

Sl.No: M21145

Course Code: MPP104T

**VINAYAKA MISSION'S RESEARCH FOUNDATION  
(DEEMED TO BE UNIVERSITY), SALEM**

**M.PHARM. DEGREE EXAMINATION – September 2021  
First Semester**

**BRANCH: PHARMACY PRACTICE**

**CLINICAL RESEARCH**

Time : Three hours

Maximum: 75 marks

**(Draw neat labeled diagrams wherever necessary  
your answer should be specific to the questions asked)**

**SECTION –A**

I. Answer any **THREE** questions: **(3 x 15 = 45)**

1. What is mean by Randomization? How is Randomization done in the clinical trial? Give its significance, method, merits and demerits in the clinical trial.
2. Write the composition, member's responsibilities, functions and challenges of Institutional Review Board.
3. Define clinical trials. Discuss in detail five various phase involved in drug development process.
4. Define investigational new drug application and describe the component and categories of investigational new drug application.

**SECTION –B**

II. Answer any **THREE** questions: **(3 x 10 = 30)**

5. Write the responsibilities of sponsor's in clinical trial.
6. Preparation of Informed Consent Form (ICF).
7. Write about various sources of bias and methods to avoid Bias.
8. Good clinical practice and its principles.

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