Sl.No. M19213 **Course Code: 3100501/3200501**

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

Pharm.D (POST BACCALAUREATE) DEGREE EXAMINATION
August 2018
Fifth Year

CLINICAL RESEARCH

Time: Three hours Maximum: 70 marks

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

1. In- detail write about the various procedures involved in investigational new drug (IND) application.
2. Explain the regulatory environment in United States of America.
3. Enumerate the drug development process.

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

4. Explain the pharmacological approach for Drug discovery.
5. Define clinical trial. Write about Phase II clinical trial.
6. Enumerate the various methods of Post Marketing surveillance.
7. Explain about any two Ethical guidelines in clinical research.
8. Write down the roles and responsibilities of Clinical research associate.
9. Define informed consent. Explain the informed consent process.
10. Write a short note on safety monitoring in clinical trials.
11. Briefly write about the designing of protocol.

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

12. Explain any four challenges in implementation of GCP guidelines.
13. What is meant by Phase-0 clinical trial?
14. Write any four responsibilities of Sponsor.
15. Write the composition of institutional Ethics committee.
16. Write a short note on Abbreviated new drug application.
17. Define clinical data management and write few of its components.

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