Rajiv Gandhi University of Health Sciences

First Semester M. Pharm Degree Examination - JAN-2019

Time: Three Hours **Max. Marks: 75 Marks**

Clinical Research Regulations
Q.P. CODE: 5124

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. Write in detail about different phases of clinical trials.
2. Enumerate in detail about historical perspectives of clinical research.
3. Describe the applicable regulations to conduct of clinical studies in USA.
4. Explain the ethical requirements for conduct of clinical research as per ICH GCP E6 guidelines.

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

5. Write a note in informed consent process.
6. Write a note on role of placebo in clinical trials.
7. Write a note on data safety monitoring boards.
8. Discuss about financial disclosure by clinical investigators.
9. Write a note on ethics of clinical research in special population.
10. Write a note on CDSCO guidelines for clinical research.
11. Write a note on Investigational device exemptions.
12. Short note on Indian GCP guidelines.
13. Write about ICMR ethical guidelines for biomedical research.
14. Write briefly about schedule Y regulations in India.

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