Name:

Enrolment No:

UPES

End Semester Examination, May 2025

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

Program: B.Sc. (Microbiology)/B.Sc. (Food, Nutrition and Dietetics) **Duration : 3 Hours**

Course Code: HSCR1005P **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 phase of clinical trials primarily focuses on the safety of a drug in healthy volunteers? A. Phase I B. Phase II C. Phase III D. Phase IV	**1.5**	**CO1**
2	The document that describes the objectives, design, methodology, statistical considerations, and organization of a clinical trial is called a _____.	**1.5**	**CO2**
3	True or False: Good Clinical Practice (GCP) guidelines are legally binding in all countries.	**1.5**	**CO3**
4	Which of the following is NOT a stakeholder in clinical research? A. Sponsor B. Investigator C. Pharmacist not involved in the trial D. Ethics Committee	**1.5**	**CO2**
5	Define the term “Adverse Event”.	**1.5**	**CO3**
6	Which of the following is an observational study? A. Randomized Controlled Trial B. Cohort Study C. Phase II Clinical Trial D. Case-Controlled Trial	**1.5**	**CO1**
7	The _____ Report of 1979 outlined basic ethical principles for conducting research involving human subjects.	**1.5**	**CO2**
8	True or False: Interventional studies always involve a control group.	**1.5**	**CO3**
9	Which unethical study led to the development of the Nuremberg Code? A. Willowbrook Hepatitis Study B. Milgram Obedience Study C. Tuskegee Syphilis Study	**1.5**	**CO1**

	D. Nazi Medical Experiments		
10	……provides international ethical guidelines for conducting biomedical research on human subjects.	**1.5**	**CO2**
11	True or False: The Institutional Review Board (IRB) is responsible for ensuring participant safety and ethical conduct in a clinical trial.	**1.5**	**CO2**
12	The first step in drug discovery involves: A. Clinical Trials B. Target Identification C. IND Filing D. Market Approval	**1.5**	**CO3**
13	What is the main purpose of using animal models in preclinical research?	**1.5**	**CO1**
14	Which regulatory body in the USA reviews and approves IND applications? A. EMA B. WHO C. FDA D. CDC	**1.5**	**CO2**
15	A molecule that interacts with a biological target and shows potential therapeutic effects is referred to as a _____ compound.	**1.5**	**CO3**
16	True or False: Pharmacodynamic involves studying how the body affects a drug, including absorption, distribution, metabolism, and excretion.	**1.5**	**CO1**
17	Define the term “Randomization”.	**1.5**	**CO2**
18	What are primary and secondary endpoints in clinical research?	**1.5**	**CO3**
19	Phase IV clinical trials are conducted: A. Before human testing B. After market approval C. In animals only D. During dose selection	**1.5**	**CO1**
20	Define the term “Vulnerable Population”.	**1.5**	**CO2**
Section B (4Qx5M=20 Marks)			
1	Explain the objectives of (Microdosing, Phase I to Phase IV) Clinical Trial Phases.	**5**	**CO1**
2	Discuss the concept of randomization and blinding in clinical trials.	**5**	**CO2**
3	Illustrate with example Primary, Secondary and Tertiary endpoints.	**5**	**CO3**
4	Explain the key steps involved in designing a clinical research protocol.	**5**	**CO2**
Section C (2Qx15M=30 Marks)			

1	Dr. Mehta is conducting a Phase II clinical trial to evaluate the dose-ranging efficacy and safety of a new oral medication for type 2 diabetes. Early preclinical data and Phase I results show good tolerability. Dr. Mehta's team is now recruiting patients with uncontrolled blood glucose levels. Questions: a. Mention the key objectives of a Phase II clinical trial, and what endpoints should be considered to evaluate the drug's efficacy and safety? (3 marks) b. Explain how Dr. Mehta selects an appropriate sample size for this Phase II trial. (4 marks) c. Discuss the challenges in patient recruitment and retention for Phase II trials, and how they can be mitigated. (4 marks) d. Describe how adverse events can be monitored and reported effectively during the trial? (4 marks)	**15**	**CO4**
2	Dr. Kapoor is leading a multicenter, randomized, double-blind Phase III clinical trial to evaluate the efficacy of a newly developed dengue vaccine across regions with high infection rates. The trial involves participants of varying ages and health statuses. Questions a. Mention trial design elements that Dr. Kapoor should consider for ensuring consistent implementation across all trial sites. (3 marks) b. Explain the responsibilities of the trial sponsor and investigator under ICH-GCP guidelines in a multicenter study? (4 marks) c. Discuss the challenges that might arise in ensuring cold-chain logistics and protocol adherence in remote or resource-limited settings. (4 marks) d. Describe the role of Independent Ethics Committees (IECs) in conducting vaccine trial. (4 marks)	**15**	**CO5**
Section D **(2Qx10M=20 Marks)**			
1	Describe different data collection methods used in clinical research.	**10**	**CO4**
2	Compare and contrast different types of epidemiological study designs. Discuss their key features, advantages, limitations, and suitable examples.	**5+5**	**CO5**