Register Number: ……..

B.TECH DEGREE EXAMINATIONS: APRIL/MAY 2014

(Regulation 2009)

Sixth 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. _____ is a type of randomization used when the study involves variation of effect of treatment based on the age and sex of the patients.
   a) Stratified block randomization b) Paraking block randomization
   c) Simple block randomization d) Dynamic random allocation
2. _____ is one of the major ways in which blinding is broken
   a) Side effect b) Psychological change
   c) Patient cooperation d) Random action
3. Commonly used clinical data management tools are
   a) CLINTRAIL, MACRO, RAVE b) ORACLE, BLAST
   c) FASTA, CLUSTAL W d) MACRO
4. Prominent open source tools of clinical data management are
   a) Open clinica b) CDME
   c) CDMS d) DBMS
5. According to the " rule of thumb" number of patients per treatment / number of strata should be
   a) ≥ 4 b) <4
   c) >4 d) $=4$
6. Phase 3 clinical trial is also known as
   a) Post marketing trail b) Therapeutic exploratory
   c) Therapeutic confirmatory Trial d) Experiment and error trial
7. The duration of exposure to any dose is expressed as
   a) mean b) median
   c) mode d) sigma
8. Clinical trials are conducted by
   a) CRO's b) CPO's
   c) CSO's d) CEO's

9. New formulations of approved drugs may be subjected to _____ studies
   a) Bioequivalence b) Bioagumentation
   c) Bioformulation d) Biotranslation
10. Which one of the following is not a core element of a clinical trial?
    a) Core design b) Data
    c) Trial d) Case study

PART B (10 x 2 = 20 Marks)

11. Mention the ethical guidelines in biomedical research.
12. Give the ethical guidelines in clinical research.
13. What is informed consent process?
14. Enumerate the role of ethical review committee.
15. Define contact research.
16. What is schedule Y1?
17. List the responsibilities of sponsors in clinical trials.
18. How to recruit the trial subjects?
19. What are the guidelines to be followed for a technical presentation?
20. Name few clinical trial laboratories in India.

PART C (5 x 14 = 70 Marks)

21. a) Write in detail about human genome project and DNA banking.

(OR)

b) i) What are the ethics to be followed during prenatal diagnosis? (7)
   ii) What principles should be maintained during transplantation? (7)

22. a) Elaborate about various ethical theories and foundations.

(OR)

b) Give a detailed account on the integrity and misconducts in clinical research via a case study

23. a) i) Write about CR business environment (7)
    ii) Elucidate CR information research (7)

(OR)

b) With the help of a case study explain about contact research

24.	a)	i)	Mention about types of clinical trials.	(4)
		ii)	Describe about the content and structure of clinical report.	(10)
			(OR)	
	b)	i)	What is data blinding and randomization, write about its role in clinical trials.	(6)
		ii)	Elaborate about data management in clinical trials.	(8)
25.	a)		Write about the current status of clinical trial laboratories in India.	
			(OR)	
	b)		Desirable about clinical research education and training in India.	

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