Rajiv Gandhi University of Health Sciences, Karnataka

Second Semester M. Pharm Degree Examination - 26-Mar-2021

[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 in detail of clinical trials types and design.
2. Discuss the roles and responsibilities of clinical research coordinator.
3. Define and explain safety pharmacology.
4. Explain ethical guidelines for Biomedical Research.
5. Write a note on pharmacovigilance in clinical practice.
6. Write a detail note on ICH-GCP guidelines.
7. Write a note on terminologies of ADR. Explain the management of ADR.
8. Composition and responsibilities of Institutional Review Board (IRB).
9. Write about data management and briefly explain its different components.
10. How PV center is established in hospital. Explain Vigi Flow.

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