KUMARAGURU college of technology
character is life

Register Number: ……..

B.TECH DEGREE EXAMINATIONS: APRIL 2015

(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. In which year Nuremburg Code is released?
   a) 1947 b) 1948
   c) 1949 d) 1950
2. What is full form of CDMS?
   a) Clinical Data Management System b) Clinical Data Maintenance System
   c) Classical Data Management System d) Clinical Data Maintenance t System
3. What is the basic principle of research on human subject?
   a) Transformation b) Mentoring
   c) Facilitating d) Respect for person
4. Who has discovered the sulfonamide?
   a) Paul Ehrlich b) Alexander Fleming
   c) Gerhard Domagk d) Waksman
5. Choose the term is related with contact research
   a) Cluster sampling b) Target achievement
   c) Ethics d) Promotional activity
6. Who have developed a systematic methodology for studying and evaluating therapeutic interventions?
   a) British Medical Research Council b) Indian Medical Research Council
   c) Indian Council of Medical Research d) National Institute of Health
7. What is the purpose for the establishing the IRB?
   a) To protect human participants in research b) To protect wild animal
   c) To protect natural habitat d) To protect wild plant

8. What is an Individual Autonomy?

a) Patient's right to receive advantageous or favorable treatment

b) Patient's have the right to decide what should be done for them with respect to their illness unless the result would be clearly detrimental to others

c) Fairly distributing the benefits and burdens of research

d) Patient's don't have the right to decide what should be done for them with respect to their illness unless the result would be clearly detrimental to others

9. What is Cohort Study?

a) Refers to time of data collection

b) Refers to time of medicine collection

c) Persons with and without disease are compared.

d) Persons with and/or without disease are followed over time

10. CGMP stands for_____

a) Current good manufacturing practices

b) Contemporary good manufacturing practices

c) Contract good manufacturing practices

d) Contract manufacturing practices

PART B (10 x 2 = 20 Marks)

11. Why do we need clinical research studies?
12. Write a short note about ethical conduct of research with human participant.
13. Why are clinical trials an acceptable form of research?
14. When do ethical questions arise?
15. Identify the primary thing of contact research.
16. Mention few sampling methods of contract research.
17. List out core components of clinical trials.
18. Name any three ethical principles of clinical trials.
19. Comment on common deficiencies leading to clinical hold.
20. State the Principles of ICH GCP.

PART C (5 x 14 = 70 Marks)

21. a) Discuss in detail about the ethical guidelines for biomedical research on Human.

(OR)

b) Elaborate briefly about specific principles of chemical evaluation.

22. a) Enumerate about ethical theories and foundation.

(OR)

b) Explain about the integrity and misconduct in clinical research.

23. a) Brief an account on regulatory affairs and contract research.

(OR)

b) Illustrate on delivery model for the CR Business environment with an example

24. a) Discuss in detail on types of clinical trials.

(OR)

b) Describe about the data blinding and randomization of clinical trials.

25. a) Explain in detail on clinical trial laboratories in India.

(OR)

b) Discuss in detail about the setting up clinical trial company based on outsourcing trends.

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