GALGOTIAS UNIVERSITY

ADMISSION NUMBER												

School of Biomedical Science

Bachelor of Science Honours in Healthcare and Clinical Research
Mid Term Examination - May 2024

Duration : 90 Minutes
Max Marks : 50

Sem II - Q1UF201T - Regulatory Affairs-I

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 monitoring.	K2	(2)
2)	Define the Major concerns that need to be covered in ICF.	K1	(3)
3)	Explain the responsibilities of Lay person and Basic scientist member.	K2	(4)
4)	Explain the responsibility of stakeholders in Clinical trial.	K2	(6)
5)	Illustrate the thalidomide disastor.	K3	(6)
6)	Illustrate the responsibilities of chairperson and member secretary.	K3	(9)
7)	Analyze and importance of documents submission for getting approval from ethics committee.	K4	(8)
8)	Analyze the NDCT 2019 implementation and India's regulatory evolution.	K4	(12)
	OR		
	Elaborate the types of essential documents and their importance in clinical research.	K4	(12)