GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Medical and Allied Sciences

Master of Pharmacy in Pharmacology
Mid Term Examination - May 2024

Duration : 90 Minutes
Max Marks : 30

Sem II - MPL204T - Clinical Research and Pharmacovigilance

General Instructions
Answer to the specific question asked
Draw neat, labelled diagrams wherever necessary
Approved data hand books are allowed subject to verification by the Invigilator

1)	Who are the members of Human subjects review board.	K1	(2)
2)	Outline the investigator play in the Ethics Committee review of a study	K2	(2)
3)	Classify the advantages of Phase - IV survillance in clinical trial.	K2	(2)
4)	What are the responsibility and the authority IRB?	K1	(2)
5)	Explain the observations done in Phase-II of a clinical trial.	K2	(2)
6)	Identify all the requirements and content of informed consent.	K3	(5)
7)	Compare the members of ethics committee with compansation rules and Consent process.	K4	(5)
	OR		
	Compare RCT and NonRCT study designs in deatail.	K4	(5)
8)	Determine the origin and activities of international conference on harmonization	K5	(10)
	OR		
	Determine the roles and responsibilities of Investigator, study coordinator, sponsor in detail.	K5	(10)