GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Biomedical Science

Master of Science in Healthcare and Clinical Research
Mid Term Examination - Nov 2023

Duration : 90 Minutes
Max Marks : 50

Sem I - Q1PM101T - Clinical Research Overview

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)	Define the Adverse Event.	K2	(2)
2)	Illustrate the Adverse drug reaction.	K1	(3)
3)	Demonstrate the five vriterias of SAE.	K2	(4)
4)	Describe the career opportunities in clinical trials.	K2	(6)
5)	Apply the different phases of trials including phase 0.	K3	(6)
6)	Utilise the ICH GCP Principles.	K3	(9)
7)	Conclusion of clinical research coordinator profile in clinical study.	K4	(8)
8)	Distinguish the unethical clinical trial happened in past.	K4	(12)
	OR		
	Distinguish the role and responsibilities of ethics committee members.	K4	(12)