

STELLA MARIS COLLEGE (AUTONOMOUS) CHENNAI –600 086
(For candidates admitted from the academic year 2011 – 12 & thereafter)

SUBJECT CODE: 11BI/PE/CR44

M. Sc. DEGREE EXAMINATION, APRIL 2014
BIOINFORMATICS
FOURTH SEMESTER

COURSE : ELECTIVE

PAPER : INTRODUCTION TO CLINICAL RESEARCH MANAGEMENT

TIME : 3 HOURS

MAX. MARKS: 100

SECTION – A

I ANSWER ALL THE QUESTIONS IN A LINE OR TWO:

(20X1=20 MARKS)

1. IND
2. NDA
3. FDA
4. GCP
5. QUALITY ASSURANCE
6. QUALITY CONTROL
7. NUREMBERG CODE
8. DECLARATION OF HELSINKI
9. SOP
10. CRF
11. IB
12. SAE
13. PLACEBO
14. PHARMACO KINETICS

15. INCLUSIVES & EXCLUSIVES

16. ICF

17. AUDIT

18. ICH

19. LD50

20. PMS

SECTION – B

ANSWER ANY FOUR QUESTIONS. EACH ANSWER SHOULD NOT EXCEED 500 WORDS. ALL ANSWERS CARRY EQUAL MARKS. DRAW DIAGRAMS WHEREVER NECESSARY (4X10=40 MARKS)

21. Describe the process of New Drug Application.
22. Enumerate the Principles of Good clinical practice.
23. Explain the Role and Constitution of Ethics Committee.
24. Describe the Indian Regulatory system.
25. Define Fraud, what are the methods adopted to detect and prevent fraud in clinical trials?
26. Write a note on Standard operating procedures.
27. Describe the process of a Pharmacodynamic study.

SECTION – C

ANSWER ANY TWO QUESTIONS. EACH ANSWER SHOULD NOT EXCEED 1200 WORDS. ALL ANSWERS CARRY EQUAL MARKS. DRAW DIAGRAMS WHEREVER NECESSARY (2X20=40 MARKS)

28. What are the four phases of drug development and trials?
29. What is Pharmacokinetics? Describe it.
30. Importance of statistics in clinical Research.
31. Describe Data Handling in clinical Trial.
