GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Biomedical Science

Master of Science Clinical Research
Mid Term Examination - May 2024

Duration : 90 Minutes
Max Marks : 50

Sem II - Q1PN202T - Clinical Trial Designing

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)	Explain the (CFR) Code of federal regulation.	K2	(2)
2)	Define the Clinical Study protocol.	K1	(3)
3)	Explain the serious adverse event (SAE) and adverse event.	K2	(4)
4)	Explain the types of trials.	K2	(6)
5)	Illustrate the designing of phase I clinical research.	K3	(6)
6)	Illustrate Phase 2 clinical trial designing.	K3	(9)
7)	Analyze of declaration of helsinki (DoH).	K4	(8)
8)	Analyze the importance of safety and efficacy endpoints.	K4	(12)
	OR		
	Analyze the selection criteria and responsibility of principle investigator.	K4	(12)