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NPTEL

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Courses » Current regulatory requirements for conducting clinical trials in India

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Unit 6 - Week 4

Register for Certification exam

Course outline

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Assignment 4

The due date for submitting this assignment has passed.
As per our records you have not submitted this assignment. **Due on 2019-03-27, 23:59 IST.**

Dear Participants,

I hope you enjoyed the lectures. We have covered the entire course.

Lecture 10: Ethical considerations. The lecture 10 has two parts, Part A and B. Lecture 10A deals with the ICMR ethical guidelines released in 2017 while Lecture 10B deals with registration and re-registration Ethics Committees with CDSCO as per Rule 122 DD.

Lecture 10A: National ethical guidelines for biomedical and health research involving human participants and children (2017)
This lecture deals with the ethical guidelines released by ICMR in 2017 covering the children guideline as well. This session helped us to understand the essential ethical requirements for conducting clinical trials in India. This lecture briefly covered statement of general principles, general ethical issues, responsible conduct of research, ethical review procedures, vulnerability, clinical trials of drugs and other interventions, public health research, social and behavioral sciences research for health, human genetics testing and research, biological materials, bio banking and datasets and research during humanitarian emergencies and disaster.

Lecture 10B: EC registration
In this lecture, we studied how to register the ethics committees with the Indian drug regulators, CDSCO. We also covered some information related to the composition of EC and their responsibilities. The lecture showed step-by-step procedure of EC registration using SUGAM portal including re- registration.

Lecture 11: Recent amendments
In this lecture, we discussed all the recent amendments related to clinical trials. We studied about all the recent developments in Schedule Y, Appendices and Rule. This lecture also apprised us about the Subject Expert Committee (SEC), and their functioning

Lecture 12: Special concerns
In this lecture, we discussed about the regulatory requirements of vaccines, bioavailability or bioequivalence studies, recombinant DNA derived products and biological products, including

Government of India
Ministry of Human Resource De

1) The national ethical guidelines for biomedical and health research involving human participants released by ICMR in 2017 has 10 sections **1 point**

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
False

2) The ethical guidelines issued by the Indian Council of Medical Research (ICMR) is applicable to researchers of following disciplines EXCEPT: **1 point**

- Modern Medicine
- Indian Systems of Medicine
- Social and behavioral science
- Medical practice

No, the answer is incorrect.
Score: 0

Accepted Answers:
Medical practice

3) Scientific misconduct means **1 point**

- Fabrication
- Falsification
- Plagiarism
- All of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
All of the above

4) The EC functioning involves the following EXCEPT: **1 point**

- Initial and continuing review
- Chairperson dictating decision
- Monitoring
- Record keeping and archiving

No, the answer is incorrect.
Score: 0

Accepted Answers:
Chairperson dictating decision

5) The documents for EC registration includes all the documents as per Appendix VII of Schedule Y. **1 point**

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
False

6) If EC re-registration is applied for _____ months before expiry of registration, then it is deemed to be continuing unless orders are passed or until registration is suspended or cancelled. ***1 point***

- One
- Two
- Three
- Six

No, the answer is incorrect.
Score: 0

Accepted Answers:
Three

7) The checklist for acceptance of application by CDSCO for ethics committee registration must include essential training details and undertaking by the committee as per the format. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

8) Fill in the blanks. [Marks 02] ***2 points***
G.S.R. 918(E) dated November 30, 2015 deals with _____ while G.S.R. 287(E) dated March 08, 2016 deals with _____.

- Serious adverse event reporting; Audio video recording
- Post marketing surveillance; Phyto-pharmaceutical drugs
- Phytopharmaceutical drugs; Post marketing surveillance
- Audio video recording; Serious adverse event reporting

No, the answer is incorrect.
Score: 0

Accepted Answers:
Phytopharmaceutical drugs; Post marketing surveillance

9) Subject Expert Committee (SEC) to advise DCG(I) in matter related to review & regulatory approvals of clinical trials and new drugs (except IND) ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

10) Registration of ethics committee is covered under Rule _____. ***1 point***

- 122DAB
- 122DD
- 122DAC
- 122DAA

No, the answer is incorrect.
Score: 0

Accepted Answers:
122DD

11) A serious adverse event is an untoward medical occurrence during clinical trial that is associated with ***1 point***

- Death
- Patient hospitalisation
- Prolongation of hospitalisation
- All of above

No, the answer is incorrect.
Score: 0

Accepted Answers:
All of above

12) Free medical management shall be given to study subjects as long as required or till such time it establish that the injury is not related to clinical trials, whichever is earlier ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

13) In the case of clinical trial related death of a subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority defined under clause (b) of Rule 22, and the financial compensation will be over and above any expenses incurred on the medical management of the subject ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
False

14) Rule _____deals with compensation in case of injury or death during clinical trial. ***1 point***

- Rule 122DAA
- Rule 122DAC
- Rule 122DAB
- None of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
Rule 122DAB

15) Rule _____deals with the permission to conduct clinical trials. ***1 point***

- Rule 122DAA

- Rule 122DAC
- Rule 122DAB
- None of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
Rule 122DAC

16) An audio-video of the informed consent is taken in case of vulnerable subjects in clinical trials of new chemical entity or new molecular entity including procedure of providing information to subject and his understating on such consent, are maintained by the investigator for records. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

17) In case of clinical trial of anti-HIV and anti-leprosy drugs, only audio of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent are maintained by the investigator for his/her records. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

18) All vaccines are considered as “new drugs”. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

19) The regulations under the Drugs and Cosmetics Rules 122A, 122B, 122D and 122E and Appendix I, I-A and XII of _____, describes all the information necessary for seeking approval of vaccines along with an application to import or manufacture for market and sale. ***1 point***

- Schedule M
- Schedule L1
- Schedule Y
- None of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
Schedule Y

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