School of Basic and Applied Sciences

BioScience

ETE - Jun 2023

Time : 3 Hours **Marks : 50**

Sem II - MBACRT2001 - Regulatory Affairs And Ethics In Clinical Research

Your answer should be specific to the question asked

Draw neat labeled diagrams wherever necessary

1.	Describe Inspection in clinical studies.	K2 CO4	(2)
2.	Describe monitoring in clinical research.	K1 CO3	(2)
3.	Describe Quality assurance in clinical trials.	K2 CO5	(2)
4.	Describe serious adverse event.	K2 CO2	(2)
5.	Define adverse drug reaction.	K1 CO1	(2)
6.	Express the 21 CFR part 11 and part 50	K4 CO6	(6)
7.	Demonstrate ethics committee composition and their roles in detail.	K3 CO1	(5)
8.	Elucidate tuskgee experiment and Nuremberg code importance.	K4 CO2	(5)
9.	Evaluate the Sponsor role to maintain the integrity and quality of clinical research.	K4 CO5	(8)
10.	Evaluate the points thet need to be mentioned under informed consent process and the necessity of it in clinical research.	K3 CO3	(8)
11.	Analyze the declaration of Helsinki and Belmont report and changes happened in clinical research industry after these two guidelines.	K4 CO4	(8)