Name: **Enrolment No:**	

UPES

End Semester Examination, December 2023

Course: Ethics in Clinical Research **Semester : III**

Program: Integrated BMSc Clinical Research **Duration : 3 Hours**

Course Code: HSCR 2016 **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	What is the primary objective of Phase 2 clinical trials?	**1.5**	**CO1**
2	The Nuremberg Code was developed in response to: a. The Tuskegee Syphilis Study b. The Thalidomide study c. The Nuremberg Trials of Nazi physicians d. The Declaration of Helsinki	**1.5**	**CO2**
3	Define the term “Vulnerable population” in Clinical Trials.	**1.5**	**CO3**
4	The Declaration of Helsinki provides ethical guidelines for: a. Conducting experiments on animals b. Environmental research c. Medical research involving human subjects d. Social science research	**1.5**	**CO1**
5	What was the primary goal of developing ICH-GCP guidelines? a. Promote competition among pharmaceutical companies b. Establish common standards for the conduct of clinical trials c. Replace regional regulations with a global standard d. Expedite drug approval processes	**1.5**	**CO2**
6	What is the primary purpose of obtaining informed consent in a clinical trial? a. To force participants to join the study b. To ensure participants are aware of all potential risks c. To protect the rights and well-being of research participants d. To exclude participants from withdrawing from the study	**1.5**	**CO3**
7	Define “Placebo Effect” in Clinical Trials.	**1.5**	**CO1**
8	What additional ethical considerations apply when conducting research involving children or minors? a. Children should never be involved in research studies b. Informed consent should be obtained from the child's legal guardian	**1.5**	**CO2**

	c. Children can provide informed consent independently if they are deemed mature minors d. Ethical considerations do not differ when involving children in research		
9	Clinical research in special populations should address: a. Potential exploitation and ensure equitable access to research opportunities b. Maximum profits for pharmaceutical companies c. Exclusion of vulnerable groups from research d. Ethical considerations are not relevant for special populations	**1.5**	**CO3**
10	What does NDA stand for in the context of the FD&C Act? a. New Drug Application b. National Drug Association c. Novel Drug Authorization d. New Drug Assessment	**1.5**	**CO1**
11	Define “Generic drugs”. Give example	**1.5**	**CO2**
12	What is the primary purpose of the FDA's acceptance of foreign clinical studies? a. To encourage outsourcing of clinical research b. To harmonize clinical trial regulations worldwide c. To ensure the safety and efficacy of medical products in the U.S. d. To expedite the drug approval process for domestic companies	**1.5**	**CO3**
13	The primary target audience of the FDA Clinical Trials Guidance Document for Good Clinical Practice includes: a. Healthcare providers b. Patients participating in clinical trials c. Sponsors, investigators, and institutional review boards (IRBs) d. Regulatory authorities and stakeholders alike	**1.5**	**CO1**
14	The European Medicines Agency (EMA) is responsible for regulating: a. Clinical research in the United States b. Clinical trials conducted worldwide c. Medicines and medical devices in the European Union d. Pharmaceutical manufacturing practices	**1.5**	**CO2**
15	Which organization is responsible for issuing the Ethical Guidelines for Biomedical Research? a. World Health Organization (WHO) b. Indian Council of Medical Research (ICMR) c. U.S. Food and Drug Administration (FDA) d. European Medicines Agency (EMA)	**1.5**	**CO3**
16	Define the important role of CDSCO in clinical trials.	**1.5**	**CO1**
17	What is the main objective of the ICH guidance documents regarding efficacy and safety? a. To establish globally accepted standards for drug approval b. To prioritize speed over safety in drug development c. To discourage international cooperation in pharmaceutical research d. To minimize regulatory oversight and ethical considerations	**1.5**	**CO2**
18	What does "IND" stand for in the context of FDA requirements? a. Investigational New Drug b. International New Drug	**1.5**	**CO3**

	c. Investigational New Data d. Individual New Drug		
19	What is the primary purpose of FDA Med Watch? a. To promote the use of unapproved drugs b. To facilitate the sale of counterfeit medicines c. To collect and disseminate information about adverse events and product complaints d. To streamline the drug approval process for pharmaceutical companies	**1.5**	**CO1**
20	What does "GVP" stand for in the context of pharmaceutical guidance? a. General Vaccine Protocol b. Good Vaccine Practices c. Good Pharmacovigilance Practices d. Global Vaccine Promotion	**1.5**	**CO2**
	Section B **(4Qx5M=20 Marks)**		
1	Explain the significance of the Good Clinical Practice Guidelines (ICH GCP E6) in the context of global clinical trials.	**5**	**CO1**
2	Describe the key principles of the ICMR Ethical Guidelines for Biomedical Research.	**5**	**CO2**
3	Discuss the ethical violations and lessons learned from the Tuskegee Syphilis Study.	**5**	**CO3**
4	Compare and contrast the key ethical principles outlined in The Belmont Report and The Declaration of Helsinki.	**5**	**CO2**
	Section C **(2Qx15M=30 Marks)**		
1	A contract research organization (CRO) is conducting a Phase II clinical trial on behalf of a pharmaceutical sponsor. During the trial, a participant experiences a severe adverse event that was previously unknown. The adverse event is not mentioned in the informed consent form, as it was not foreseen. The participant is now concerned about the safety of the trial and the adequacy of informed consent. 1. What do you understand by Severe Adverse Event? (4 marks) 2. How should the CRO and the sponsor respond to the participant's concerns while ensuring adherence to GCP guidelines and the ethical conduct of the trial? (5 marks) 3. What actions can be taken to address unexpected adverse events and enhance participant safety while respecting the principles of informed consent? (6 marks)	**15**	**CO4**
2	A research institution in India is conducting a clinical trial to test a potential treatment for a rare genetic disorder. The trial includes participants who are children with the disorder. The parents of some participants have limited education and may not fully comprehend the implications of their child's involvement in the trial. The research team is struggling to obtain fully informed consent due to language and educational barriers. Ques 1. Design the Informed Consent Form for this study. (4 marks) Ques 2. How can the research institution address the challenges related to obtaining informed consent from parents with limited education, while still complying with Indian regulations and ensuring the ethical conduct of the trial? (5 marks)	**15**	**CO5**

	Ques 3. What steps should be taken to ensure that participants, particularly those from vulnerable populations, fully understand the nature and risks of their participation in the trial? (6 marks)		
Section D (2Qx10M=20 Marks)			
1	Discuss in detail about ISO 14155 regulation. Describe the role of regulatory authorities in assessing compliance with ISO 14155.	**10**	**CO4**
2	Explain the objectives and key functions of the FDA Med Watch program. Discuss the significance of healthcare professionals, patients, and pharmaceutical companies reporting adverse events and product complaints to Med Watch	**10**	**CO5**