Name: Enrolment No:	

UPES

End Semester Examination, December 2024

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

Program: BSc Clinical Research **Duration : 3 Hours**

Course Code: HSCR1001 **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 of the following is the primary objective of Phase I clinical trials? A) To determine the drug's efficacy. B) To assess the safety and dosage of a new drug or treatment. C) To confirm the drug's therapeutic effect. D) To monitor long-term side effects.	1.5	CO1
2	Which of the following is a historical document laid the foundation for ethical principles in clinical research involving human subjects? A) The Helsinki Declaration B) The Nuremberg Code C) The Belmont Report D) The GCP Guidelines	1.5	CO2
3	In clinical research, which regulatory body oversees drug approvals in the United States? A) EMA (European Medicines Agency) B) WHO (World Health Organization) C) FDA (Food and Drug Administration) D) NIH (National Institutes of Health)	1.5	CO3
4	The term "Informed Consent" in clinical research refers to: A) A legal contract requiring participants to complete the study. B) A process by which participants are fully educated about the study and voluntarily agree to participate. C) A form filled out after the study is completed. D) A consent given by the sponsor of the study to start a clinical trial.	1.5	CO1
5	What does GCP stand for in clinical research? A) General Clinical Protocol B) Global Clinical Practices C) Good Clinical Practice D) Guidelines for Clinical Participants	1.5	CO2
6	Which of the following is the first step in the drug discovery process? A) Clinical Trials B) Target Identification C) Lead Optimization D) Preclinical Testing	1.5	CO3
7	Which technology is commonly used in identifying potential drug targets by studying gene expression patterns? A) X-ray crystallography B) Genomics C) Mass spectrometry D) Pharmacokinetics	1.5	CO1
8	Define "Phase 0 Study".	1.5	CO2
9	What is the primary purpose of filing IND application with FDA? A) To seek approval for the marketing of a new drug B) To request permission to begin clinical trials in humans C) To obtain a patent for a new drug	1.5	CO3

	D) To conduct preclinical testing		
10	Define “Adverse Event”.	**1.5**	**CO1**
11	Which phase of drug discovery involves testing compounds in living organisms? A) Target Identification B) Preclinical Testing C) Lead Optimization D) Clinical Trials	**1.5**	**CO2**
12	The Declaration of Helsinki is primarily concerned with: A) Ethical principles for medical research involving human subjects B) Guidelines for pharmaceutical manufacturing C) Marketing strategies for new drugs D) Animal welfare in research studies	**1.5**	**CO3**
13	In Good Clinical Practice (GCP), an Institutional Review Board (IRB) is primarily responsible for: A) Reviewing study design and budgets B) Monitoring compliance with FDA regulations C) Ensuring participant protection and ethical standards D) Analyzing clinical trial data	**1.5**	**CO1**
14	What is “Informed Consent”?	**1.5**	**CO2**
15	Define the term “Randomization”.	**1.5**	**CO3**
16	The primary goal of ICH E6 (R2) Good Clinical Practice guidelines is to: A) Improve the speed of clinical trial approvals B) Ensure the safety, rights, and well-being of trial participants C) Decrease the cost of drug development D) Promote rapid data analysis	**1.5**	**CO1**
17	Blinding in a clinical trial is primarily used to: A) Prevent patient dropout B) Eliminate selection bias C) Prevent the influence of participants' and researchers' expectations on study outcomes D) Ensure all participants receive the treatment	**1.5**	**CO2**
18	Define “Placebo Treatment” in clinical research.	**1.5**	**CO3**
19	In India, clinical trials are regulated by which organization? A) Food and Drug Administration (FDA) B) Medicines and Healthcare products Regulatory Agency (MHRA) C) Central Drugs Standard Control Organization (CDSCO) D) European Medicines Agency (EMA)	**1.5**	**CO1**
20	High-throughput screening (HTS) in drug discovery is primarily used to: A) Analyze clinical trial data B) Identify and select lead compounds C) Conduct toxicity testing D) Synthesize potential drugs	**1.5**	**CO2**
Section B (4Qx5M=20 Marks)			
1	Explain the primary objectives of clinical trial regulations.	**5**	**CO1**

2	Discuss the historical evolution of clinical research.	**5**	**CO2**
3	Name the essential documents required for IND application process.	**5**	**CO3**
4	Discuss the composition of Institutional Ethics Committee.	**5**	**CO2**
	Section C **(2Qx15M=30 Marks)**		
1	**A pharmaceutical company is conducting a Phase II clinical trial to test the efficacy of a new pain medication. The trial is double-blind, randomized, and involves two groups: one receiving the experimental drug and the other receiving a placebo. The research team decided to use random number generation to allocate participants to these groups. They use a standard random number table for the task. However, the allocation process is done manually by the trial coordinators, who sometimes experience delays in generating random numbers during the enrollment process.** 1. Explain the importance of random number generation in the randomization process of clinical trials. (5 marks) 2. What are the potential risks associated with manually generating random numbers in this case? (5 marks) 3. Discuss the role of computerized random number generators (CNRGs) in improving the randomization process. (5 marks)	**15**	**CO4**
2	**A clinical trial is being conducted in a country where the majority of participants speak a language other than English. The trial documents, including the informed consent form (ICF), are provided only in English. Some participants struggle to understand the terms and implications of the informed consent process due to language barriers.** 1. Discuss the potential issues related to obtaining informed consent in a non-English-speaking population. (5 marks) 2. What steps should the research team take to ensure that participants fully understand the consent form and the study? (5 marks) 3. How can researchers mitigate language barriers during the consent process to ensure that participants are making informed decisions? (5 marks)	**15**	**CO5**
	Section D **(2Qx10M=20 Marks)**		
1	Outline the key elements that must be included in a clinical research protocol and discuss how these elements contribute to the scientific integrity and ethical soundness of a clinical trial.	**10**	**CO4**
2	Given a population of 10,000 individuals, an estimated disease prevalence of 10%, and a desired margin of error of 3%, calculate the required sample **size** for a study to estimate the prevalence of this disease with 95% confidence. Use the formula for sample size in prevalence studies and show all calculations. **Or** Explain the Drug Discovery Process.	**10**	**CO5**