Exam Date & Time: 19-Dec-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Clinical Research [PPR-MPP104T - S2]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Define IRB/IEC. Mention and explain its constitution and function (10)

2) Mention the roles and responsibilities of sponsor, investigator and CRO (10)

3) Describe the contracts and agreements in clinical research (10)

4) Define informed consent. Explain in detail about the informed consent process (10)

5) Differentiate the audits in clinical trial and explain its importance (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) Explain drug dosage forms and drug characterization in clinical research (5)

7) Define and elaborate phase 0, 1 and 2 clinical trials (5)

8) What are the roles and responsibilities of monitor in clinical research? (5)

9) Explain and list the clinical data management activities in clinical research (5)

10) How do you manage the discrepancies in clinical data (5)

-----End-----