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MHS-016

POST GRADUATE DIPLOMA IN BIOETHICS

Term-End Examination

00064

December, 2014

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.* *50×1=50*

1. Voluntary informed consent can be waived when

(1) the participant and the researcher do not come into contact

(2) it is necessitated in emergency situations

(3) it is impractical to conduct an important research

(4) All of the above

2. The over-riding principle governing ethical research behaviour is

(1) To protect research participants and their communities from harm

(2) To avoid dealing with sensitive topics

(3) To obtain an informed consent from the participants

(4) To preserve the anonymity of the research participants

3. The three pillars of Bioethics (principles) are

(1) Beneficence /Non-maleficence, Autonomy, Privacy

(2) Beneficence /Non-maleficence, Respect for individuals, Justice

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

(4) Autonomy, Justice and Privacy / Confidentiality

4. Which of the following is an example of unethical practices ?

(1) As a student of a university, you are not required to participate in any study

(2) If some of the results in a research are different from the others, it is okay to delete the different ones

(3) It is unethical to coerce children to participate in research without parental approval

(4) It is okay to conduct research on students under the age of 18, but you must first gain parental approval

5. If you collect data from a patient who had not been asked to give consent, which of the following principles would you have broken ?

(1) Respect for individuals and human rights

(2) Beneficence and autonomy

(3) Non-maleficence and autonomy

(4) Non-maleficence and confidentiality

6. Which of the following is not an ethical guidline for conducting research with humans ?

(1) Getting consent of the participant

(2) Telling participants that they must continue till the study has been completed

(3) Keeping participant's identity anonymous

(4) Telling participants they are free to withdraw at any time

7. Historically speaking, ethical review of research came about because

(1) People found that it would generate job for ethicists

(2) Of serious failings of some researchers to ensure that trial participants are not exploited or harmed during the trial

(3) Researchers found that without ethical review they would have problems publishing their findings

(4) Legislators deemed it necessary to force ethical review process upon the researchers

8. The theory of _____ would state that if an act produces more good than bad, the act is ethically correct.

(1) Justice

(2) Autonomy

(3) Beneficence

(4) Rightfulness

9. The ICMR Ethics guidelines describe _____ number of general ethical principles.

(1) 10

(2) 11

(3) 12

(4) 13

10. The current version of the ICMR Ethics guidelines is

(1) I Version

(2) I Revision

(3) II Revision

(4) III Revision

11. The Declaration of Helsinki is a document of

(1) The American Medical Association

(2) The Helsinki Health Institution

(3) The World Medical Association

(4) The World Health Organisation

12. The Helsinki Declaration is a document adopted during

(1) 1964, after the 18th WMA General Assembly

(2) 2008, after 18 amendments

(3) Both (1) and (2)

(4) None of the above

13. The current version of Helsinki Declaration states that the control arm participants should generally receive
(1) The "best current" treatment
(2) The "best current proven" treatment
(3) The "best locally available" treatment
(4) "No Treatment"

14. The consenting process happens
(1) Before the start of the trial process
(2) After the completion of the screening process
(3) Before end of the trial process
(4) Throughout the trial process

15. Which of the following is not appropriate to include in a consent form ?
(1) Information about how the research data would be used
(2) The names and contact details of all people who are participating in the project
(3) The names and contact details of the investigator
(4) The aim and methodology of the project

16. Which of the following is correct if a participant wishes to withdraw from a study ?
(1) Participation is voluntary and they can withdraw at any time
(2) They must continue to participate as they have signed the consent form
(3) Withdrawal from the study has to occur through the Ethics Committee
(4) They may be able to withdraw if they negotiate with the research team

17. One important requirement of the consent is that the participants have been
(1) Told they are selected as they meet the criteria of inclusion
(2) Told that they need to read the study proposal
(3) Informed of the risks and benefits of the study
(4) Informed the study has been approved by the Ethics Committee

18. Assume you are a research participant and are provided with the information sheet. Which of the following statements best includes the information you would expect to see in it ?
(1) A brief summary of literature review, focus of the research and how it will affect you
(2) What the research is about, benefits of the study and how your privacy will be respected
(3) A brief summary of the literature review, how findings will be disseminated and its impact
(4) What the research is about, benefits and risks of the research and how privacy and confidentiality of data will be maintained

19. Waiver of consent can be done for all except
(1) Minimal risk studies
(2) Outbreak investigations
(3) Studies on anonymised biologicals
(4) Life threatening emergency situations

20. Informed consent refers to
(1) Principle of autonomy
(2) Voluntary but uninformed decision-making
(3) Voluntary decision making by competent individual after understanding the information
(4) Permission to participate in research

21. When is assent mandatory in procuring informed consent ?
(1) When the participant is a minor
(2) When the participant is unconscious
(3) When the participant is a mature minor capable of making decisions
(4) When the participant is mentally unstable

22. Can the requirement for informed consent be waived ?
(1) Yes, with the consent of the participant
(2) Yes, at the discretion of the investigator
(3) No, unless a designated Ethics Committee approves
(4) Never

23. Who gives consent in cases of minors who have no parents or guardians ?
(1) Consent waived, as it is unnecessary
(2) Nobody
(3) A social worker
(4) Legal guardians

24. The conflict of interest can be avoided by
(1) The investigators should declare conflicts of interest the application submitted to IEC for review
(2) Institutions and IECs need self-regulatory processes to monitor, prevent and resolve such conflicts of interest
(3) The IEC can determine the conditions for management of such conflicts in its SOP manual
(4) All of the above

