Name: **Enrolment No:**	UPES UNIVERSITY OF TOMORROW

UPES

End Semester Examination, December- 2024

Course: Good Clinical Practice: Conducting Clinical Trials **Semester: V**

Program: Integrated B.Sc., M.Sc.- Clinical Research **Duration : 3 Hours**

Course Code: HSCR 3012 **Max. Marks: 100**

Instructions: Read all the questions carefully.

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q1.	Name the person responsible for the conduct of the clinical trial at a trial site…… A) Clinical Research Coordinator B) Monitor C) Investigator D) Sponsor	1.5	CO1
Q2.	State the principle 10 of GCP.	1.5	CO1
Q3.	The full form of DSMB is …….	1.5	CO1
Q4.	Express what do you mean by Good Clinical Practices?	1.5	CO1
Q5.	State and define the principle 1 of GCP.	1.5	CO1
Q6.	In how many phases clinical research study is conducted? A) 1 B) 4 C) 5 D) 3	1.5	CO1
Q7.	In clinical research studies, conflict of interest is a risk factor for scientific misconduct. A) True B) False	1.5	CO1
Q8.	Adverse Drug Reaction reporting is mandatory during clinical trials. A) True B) False	1.5	CO1
Q9.	According to the principles of ICH GCP, what is the most important consideration when conducting a clinical trial? A) Data accuracy B) Protection of trial subjects C) Process adherence D) Statistical quality checks	1.5	CO2
Q10.	Define an Adverse Event (AE).	1.5	CO2

Q11.	State the document created in 1964, Which forms the basis of ethical considerations in clinical research? A) Declaration of Belfast B) Declaration of Helsinki C)Declaration of Geneva D) None of the above	1.5	CO3
Q12.	An IRB stand for……...? A) Investigational Review Board B) Internal Review Board C)Institutional Review Board D) International Review Board	1.5	CO3
Q13.	An ICH stand for? A) International Convention on Homogenization B) International Conference on Harmonisation C) International Conference on Homogenization D) International Convention on Harmonisation	1.5	CO3
Q14.	According to ICH GCP the investigator should be qualified by..... A) Training and experience B) Education and training C) Education and experience D) Education, training and experience	1.5	CO3
Q15.	A clinical trial must have IRB/IEC approval before it can begin. A) True B) False	1.5	CO3
Q16.	In which case should a risk/benefit determination need to be performed?	1.5	CO4
Q17.	The primary function or role of the IRB is to safeguard ……. by training researchers in research ethics and best practices and reviewing research proposals. A) Human subject B) Rights C) Clinical research D) Education	1.5	CO4
Q18.	State the meaning of "beneficence" under Good Clinical Practices.	1.5	CO4
Q19.	Write the full form of CIOMS.	1.5	CO5
Q20.	The full form of CFR is …….	1.5	CO5
	Section B **(4Qx5M=20 Marks)**		
		5	
Q1.	Discuss the process of Informed consent of vulnerable population in clinical trials.	**(2+3)**	CO1

Q2.	Explain the meaning of "respect for persons" according to the Belmont Report; CIOMS Guidelines and how is it most directly implemented within GCP?	**5**	CO2
Q3.	Illustrate how clinical research is ethically challenging. Enlist the information that should be included in a study protocol.	**(2+3)**	CO2
Q4.	Categorize different vulnerable populations and their consent process for clinical trial conduct.	**5**	CO3
Section C **(2Qx15M=30 Marks)**			
		15	
Q1.	***Case study A:*** *In 2002, Novo Nordisk conducted a large Phase III clinical trial in 32 countries, including India, for the drug Ragaglitazar, which was a treatment option for diabetes. Approximately 2,500 subjects were enrolled in the trial all over the world, including the EU and USA. However, the drug was not fully tested on animals.* **Question I.** Has there been a compliance with ethical guidelines. Share your opinion. **Question II.** Should this Phase III trial be suspended? Justify your answer. ***Case study B:*** *In Trivandrum, the Kerala Regional cancer treatment center conducted a clinical trial for the drug Nordihydroguaiaretic acid (NDGA) for the treatment of oral cancer during 1999-2000. The sponsor of the trial was Johns Hopkins University Hospital. The drug was administered to 26 patients before the animal safety was known; moreover, patients were not informed that they were taking part in a trial and that they can deny participation. Two patients died in this trial.* **Question III.** What are the various ethical violations made in this trial? **Question IV.** Who should be blamed for such violations?	**(3+4+4+4)**	CO4
Q2.	***Case study A:*** *The drug Letrozole was approved all over the world for the treatment of breast cancer in post-menopausal women but was never authorized for any other indication in India. In 2003, Sun Pharmaceutical conducted a clinical trial of Letrozole for the treatment of inducing ovulation. The USFDA and British Authority had already labeled Letrozole as embryotoxic, fetotoxic, and teratogenic at minuscule doses. At more than 9*	**(3+4+4+4)**	CO4

	centers across India, approximately 300 women were enrolled in this trial without their prior knowledge or consent. The trial was conducted without any permission from the DCGI, and animal testing was also not done for a new indication. Moreover, it was conducted by an investigator who just had a diploma in gynecology. **Question I.** Was this trial ethical as per various regulatory guidelines? Justify your answer with respect to merits (if yes) or violations (if no). **Question II.** What are the various ethical violations made in this trial? ***Case study B:*** *In 2009, many people in the Maharaja Yashwantrao Public hospital were* *unknowingly enrolled in the clinical trial for Tonapofylline, a drug developed by Biogen Idec. Most of the patients were poor and illiterate and were informed that some charity was going to pay for their expensive treatments. Some of the patients in this trial suffered cardiac arrest and seizures.* **Question III.** Was this trial ethical as per various regulatory guidelines? Justify your answer with respect to merits (if yes) or violations (if no). **Question IV.** What are the various types of ethical violations made in this trial?		
Section D **(2Qx10M=20 Marks)**			
		10	
Q1.	Describe the organization of ICH. Discuss on the ICH process for guidelines development.	(6+4)	CO3
Q2.	Discuss the composition of the IRB. What are the types of IRB review process? Explain any one with suitable example.	(3+3+4)	CO5