Rajiv Gandhi University of Health Sciences, Karnataka

Second Semester M. Pharm Degree Examination - 15-Dec-2020

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

CLINICAL RESEARCH AND PHARMACOVIGILANCE

Q.P. CODE: 5180

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

Answer All The Questions **10 X 7.5 = 75 Marks**

1. Explain the roles and responsibilities of clinical trial personnel.
2. Give detailed information regarding to Pharmacoeconomics.
3. What are the roles and responsibilities of principle investigator?
4. Explain in detail of RCT and non-RCT.
5. Give the organizational structure for a typical Phase –II clinical trials of Phase-III clinical trials.
6. Draw IND review flow chart. Add on clinical research regulation in India.
7. Explain the ethical guidelines for biomedical research on human subjects.
8. Define Pharmacovigilance and explain the role of stake holders in Pharmacovigilance.
9. Define ADR and explain how ADR will be managed.
10. Explain ICH-GCP principles for clinical trials.

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