

# Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharma-D (Post Baccalaureate) Degree Examination – Sep 2012

**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. Explain the ethical guidelines for clinical research
2. Discuss the different Pharmacological action studies in the drug development process
3. Write a note on clinical data management in clinical trials

#### SHORT ESSAYS (Answer any six)

**6 x 5 = 30 Marks**

4. Explain CDSCO guidelines
5. Explain the phase II clinical trials
6. Write a note on drug characterization
7. Discuss about IND application
8. Role and responsibilities of auditors
9. Write a note on CRA
10. What are the different regulatory systems in USA, EUROPE and INDIA
11. Write a note on challenges in the implementation of ICH guidelines

#### SHORT ANSWERS

**10 x 2 = 20 Marks**

12. Informed consent
13. Protocol
14. Phase IV
15. Composition of IEC
16. Therapeutic index
17. Members of ICH
18. Chronic toxicity
19. Cohort studies
20. Safety monitoring
21. Investigator

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