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MHS-016

POST GRADUATE DIPLOMA IN BIOETHICS (PGDBE)

Term-End Examination

00347

December, 2016

MHS-016 : RESEARCH ETHICS – I

Time : 2 hours *Maximum Marks : 70*

PART A

*Attempt **all** questions. Each question carries **one** (1) mark. Select the most appropriate choice from the given choices for each of the following questions. Write your answers on the Answer Sheet provided to you.* *50×1=50*

1. Expedited review happens in
   (1) High risk studies
   (2) Minimal risk studies
   (3) Emergency situations
   (4) All of the above

2. The minimal risk proposals exempted from review include
   (1) Instructional techniques
   (2) Interview procedures
   (3) Behavioural studies
   (4) All of the above

3. According to the ICMR, how long should IEC records be maintained after the completion of the study ?
   (1) Minimum 3 years
   (2) Maximum 3 years
   (3) Minimum 3 months
   (4) Maximum 6 months

4. SOP stands for

(1) System Operation Protocol

(2) Standard Operating Protocol

(3) Scientific Operational Protocol

(4) System Operating Programme

5. Which of the following is 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 under IEC

6. Kasturba Manipal Hospital is accredited for research and clinical trial by

(1) AAHRPP

(2) SIDCER

(3) Both (1) and (2)

(4) Neither of the above

7. The areas of research which do ***not*** require special considerations by IEC are

(1) Children

(2) Pregnant and nursing women

(3) International Collaborative Research

(4) Geriatric Population/Senior citizens

8. A proposal was submitted on November 1st, 2012 and reviewed on July 2nd, 2013. Ideally, which month should it have been reviewed ?

(1) May 2013

(2) June 2013

(3) August 2013

(4) November 2013

9. An ongoing project should be reviewed

(1) At regular intervals of 6 months – 1 year

(2) Once in 3 months

(3) Once in 2 years

(4) No need for review upon approval

10. If an IEC member has conflict of interest in a project, he/she should withdraw from IEC

(1) While the project is being discussed

(2) Anytime during the project

(3) During completion of the project

(4) None of the above

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

(1) Review of HMSC and DCGI

(2) Details of funding agent

(3) Memorandum of Understanding between collaborative partners

(4) All of the above

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

(1) Details of research participants

(2) Curriculum vitae of investigators with inclusion of qualification and experience

(3) Inclusion and exclusion criteria for entry of participants

(4) Both (2) and (3)

13. IEC has

(1) Quorum of 8 – 12 members

(2) Subject experts

(3) Research team

(4) Both (1) and (2)

14. Terms of appointment of IEC members include

(1) Policy of removal

(2) Replacement

(3) Duration of term

(4) All of the above

15. IEC members are trained through

(1) Human protection ethics training

(2) Relevant orientation course

(3) Clinical practice for drug trial review

(4) All of the above

16. Proposals are categorised into

(1) Exemption from review, expedited, full review

(2) High risk, full, expedited

(3) Partial, high risk, full review

(4) Expedited, partial, high risk

17. Qualities of a principal investigator is

(1) Competent in biomedical research methodology

(2) Observant of rights and welfare of the participants

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

(4) All of the above

18. IEC can choose to waive the consent

(1) For left-over sample after clinical investigation

(2) If participants' privacy is breached

(3) In situations with no available surrogate consent

(4) All of the above

19. If a participant withdraws from a study, then he/she receives

(1) Benefit of full compensation

(2) Half of the benefits/compensation

(3) No compensation

(4) None of the above

20. Undue compensation includes

(1) Free medication

(2) Insurance for unrelated conditions

(3) Both the above

(4) None of the above

21. Vulnerable study group means

(1) Lactating mothers

(2) Economically disadvantaged people

(3) Geriatric population

(4) Pregnant women

22. The investigator can inform the media about

(1) Preliminary findings

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

(3) Assure clinical application for human use, while in mid trial

(4) None of the above

23. A legally acceptable/authorized representative can be

(1) A relative/A care taker

(2) An investigator

(3) An unrelated witness

(4) Any adult person

24. Mutatis Mutandis 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

25. The ICMR Code has certain general and specific principles which specifically pertain to

(1) Epidemiology, clinical trials, gynaecology and transplantation

(2) STD, HIV/AIDS, genetics and clinical trials

(3) Interventional clinical trials, epidemiology, genetics, transplantation and ART

