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 - Q1PN201T - Regulatory affairs in Clinical Research

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 Code of federal regulation.	K2	(2)
2)	Define the Clinical trial protocol.	K1	(3)
3)	Explain the serious adverse event and adverse event.	K2	(4)
4)	Explain the evolution of regulatory bodies.	K2	(6)
5)	Illustrate the compensation to subjects for clinical trial related injuries.	K3	(6)
6)	Illustrate the ICH GCP Principles.	K3	(9)
7)	Analyze of declaration of helsinki.	K4	(8)
8)	Analyze the importance of investigational brochure.	K4	(12)
	OR		
	Analyze the selection criteria and responsibility of principle investigator.	K4	(12)