

Sl.No. M21126

Course Code: 3100501/3200501

**VINAYAKA MISSION'S RESEARCH FOUNDATIONS, SALEM
(Deemed to be University)**

**Pharm.D/ Pharm.D (POST BACCALAUREATE) DEGREE
EXAMINATION - September 2021
Fifth Year**

CLINICAL RESEARCH

Time: Three hours

Maximum: 70 marks

I. Write essays on any **TWO** questions: (2 x 15 = 30)

1. Define Clinical Trials? Discuss in detail five various phases involved in drug development process.
2. Define investigational new drug application and describes the component and categories of investigational new drug application.
3. what are the roles and responsibilities of auditors in clinical research. Define serious adverse event in clinical trial and responsibilities of investigators in reporting.

II. Write short answers on any **SIX** questions: (6 x 5 = 30)

4. Informed consent process
5. Central drug standard control organisation and food and drug administration.
6. Randomization.
7. Significance of post marketing surveillance.
8. Roles and responsibilities of Investigations.
9. Clinical research co ordinator.
10. Protocol amendment in clinical research
11. Data migration and archiving?

III. Write short notes on any **FIVE** question: (5 x 2 = 10)

12. Mention the role of IEC in research.
13. Write a not on schedule Y.
14. Write a not on GCP.
15. Impartial witness..
16. Explain Human Subjects.
17. Define Case report form (CRF).
