Rajiv Gandhi University of Health Sciences, Karnataka

Second Semester M. Pharm Degree Examination - 24-Nov-2022

[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 different types of study designs of clinical trials.
2. What is Informed Consent Form (ICF)? Discuss about structure and content of ICF for clinical study.
3. WHO causality assessment scale.
4. Discuss importance of Pharmacovigilance.
5. Describe post marketing surveillance.
6. Discuss ethical guidelines for biomedical research.
7. Write a note on Interventional study.
8. Describe the preparation **of** protocol in clinical trails.
9. Discuss in details about case report form.
10. Draw IND review flow chart. **Explain the** clinical research regulation in India.

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