Name:

Enrolment No:

UPES

End Semester Examination, December 2023

Course: Fundamentals of Clinical Research **Semester : V**

Program: Integrated BMSc FND/ Integrated BMSc Microbiology **Duration : 3 Hours**

Course Code: HSCR 30100 **Max. Marks: 100**

Instructions: Attempt all Sections

S. No.	Section A Short answer questions/ MCQ/T&F/One line answer (20Qx1.5M= 30 Marks)	Marks	COs
1	Which organization is responsible for the regulation of clinical research involving human subjects in the United States? a) FDA b) CDC c) IRB d) WHO	**1.5**	**CO1**
2	In clinical research, what is the primary purpose of Informed Consent? a) To guarantee a participant's eligibility for a clinical trial. b) To provide detailed medical treatment options to participants. c) To ensure that participants understand the study, and its risks, and voluntarily agree to participate. d) To obtain insurance coverage for research-related injuries	**1.5**	**CO2**
3	Which phase of clinical trials involves testing a new drug or treatment in a small group of healthy volunteers to evaluate its safety and dosage?	**1.5**	**CO3**
4	Good Clinical Practice (GCP) guidelines provide a standard for the conduct of clinical trials. Which international organization developed GCP guidelines?	**1.5**	**CO1**
5	The _____ is a set of ethical principles established in the aftermath of the Nuremberg Trials, which laid the foundation for ethical clinical research.	**1.5**	**CO2**
6	Define “Randomization” in clinical trials.	**1.5**	**CO3**
7	Why is blinding done in clinical trials?	**1.5**	**CO1**
8	Which government body is responsible for the registration of Ethics Committees in India? a) CDSCO b) ICMR c) DCGI d) NABH	**1.5**	**CO2**
9	The practice of conducting a clinical trial by Good Clinical Practice (GCP) guidelines is essential for ensuring the _____ of data collected. a) Confidentiality b) Validity c) Cost-effectiveness d) Publicity	**1.5**	**CO3**

10	Define “Phase 0 Trials” in Clinical Research.	**1.5**	**CO1**
11	What is preclinical study?	**1.5**	**CO2**
12	In the European Union, _____ provides scientific guidelines for medicinal products for human use.	**1.5**	**CO3**
13	Define “Diverse Population” in clinical trials.	**1.5**	**CO1**
14	In clinical research, what does "AE" stand for? a) Adverse Event b) Annual Evaluation c) Authorized Examiner d) Adverse Experiment	**1.5**	**CO2**
15	Mention the important function of IEC.	**1.5**	**CO3**
16	Define “CRF”	**1.5**	**CO1**
17	Both the USA and the EU emphasize the importance of compliance with Good Clinical Practice (GCP) guidelines to ensure the quality and _____ of clinical trial data.	**1.5**	**CO2**
18	What is post marketing surveillance?	**1.5**	**CO3**
19	Mention key stakeholders in clinical research.	**1.5**	**CO1**
20	Define “Data Safety Monitoring Boards”.	**1.5**	**CO2**
	Section B **(4Qx5M=20 Marks)**		
1	Discuss the History of Clinical Research.	**5**	**CO1**
2	Describe the constitution and purpose of an Institutional Review Board (IRB).	**5**	**CO2**
3	Design CRF for conducting clinical trials.	**5**	**CO3**
4	Explain important sections in an informed consent form.	**5**	**CO2**
	Section C **(2Qx15M=30 Marks)**		
1	a) In the context of clinical research, discuss the importance of adhering to ethical and regulatory guidelines. (5 marks) b) Explain how these guidelines ensure the safety, rights, and well-being of research participants, as well as the quality and integrity of research outcomes. (5 marks) c) Provide examples of specific guidelines or principles, such as informed consent, beneficence, and the Declaration of Helsinki, and discuss their application in clinical research to uphold the highest ethical standards." (5 marks)	**15**	**CO4**
2	a) Compare and contrast the role and importance of global clinical research guidelines, including those provided by regulatory bodies US FDA, EMA, CDSCO. (5 marks) b) Explain how these guidelines ensure ethical conduct and data integrity in clinical trials. (5 marks) c) Highlight the key components of good clinical practice (GCP) and how they contribute to the quality and reliability of research outcomes." (5 marks)	**15**	**CO5**
	Section D		

(2Qx10M=20 Marks)			
1	Discuss the role and responsibility of investigator and auditors in clinical trials.	**10**	**CO4**
2	Describe the necessary documentation in clinical research and the regulatory prerequisites.	**10**	**CO5**