Rajiv Gandhi University of Health Sciences

First Semester M. Pharm Degree Examination - Dec-2017

[Time: 3 Hours] [Max. Marks: 75]

Clinical Research
Q.P. CODE: 5140

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

LONG ESSAY (Answer any Three) **3 X 10 = 30 Marks**

1. Explain the preparation of Case report form and Informed consent.
2. Explain the roles and responsibilities of investigator.
3. Discuss in detail the various phases of clinical trials.
4. Explain the constitution and functions of Institutional Review Board.

SHORT ESSAY (Answer any Nine) **9 X 5 = 45 Marks**

5. Briefly explain research study designs based on sampling methods.
6. Discuss about contract research organization and its responsibilities.
7. Explain quality control and quality assurance in clinical trial data management.
8. Explain the different health outcome measures in clinical research.
9. What is trial master file? Explain its preparation and maintenance.
10. What are the responsibilities of stake holders in audit process? Add a note on preparing for FDA inspections.
11. Explain the different randomization techniques.
12. What is meant by close out visit report? Explain in detail.
13. Explain the guideline for the preparation of study protocol.
14. What are the responsibilities of stake holders in audit process?

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