk

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

(3) Research devised only for children

(4) All of the above

27. Which information needs to be given to the participant before obtaining Informed consent ?

(1) Nature of the procedure, associated risks and benefits, contact details of the research team

(2) Nature of the procedure, benefits, excessive reimbursement

(3) Monetary compensation, free transportation and medication

(4) Participant does not have to be informed about any details

28. Gatekeeper's permission involves obtaining permission from

(1) Head of the family of the participant

(2) Panchayat head, school teacher, warden

(3) Drug Registration Authority

(4) Institutional Ethics Committee (IEC)

29. From children between 2 – 7 years of age

(1) Assent to be obtained from children and consent from parent or LAR (legally acceptable/authorized representative)

(2) Consent from parent/LAR

(3) Consent required from children

(4) Assent/consent of parents/LAR and unrelated witness

30. Who is an emancipated minor ?

(1) < 14 years of age

(2) Working teenager

(3) Legally married

(4) (2) and (3)

31. How many components constitute the Informed consent document ?

(1) 4

(2) 2

(3) 3

(4) 6

32. When should Informed consent be obtained preferably ?

(1) Day of the trial

(2) One or more days before the trial

(3) At least one month in advance

(4) 6 months in advance

33. Which of the following statements are true ?

(1) Conceptualization of consent form is based on Western thinking that all adults are capable of independent decisions.

(2) Participants should be debriefed after completion of the research.

(3) Both of the above

(4) None of the above

34. Independence and competence are the hallmarks of which scientific body ?

(1) ICMR

(2) Institutional Ethics Committee

(3) Scientific Review Committee

(4) Drugs Registration Authority

35. Which of the following constitutes an IEC ?

(1) Quorum of 8 – 12 members

(2) Research team

(3) Subject experts

(4) (1) and (3)

36. Which of the following is/are included in the terms of appointment of IEC members ?

(1) Policy for removal

(2) Replacement

(3) Duration of term

(4) All of the above

37. IEC members are trained through

(1) Relevant orientation courses

(2) Clinical practice of drug trial review

(3) Human protection ethics training

(4) All of the above

38. Which three reviews are followed for proposals ?

(1) Exemption from review, partial review, expedited review

(2) Expedited review, high risk review, full review

(3) Exemption from review, expedited review, full review

(4) Exemption from review, high risk review, partial review

39. Which of the following does the study protocol include in the application to IEC ?

(1) Signatures and details of research participants

(2) CVs of investigators which include qualification and experience

(3) Inclusion and exclusion criteria for entry of participants

(4) (2) and (3)

40. In an International collaborative study, what is the requirement for exchange of biological material ?

(1) Memorandum of understanding between collaborative partners

(2) Details of funding agency

(3) Review of HMSC and DCGI

(4) All of the above

41. If an IEC member has any conflict of interest in the project he/she should withdraw from IEC

(1) While the project is being proposed

(2) At the completion of the project

(3) While the project is being discussed

(4) At any time during the project

42. How frequently should the ongoing projects be reviewed ?

(1) Regular intervals of 1 – 3 months

(2) Regular intervals of 6 months – 1 year

(3) Once in 2 years

(4) No need for review upon initial approval

43. A proposal was submitted to IEC on November 1st, 2012. Ideally, by which month should it have been reviewed ?

(1) August 2013

(2) November 2013

(3) May 2013

(4) July 2013

44. Tata Memorial Hospital is accredited by

(1) SIDCER

(2) AAHRPP

(3) Both of the above

(4) None of the above

45. Which area of research does ***not*** require special consideration by IEC ?

(1) Children

(2) Pregnant and nursing women

(3) International collaborative research

(4) Geriatric population

46. According to ICMR guidelines, for how long should IEC records be maintained after completion of study ?

(1) Minimum of 3 years

(2) Maximum of 3 years

(3) Minimum of 3 months

(4) Maximum of 3 months

47. What is the full form of SOP ?

(1) Standard Operating Programme

(2) Scientific Organizing Proposal

(3) Standard Operating Procedures

(4) Systemic Organizing Protocol

48. Which among the following is ***not*** necessary for an IEC to function smoothly and efficiently ?

(1) Full-time secretariat

(2) Record-keeping space

(3) Members to be compensated for their time

(4) Fund allocation by all institutions

49. The minimal risk proposals exempted from review include

(1) Instructional techniques

(2) Interview procedures

(3) Behavioural studies

(4) All of the above

50. When does an expedited review happen ?

(1) Minimal risk studies

(2) In emergency situations

(3) Only for international proposals

(4) None of the above

PART B

Write short notes (in 200 – 300 words) on each of the following questions. Each question carries five (5) marks. *4×5=20*

51. ICMR guidelines for project proposal application requirements

52. Contents of Informed consent form and the details involved in its development

53. Participation of children, pregnant women and lactating mothers in research

54. Institutional Ethics Committee and its role in scientific research