



**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

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