

# Question Paper

Exam Date & Time: 31-Mar-2021 (01:30 PM - 04:30 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) Explain various types of IND application. Explain regulatory process for IND application to the FDA. (10)
- 2) Discuss Various phases of clinical trials in detail. (10)
- 3) Discuss essential components of clinical trial agreement in detail. (10)
- 4) Discuss Safety reporting in clinical trials. (10)
- 5) Discuss different type of audits conducted in clinical trials. (10)

### SECTION - B

**Answer all the questions.**

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

- 6) Discuss constitution and responsibility of Institution Ethics Committee. (5)
- 7) Discuss role and responsibility of Investigator towards Informed consent process in detail. (5)
- 8) Enlist various essential documents for clinical trials and explain any one in detail. (5)
- 9) Discuss Roles and Responsibilities of the CDM Team. (5)
- 10) Write a short note on The Digital Information Security in Healthcare Act (DISHA). (5)

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