

2874_2011_1_S184.doc

Rajiv Gandhi University of Health Sciences, Karnataka

Fifth Year Pharma - D (Post Baccalaureate) Degree Examination – Feb/March 2011

Time: Three Hours**Max. Marks: 70 Marks**

CLINICAL RESEARCH

Q.P. CODE: 2874

Your answers should be specific to the questions asked
Draw neat labeled diagrams wherever necessary

LONG ESSAYS (Answer any two)**2 x 10 = 20 Marks**

1. Discuss in detail about the Institutional Review Board
2. What is safety monitoring? Explain in detail
3. What are the different post marketing surveillance methods? Explain them

SHORT ESSAYS (Answer any six)**6 x 5 = 30 Marks**

4. Explain clinical trials for vaccines
5. Write a note on clinical research associate
6. Write a note on clinical data management
7. Discuss ICH-GCP guidelines
8. Explain protocol preparation in clinical research
9. Roles and responsibilities of an auditor in clinical trials
10. Write a note on abbreviated new drug application
11. Explain the challenges in implementation of guidelines

SHORT ANSWERS**10 x 2 = 20 Marks**

12. Adverse reaction reporting
13. ICMR
14. Phase III
15. Double blind studies
16. Contract research coordinator
17. Case report form
18. Criss- cross method
19. Waiver of consent
20. Carcinogenicity
21. Research involving children
