

Name. _____		Printed Pages:01		
Student Admn. No.: _____				
School of Basic and Applied Sciences Backlog Examination, June 2023 [Programme: B.Sc. Medical Biotechnology] [Semester: IV] [Batch: 2020-23]				
Course Title: Fundamentals of Clinical Research		Max Marks: 100		
Course Code: BBBMBT4004		Time: 3 Hrs.		
Instructions:	1. All questions are compulsory. 2. Assume missing data suitably, if any.			
		K Level	COs	Marks
SECTION-A (15 Marks)		5 Marks each		
1.	What do you mean by Clinical Trial? What are the different phases of clinical trial?	K1	CO1	5
2.	Interpret what do you mean by randomization? List the advantages of randomization in clinical trial.	K2	CO2	5
3.	Differentiate between tangible and intangible property?	K1	CO3	5
SECTION-B (40 Marks)		10 Marks each		
4.	Discuss the importance of IPR	K2	CO4	10
5.	Describe briefly the different area/module of ICH guideline	K3	CO5	10
6.	Discuss the function of ICMR.	K3	CO6	10
7.	Interpret the role of ICH GCP in Clinical Trial. OR Interpret what are the different areas of harmonization covered by ICH?	K4	CO1	10
SECTION-C (45 Marks)		15 Marks each		
8.	Analyze the different types of clinical trial designs.	K4	CO2	15
9.	Discuss the different types of IPR.	K5	CO3	15
10	Describe the steps of harmonization process of ICH guidelines Or Interpret the role and responsibilities of different stakeholders in clinical trial	K5	CO4	15