Name:

Enrolment No:

UPES

End Semester Examination, December 2023

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

Program: B.Sc. Clinical Research **Duration: 3 Hours**

Course Code: HSCR2006 **Max. Marks: 100**

Instructions:

1. **This question paper consists of four sections.**
2. **All sections are compulsory.**
3. **Attempt all questions.**

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q1	State any **THREE** ethical responsibilities of clinical researchers.	**1.5**	**CO1**
Q2	List any **THREE** international codes/guidelines for ethical conduct of research.	**1.5**	**CO2**
Q3	Discuss any **TWO** important principles of ethical framework for research on human subjects.	**1.5**	**CO1**
Q4	Discuss "social value" in context of ethics of research.	**1.5**	**CO3**
Q5	Explain the meaning of "fair subject selection" as per the principles of ethical framework.	**1.5**	**CO3**
Q6	State the objectives of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).	**1.5**	**CO4**
Q7	List any **THREE** topics of guidelines produced by ICH.	**1.5**	**CO4**
Q8	State any **THREE** sections included in ICH GCP.	**1.5**	**CO4**
Q9	State the purpose of 505(b) (1) pathway of the US FD&C act.	**1.5**	**CO2**
Q10	List any **THREE** clinical trial guidelines applicable in India.	**1.5**	**CO2**
Q11	State any **THREE** responsibilities of Drugs Controller General of India (DCGI).	**1.5**	**CO3**
Q12	Define category A clinical trials as per the categorisation of clinical trials by DCGI.	**1.5**	**CO3**

Q13	List any **THREE** objectives of GHTF.	**1.5**	**CO5**
Q14	Define analytical performance of an in vitro diagnostic (IVD) medical device.	**1.5**	**CO5**
Q15	Explain the objectives of Drugs and Cosmetics Act 1940.	**1.5**	**CO3**
Q16	List any **THREE** sets of data to be submitted with form 44 of schedule Y of Drugs and Cosmetics Act 1940 for permission to import and/ or manufacture of new drugs for sale or to undertake clinical trials.	**1.5**	**CO3**
Q17	Define Clinical performance of an IVD medical device.	**1.5**	**CO5**
Q18	List any **THREE** categories of products covered under FDA MedWatch program.	**1.5**	**CO4**
Q19	Define EudraLex.	**1.5**	**CO4**
Q20	Define clinical research organisation (CRO) as specified in ICH GCP.	**1.5**	**CO4**
	Section B **(4Qx5M=20 Marks)**		
Q1	Discuss "Tuskegee Syphilis Study" as an example of unethical research.	**5**	**CO1**
Q2	Discuss any **FIVE** guidelines covered by Nuremberg Code of ethics 1949.	**5**	**CO1**
Q3	Summarise the history of evolution of ICH.	**5**	**CO4**
Q4	Describe the objectives of ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.	**5**	**CO2**
	Section C **(2Qx15M=30 Marks)**		
Q1	Discuss any **TEN** principles stated in ICH GCP guidelines.	**15**	**CO4**
Q2	Illustrate the decision-tree/flowchart for clinical performance study design as per GHTF study group 5 guidance documents.	**15**	**CO5**
	Section D **(2Qx10M=20 Marks)**		
Q 1	Discuss in detail the content of investigators brochure as per ICH GCP guidelines.	**10**	**CO3**
Q2	Differentiate EU-CTD and EU-CTR pathways for carrying out clinical trials in member states of the European Union.	**10**	**CO2**