Sl.No. M22111 **Course Code: 3100501/3200501**

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

Pharm.D (Post Baccalaureate)DEGREE EXAMINATION - February 2020
Fifth Year

CLINICAL RESEARCH

Time: Three hours Maximum: 70 marks

I. Write essays on any **TWO** questions: (2 x15 = 30)

1. Explain the drug characterization and dosage form techniques involved in drug discovery.
2. Enumerate the composition, responsibilities and protocol involved in institutional review board.
3. Discuss the international conference on hormonisation and central drug standard control organization guidelines on good clinical practice.

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

4. Mention the four phases of clinical trial.
5. Write the role of sensor, investigation in clinical trial.
6. Differentiate case - control and cohort studies in surveillance.
7. Outline the abbreviated new drug application review process
8. Describe the drug regulatory requirements, for united states of America.
9. Write the requirements for clinical study documentation protocol.
10. Explain the significance of data management in clinical study.
11. How to assess safety monitoring in clinical trials?

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

12. Stormed consent process.
13. Role of contract research coordinators.
14. Mention the ethical guidelines in clinical research.
15. What is LD, MLD and MTD in toxicology screening?
16. Functions of participation identification centers.
17. State any four components of data management.

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