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 2016
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. FDA
2. Randomization
3. Pro-drug
4. Target validation
5. Candidate drug
6. WHO
7. Neurenberg code 1949
8. Biosafety
9. Clinical trial
10. Informed Consent
11. Quality assurance
12. Data monitoring
13. CRF
14. IND
15. ANDA
16. Need of data management
17. Diagnostic trial
18. Responsibilities of ethics committee
19. GLP
20. In vitro systems in toxicology testing

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SECTION – B

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

21. Explain the role of statistics in clinical research
22. Discuss the preparation procedure for a successful clinical study.
23. Elucidate the responsibilities of Ethics committee.
24. Describe about FDA audits & inspections.
25. List out the responsibilities of an investigator.
26. Write the protocol for safety assessment.
27. Describe the central quality control of data.

SECTION – C

ANSWER ANY TWO QUESTIONS. EACH ANSWER SHOULD NOT EXCEED1200 WORDS. All QUESTIONS CARRY EQUAL MARKS. DRAW DIAGRAMS WHEREVER NECESSARY (2X20=40 MARKS)

28. Explain the different phases of clinical trials.
29. A. Explain GCP & ICH.
    B. Write notes on study design
30. Explain post drug approval activities in detail
31. A. Discuss the informed consent process in clinical research management.
    B. Illustrate the need of record keeping & retention.

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