GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Biomedical Science

Master of Science Clinical Research
Semester End Examination - Jun 2024

Duration : 180 Minutes
Max Marks : 100

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)	Define the Adverse Event.	K1	(2)
2)	Explain the good clinical practice.	K2	(4)
3)	Explain between protocol and investigator brochure.	K2	(6)
4)	Illustrate the importance of Indian Council of Medical Research.	K3	(9)
5)	Illustrate the documents retrieval and archival process.	K3	(9)
6)	Examine the ethical concerns during ICF process.	K5	(10)
7)	Analyze the Phase III Clinical Trial.	K4	(12)
8)	Examine the elements of informed consent.	K5	(15)
9)	Examine the European medicine agency (EMEA) guidelines.	K5	(15)
10)	Elaborate the Sponsor responsibility for maintaining the integrity clinical trial data.	K6	(18)