GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Biomedical Science

Master of Science in Medical Biotechnology
Semester End Examination - Nov 2023

Duration : 180 Minutes
Max Marks : 100

Sem III - MBAMTT3008 - Regulatory Affairs and Ethics 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 Informed consent form.	K1	(2)
2)	Demonstrate the structure of protocol.	K2	(4)
3)	Differentiate between Independent ethics committee and institutional ethics committee.	K2	(6)
4)	Utilise the responsibilities of USFDA.	K3	(9)
5)	Utilise the importance of Indian Council of Medical Research.	K3	(9)
6)	Justify the reason for terminating the clinical research.	K5	(10)
7)	Distinguish the ICMR Principles.	K4	(12)
8)	Interpret the European Agency for Evaluation of medicinal Products.	K5	(15)
9)	Interpret the documents required before the commencement of trial and during the trial.	K5	(15)
10)	Elaborate the principle investigator role and responsibilities in clinical trial.	K6	(18)