Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Regular/Supplementary Examinations July 2025

Clinical Research

Time: 3 Hours **Total Marks: 70**

- ***Answer all questions to the point neatly and legibly • Do not leave any blank pages between answers • Indicate the question number correctly for the answer in the margin space***
- ***Answer all parts of a single question together • Leave sufficient space between answers***
- ***Draw table/diagrams/flow charts wherever necessary***

Essay: **(3x10=30)**

1. What is Investigational New Drug (IND) application. Explain the IND submission process
2. Explain a Case Report Form (CRF) and prepare a model case report form for a clinical study
3. Discuss the role and responsibilities of various stakeholders as per ICH-GCP

Short notes: **(8x5=40)**

4. What are the various pharmacological approaches to drug discovery.
5. Describe the ANDA submission process.
6. Discuss the Informed Consent Form (ICF) and its importance.
7. Explain the compensation for injury in clinical trial
8. Discuss the special attention required for recruiting vulnerable participants in the clinical trials
9. Give a note on regulatory environments for clinical trials in USA
10. Explain composition and responsibilities of IRB in clinical research
11. Give a note on Clinical Data Management (CDM)

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