25. The following are forms of compensation payable to participants except
(1) Participation
(2) Physical injury
(3) Ancillary care to participants
(4) Ancillary care to participant's spouse

26. Which is true for compensation in the event of withdrawal from the study ?
(1) When a participant withdraws, he/she is paid the amount prorated to the amount of participation
(2) When participant is withdrawn for medical reasons related to the study
(3) Both (1) and (2)
(4) None of the above

27. The age of assent as per ICMR Ethics Guidelines 2006 is _____ from mature minors.
(1) 6 years
(2) 7 years
(3) 8 years
(4) 9 years

28. Vulnerable population in research includes
(1) Children, pregnant women, prisoners
(2) Students, employees, defence personnel
(3) Both (1) and (2)
(4) None of the above

29. Research involving vulnerable population must always
(1) Secure informed consent from participants
(2) Leave participants better off than they were before
(3) Follow local standards of care
(4) Address questions that cannot be answered by conducting research on other non-vulnerable population

30. Which of the following is not an ethical practice ?
(1) Obtaining consent to participate in research prior to the project starting
(2) Sharing data with other organisations who have a legitimate interest in your research
(3) Keeping records under lock and key
(4) Using pseudonyms to protect participant's identity

31. Which of the following is not a suggested method to ensure confidentiality of research data ?

(1) Share the names of the participants with other researchers

(2) Names should never be used in publications

(3) Assure that the data collected will be kept confidential

(4) Data be collected from anonymous participants

32. Researchers can ensure confidentiality by

(1) Using identification numbers for participants

(2) Not discussing data of participants with others

(3) Keeping the identifying information separate from the data

(4) All of the above

33. Ideally, the research participant's identity is not known to the researcher. This is called

(1) Privacy

(2) Confidentiality

(3) Anonymity

(4) All of the above

34. Undue compensation would include the following :

(1) Provision for insurance for unrelated conditions

(2) Free medication which is generally not available

(3) Academic credits

(4) All of the above

35. Who among the following are susceptible to conflict of interest ?

(1) Researchers

(2) Authors

(3) Editors

(4) All of the above

36. If the researcher finds he/she is having conflict of interest, he/she should not do which of the following ?

(1) Keep the information to himself/herself so as not to frighten the participants

(2) Disclose the information to participants

(3) Disclose the information to Ethics Committee

(4) Avoid such conflicts in the future

37. The following are the ways to avoid conflict of interest :

(1) Declaring / disclosing to participants and Ethics Committee

(2) Institutions and Ethics Committees need self regulatory process to monitor, prevent and resolve conflicts

(3) Both (1) and (2)

(4) None of the above

38. During the conduct of a large drug trial, preliminary analysis shows that there are three times as many participants in the experiment group who experienced severe nausea and vomiting as compared to the control group. Two of the participants were severe enough warranting hospitalisation. This is despite the fact that the preliminary analysis shows that there may be a moderate benefit with the drug. What should be done ?

(1) The trial should be stopped immediately

(2) The adverse events should be reported to Data Safety Monitoring Board and the serious adverse events must be reported to the Ethics Committee

(3) Complete all trial as it is

(4) The adverse events are not serious enough to report

39. The Data and Safety Monitoring Board will report its findings of the study to

(1) Sponsor

(2) Investigator

(3) Ethics Committee

(4) All of the above

40. The Chairman of an Ethics Committee can be anyone except

(1) Religious head

(2) Lawyer

(3) Ethicist

(4) Head of the Institution

41. An Ethics Committee needs to have written Standard Operating Procedures for

(1) Addressing the purpose, scope and procedures

(2) Achieving uniformity in procedures

(3) Both (1) and (2)

(4) None of the above

42. A person responsible for the execution of the protocol is

(1) Sponsor

(2) Investigator

(3) Monitor

(4) Ethics Committee

43. IEC is an Acronym for

(1) Informational Ethics Committee

(2) International Ethics Committee

(3) Internal Ethics Committee

(4) All of the above

44. A researcher must seek approval from an Ethics Committee if they intend to

(1) Collect data by interview (or) survey

(2) Collect data by observing people

(3) Perform an intervention / treatment

(4) All of the above

45. Which of the following is not an underlying goal of Ethics Committee ?

(1) To promote the rights and welfare of participants

(2) To promote shared decision making between participants and researchers

(3) To promote fair policies and procedures that maximise the likelihood of achieving good, participant centred outcomes

(4) To improve the public perception of health care professionals and institutions

46. Scientific misconduct refers to

(1) A researcher accidentally misquoting data

(2) Fabrication, falsification, plagiarism or some other deviation from what is commonly accepted by the scientific community

(3) Failure to achieve expected results

(4) Accidental failure to cite a source

47. The ICMR Ethics Guidelines 2006 recommends archiving of study related files for

(1) 3 years from the start of the study

(2) 3 years from the completion of the study

(3) 15 years from the start of the study

(4) 15 years from the completion of the study

48. The following are the types of records to be archived and maintained except

(1) SOP of EC functioning

(2) Agenda and minutes of the Ethics Committee Meetings

(3) Laboratory working manual and SOP

(4) Study files with all PI submissions, decisions and communications

49. The following are responsible for providing post-trial access to the study participants *except*

(1) Sponsor

(2) Monitor

(3) Investigator

(4) Ethics Committee

50. Providing post-trial access can be done by

(1) a-priori agreement

(2) Mentioning it in the study protocol

(3) Both (1) and (2)

(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. Basic ethical principles in human participant research

52. Components of participant information sheet

53. Vulnerable population in research

54. Expedited review