Name:

Enrolment No:

UPES

End Semester Examination, December 2023

Course: Global Regulations of Clinical Trials **Semester : III**

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

Course Code: HSCR 2008 **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	Schedule Y is a set of regulations in India that govern the conduct of _____ clinical trials. a. Pharmaceutical b. Medical device c. Both a and b d. None of the above	**1.5**	**CO1**
2	The ethical considerations in clinical research include ensuring _____ and _____ of study participants. a. Privacy; confidentiality b. Financial disclosure; informed consent c. Biostatistics; data analysis d. IND; NDA	**1.5**	**CO2**
3	The FDA's Center for Drug Evaluation and Research (CDER) is responsible for the review and evaluation of _____ applications	**1.5**	**CO3**
4	ICH E4 provides guidance on dose-response information to support _____ registration.	**1.5**	**CO1**
5	E7 offers guidance on conducting studies in support of the _____ population, focusing on specific considerations for the elderly. a. Pediatric b. General c. Adolescent d. Geriatric	**1.5**	**CO2**
6	General considerations for clinical trials, including design and conduct, are addressed in ICH _____. a. E4 b. E7 c. E8 d. E10	**1.5**	**CO3**
7	CFR 21 Part 50 provides regulations for the protection of _____ in clinical research. a. Animals b. Data c. Human subjects d. Informed consent	**1.5**	**CO1**
8	The principle of _____ in clinical research involves disclosing any potential conflicts of interest by clinical investigators.	**1.5**	**CO2**

	a. Non-disclosure b. Financial disclosure c. Privacy d. Biostatistics		
9	CFR 21 Part 312 pertains to the submission of an Investigational New Drug (IND) application to the _____. a. US FDA b. ICMR c. CDSCO d. WHO	**1.5**	**CO3**
10	The IND application includes data on _____, pharmacology, toxicology, and human experience with the investigational drug. a. Financial disclosure b. Informed consent c. Biostatistics d. Safety and efficacy	**1.5**	**CO1**
11	CFR 21 Part 314 is concerned with the application for FDA approval to market a _____. a. New medical device b. Generic drug c. New drug d. Biologic	**1.5**	**CO2**
12	The NDA submission process involves a comprehensive review of data from _____ trials and other sources. a. Post-marketing b. Pre-IND c. Investigational d. Generic drug	**1.5**	**CO3**
13	CFR 21 Part 320 focuses on bioavailability and _____ requirements for drug products. a. Safety b. Efficacy c. Bioequivalence d. Privacy	**1.5**	**CO1**
14	Bioavailability studies assess the _____ of an administered drug product compared to a reference standard. a. Absorption b. Financial disclosure c. Informed consent d. Biostatistics	**1.5**	**CO2**
15	Match the regulatory body with its role in clinical research in India: A. DCGI i. Approves clinical trials B. CDSCO ii. Sets guidelines for ethics in research C. ICMR iii. Regulatory authority for the USA D. US FDA iv. Regulates medical device clinical trials	**1.5**	**CO3**
16	True or False: Biomedical research involving vulnerable populations, such as children or prisoners, is subject to the same ethical considerations as research involving non-vulnerable populations. a. True b. False	**1.5**	**CO1**
17	In the review process, an ethics committee evaluates whether the potential benefits of a research study outweigh the _____. a. Potential conflicts of interest b. Autonomy of participants c. Risks and potential harms d. Scientific validity of the research	**1.5**	**CO2**
18	How will you define randomization-controlled trials in clinical studies?	**1.5**	**CO3**

19	Mention any two factors that has to be considered while doing clinical trials in pediatric population.	**1.5**	**CO1**
20	True or False : The confidentiality of information that could identify participants should be protected in accordance with applicable privacy and data protection regulations. (a) True (b) False	**1.5**	**CO2**
	Section B **(4Qx5M=20 Marks)**		
1	Discuss the importance of biostatistics principles in clinical research with examples.	**5**	**CO1**
2	Describe the concept of financial disclosure by clinical investigators as outlined in CFR 21 Part 54.	**5**	**CO2**
3	Explain factors that FDA should consider when assessing the safety and efficacy of a new drug.	**5**	**CO3**
4	Describe how pharmacokinetic studies helps in ensuring the quality of generic drugs.	**5**	**CO2**
	Section C **(2Qx15M=30 Marks)**		
1	Case Study 3: Protection of Human Subjects and Informed Consent Scenario: You are a clinical research coordinator at a major academic medical center, overseeing a clinical trial for a potentially life-saving medical device. The study involves adult patients with a severe, rapidly progressing disease for which there are limited treatment options. The trial has been well-designed and approved by the institutional review board (IRB). However, during the informed consent process, a participant expresses doubts about participating, stating they feel coerced (forced) to join due to a lack of alternative treatments. Questions: 1. How should you address the participant's concerns regarding feeling coerced? What ethical principles and guidelines should guide your response? (5 marks) 2. Explain the role and responsibilities of the institutional review board (IRB) in ensuring the ethical conduct of clinical trials. How can the IRB help address the participant's concerns? (5 marks) 3. Discuss the elements that constitute a valid informed consent process and the importance of voluntary participation in clinical research. (5 marks)	**15**	**CO4**
2	Case Study 4: Regulatory Challenges in Global Clinical Trials Scenario: You are a regulatory affairs specialist at a multinational pharmaceutical company planning to conduct a global clinical trial for a novel vaccine. The trial aims to assess the vaccine's efficacy in preventing a highly contagious and potentially deadly disease. Your company has secured approval from regulatory authorities in the home country and is seeking approvals from multiple countries to expand the trial. During the process, you encounter variations in regulatory requirements and differing timelines for approvals.	**15**	**CO5**

	Questions: 1. Describe the key challenges and complexities associated with conducting global clinical trials across multiple countries with varying regulatory requirements. (5 marks) 2. Explain the significance of harmonization efforts and international guidelines in facilitating global clinical research. How can these efforts address regulatory challenges? (5 marks) 6. Discuss the ethical considerations when conducting clinical trials in regions with limited access to healthcare and research resources. How can these concerns be addressed during the planning and execution of global trials? (5 marks)		
Section D **(2Qx10M=20 Marks)**			
1	Discuss the critical elements of an informed consent form in clinical research, emphasizing the importance of clear and comprehensive communication with research participants. Explain how the informed consent process can be improved to enhance participant understanding and autonomy.	**10**	**CO4**
2	Outline the stages of the drug development process, from preclinical studies to post-marketing surveillance. Discuss the key regulatory milestones and requirements at each stage, emphasizing their impact on drug approval.	**10**	**CO5**