

STELLA MARIS COLLEGE (AUTONOMOUS) CHENNAI –600 086
(For candidates admitted from the academic year 2015 – 2016)

SUBJECT CODE: 15BI/PC/CR44

M. Sc. DEGREE EXAMINATION, APRIL 2017
BIOINFORMATICS
FOURTH SEMESTER

COURSE : CORE
PAPER : BASICS OF CLINICAL RESEARCH MANAGEMENT
TIME : 3 HOURS **MAX. MARKS: 100**

SECTION – A

ANSWER ALL THE QUESTIONS IN A LINE OR TWO: (20X1=20 MARKS)

1. Etiology
2. Drug
3. Toxicity
4. CRO
5. CRF
6. GCP
7. Lipiski's Rule
8. NDA
9. Informed Consent
10. Declaration of Helsinki
11. Inclusion Criteria
12. Drug Discovery
13. Pharmacodynamics
14. Bioethics
15. Pharmacovigilance
16. Clinical trials
17. SAE
18. PMS
19. Nuremberg code
20. Data Monitoring Committee

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. SOP
22. ICH- GCP Guidelines
23. History of Drug Development
24. Phases of Clinical Trials
25. Query and Data Management
26. Pharmaco epidemiology
27. History of Drug Development

SECTION – C

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

28. Schedule Y- Rules and Regulations
29. FDA Audits and Inspections - EU Regulatory Affairs
30. Importance of Statistics in Clinical Research
31. Patent Regulatory Bodies.
