KUMARAGURU college of technology
character is life

Register Number: ……..

B.TECH DEGREE EXAMINATIONS: APRIL/MAY 2016

(Regulation 2009)

Eighth Semester

BIOTECHNOLOGY

BTY214: Clinical Research and Management

Time: Three Hours **Maximum Marks: 100**

Answer all the Questions:-

PART A (10 x 1 = 10 Marks)

1. The abortion act of ____ legalized termination of pregnancy in case of abnormalities
   a) 1950 b) 1960
   c) 1967 d) 1970
2. Duration to complete Human Genome Project (HGP) is _____
   a) 13 years b) 15 years
   c) 14 years d) 12 years
3. _____ is manipulating research materials , equipments or process or changing or omitting data results such that the results research is not accurately represented in the research record
   a) Falsification b) Plagiarism
   c) Fabrication d) Stealing
4. Clinical researchers subscribe to three basic elements (write the false answer given)
   a) Scientific integrity b) Scientific disgrace
   c) Patient safety d) Investigator objectivity
5. The GCP guidelines are given by the _____
   a) Ethics Committee b) DCGI (Drug Control General of India)
   c) Food Drug admistration (FDA) d) New Drug Application NDA
6. A significant portion of R&D budget are spent on outsourcing services offered by the _____
   a) CRO industry b) ICH
   c) IRB d) CDCSO
7. In case of serious adverse event (SAE) during a clinical trial same should be reported promptly to the regulatory authority
   a) Within 07 calendar days b) Within 24 calendar days
   c) Within 14 calendar days d) Within 28 calendar days

8. The effectiveness of the drugs is tested in _____ of clinical trial

a) Phase I b) Phase II

c) Phase III d) Phase IV

9. The randomized, controlled, double-blind clinical trial is the_____ for the assessing treatment effects

a) Pharmacology b) Law throne effects

c) Controlled groups d) Gold standard

10. Clinical trial for any drug shall be initiated only after the permission is granted by _____

a) Sponsors agency b) Clinical trial investigator

c) Ethical committee of india d) Regulatory authority of India

PART B (10 x 2 = 20 Marks)

11. Name four guidelines to be followed when using human subjects
12. Write short note on ethical issue of placebo effect.
13. What are the various suggestions over the human genome project?
14. What are the several major ethical theories which attempt to supply basic principles?
15. Define COI
16. Name the few multinational clinical research organisation
17. What is schedule Y?
18. What is preclinical testing?
19. What are the criteria's for protocol approval in contract research?
20. What are the important roles of the intuitional review board?

PART C (5 x 14 = 70 Marks)

21. a) Write a detailed note on ethical guidelines for biomedical research

(OR)

b) What is human genome project (HGP)? Give an detail account on ethical guidelines of HGP

22. a) Explain the principles and ethical guidelines in transplantation of organs.

(OR)

b) Write a detailed account on integrity and misconduct in clinical research

23. a) Write in detail about the structures and content of clinical research study report.

(OR)

b) Explain in detail about the application process for contract research using schedule Y1.

24. a) Explain the responsibilities of sponsor and investigator in detail.

(OR)

b) Write the contents of clinical report and explain about data blinding and randomization.

25. a) Explain in detail about setting up clinical trials laboratories in India

(OR)

b) Explain briefly on regulatory affairs in clinical research.

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