(4) None of the above

26. The Supreme Court's opinion on confidentiality about HIV/AIDS in India is

(1) Right to privacy not absolute, individual with HIV should tell his/her sex partner

(2) Right to privacy absolute, individual's wish whether or not to disclose the status to his/her partners

(3) No opinion on confidentiality

(4) None of the above

27. Nuremberg Code was formulated in

(1) 1947

(2) 1948

(3) 1949

(4) 1950

28. The ICMR principle which highlights autonomy is

(1) Principle of maximization of public, interest and distributive justice

(2) Principle of voluntariness, informed consent and community agreement

(3) Principle of non-exploitation

(4) None of the above

29. From children between 2 – 7 years of age

(1) Assent should be obtained from children and consent from parent/legally authorized/acceptable representatives

(2) Consent from parent should be obtained

(3) Consent from children should be obtained

(4) None of the above

30. How many components constitute the Informed consent document ?

(1) 2

(2) 3

(3) 4

(4) 5

31. Informed consent should be obtained preferably

(1) On the day of the trial

(2) One or more days before the trial begins

(3) 6 months before

(4) 1 year before

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

(1) ICMR

(2) IEC

(3) AAHRPP

(4) All of the above

33. Conflict of interest is

(1) Business interest with a company developing the product

(2) A disagreement between the investigators of a study

(3) Both the above

(4) None of the above

34. Post trial access is stated in Helsinki Declaration in which of these years ?

(1) 2000, 2006, 2008

(2) 2001, 2010, 2011

(3) 2000, 2004, 2008

(4) None of the above

35. Latest Helsinki Declaration is the

(1) 6^{th} declaration 2008

(2) 5^{th} declaration 2007

(3) 8^{th} declaration 2008

(4) 10^{th} declaration 2012

36. ICMR updated its guidelines in

(1) 2000

(2) 1998

(3) 2001

(4) 2005

37. Conflict of interest should be informed to

(1) Journals

(2) Research participants

(3) IEC

(4) All of the above

38. ICMR 2006 revisions include

(1) HIV/AIDS and genetics

(2) Molecular studies and HIV/STD

(3) Cancer and genetics

(4) STD and genetics

39. Who decides the exemption of a proposal from review ?

(1) IEC

(2) ICMR

(3) Legal expert

(4) Investigator

40. Collection of a biological specimen for research purpose for prospective study should be

(1) Invasive

(2) Coercive

(3) Disfiguring

(4) Non-invasive

41. Helsinki Declaration has been revised

(1) 5 times

(2) 8 times

(3) 7 times

(4) 11 times

42. IEC should be

(1) Multidisciplinary

(2) Multisectorial

(3) Both (1) and (2)

(4) None of the above

43. DSMB means

(1) Data Safety Monitoring Board

(2) Documentation Safety Monitoring Board

(3) Digital Safety Monitoring Board

(4) None of the above

44. A study testing a drug in children should be conducted after

(1) Animal trials

(2) Phase-II trials in humans

(3) Phase-III trials in humans

(4) Phase-I trials in animals

45. Components of an Informed consent are

(1) Information, compensation and autonomy

(2) Comprehension, information and voluntariness

(3) Compensation, voluntariness and autonomy

(4) Information, comprehension and autonomy

46. Helsinki Declaration is a document of

(1) American Medical Association

(2) World Medical Association

(3) World Health Organisation

(4) Helsinki Medical Association

47. IEC is an acronym for

(1) Information and Ethical Committee

(2) Institutional Ethics Committee

(3) Indian Ethics Committee

(4) Internal Ethics Committee

48. SIDCER stands for

(1) Strategic Initiative for Developing Capacity in Ethical Review

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

(3) Social Institute for Development of Codes in Ethics and Research

(4) None of the above

49. Experimental Research should be conducted in a

(1) Fair, honest, impartial and transparent manner

(2) Fair, dishonest, partial and transparent manner

(3) Biased, honest, partial and selective manner

(4) Honest, impartial and transparent manner

50. The rights and dignity is protected by

(1) Distributive justice

(2) Confidentiality

(3) Informed consent

(4) All of the above

PART B

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

51. Designer Babies

52. Records to be maintained by IEC and their Monitoring Methods

53. Are Scientists playing God ? Comment.

54. Vulnerable Populations in a Research

55. Three-parent Reproduction

56. Nuremberg Code