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.	The full form of CFR is ……	1.5	CO1
Q2.	The full form of IEC is ……	1.5	CO1
Q3.	Document mandatory to enroll the human subject in a clinical research study is…… A) Protocol B) Case Report Form C) Informed Consent Form D) Investigators Brochure D)	1.5	CO1
Q4.	Preclinical studies are conducted on animals and artificial cells in labs. A) True B) False	1.5	CO1
Q5.	To begin with a clinical research study, it is mandatory to get approval from…… A) Sponsor B) Investigator C) Regulator D) Both Regulators and Ethics committee	1.5	CO1
Q6.	Name the person responsible for preparing essential documents like protocol/ investigators brochure/ informed consent form/ case report form during clinical trials. A) Investigator B) Ethics committee C) Scientist D) Sponsor	1.5	CO1
Q7.	The full form of DSMB is ……	1.5	CO1
Q8.	State and define the principle 1 of GCP.	1.5	CO1
Q9.	In how many phases clinical research study is conducted? A) 1 B) 4 C) 5 D) 3	1.5	CO2

Q10.	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	CO2
Q11.	State the principle 4 of GCP.	1.5	CO2
Q12.	An IRB stand for……...? A) Investigational Review Board B) Internal Review Board C)Institutional Review Board D) International Review Board	1.5	CO2
Q13.	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
Q14.	The ICH was founded in the ……. (year) and at …… (place).	1.5	CO2
Q15.	The Federal law allows for human-subject research of minimal risk to be exempt from IRB review. A) True B) False	1.5	CO3
Q16.	Adverse Drug Reaction reporting is mandatory during clinical trials. A) True B) False	1.5	CO3
Q17.	The IRB is one part of the research enterprise designated to protect human subjects. A) True B) False	1.5	CO3
Q18.	The CIOMS was formed in the year……. A) 1945 B) 1947 C) 1949 D)1990	1.5	CO3
Q19.	Write the full form of CIOMS	1.5	CO3
Q20.	The federal policy requires that an IRB have at least …… A) 3 members B) 4 members B) 5 members D) 6 members	1.5	CO4
	Section B **(4Qx5M=20 Marks)**		
		5	
Q1.	Describe the meaning of "respect for persons" according to the Belmont Report; CIOMS Guidelines and how is it most directly implemented within GCP?	(5)	CO1

Q2.	Outline the process of Blinding / Masking in the clinical trial. State what makes clinical research ethical?	(2+3)	CO1
Q3.	Categorize different vulnerable populations and their consent process for clinical trial conduct.	(5)	CO3
Q4.	State the composition of IRB? Describe the main responsibilities of IRB.	(2+3)	CO5
Section C **(2Qx15M=30 Marks)**			
		15	
Q1.	***Case study A:*** *Two leading Indian companies, namely Biocon (Insulin) and Shantha Biotechnics (Streptokinase), conducted a Phase III trial in Hyderabad. The trial was for recombinant insulin and streptokinase for the treatment of clot-busting in heart attack and diabetes. Companies conducted this trial without obtaining approval from Genetic Engineering Approval Committee. Moreover, they did not inform patients about the trial, which unfortunately led to the death of eight patients.* **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. This trial was later suspended.* **Question III.** Discuss the reasons of the trial suspension? **Question 1V.** Point out the personnel who are to be blamed for trial suspension?	(3+4+4+4)	CO4
Q2.	***Case study A:*** *In an asthmatic trial at Maharaja Yashwantrao Public Hospital, an inhaler was to be evaluated. During the trial, as a side-effect patients started to lose their sight and developed cataracts. Doctors in the hospital removed the cataracts, but those who took part in the trial were unaware of the side effects in the first place. A person (practicing as a doctor in the hospital and served as a*	(3+4+4+4)	CO4

	whistle-blower) determined that some patients were visiting the hospital regularly and were given special attention. Subsequently, he realized that these patients were enrolled in clinical trials, but most of them did not know that they were taking part in clinical trials. They were told by investigators that the drugs being given to them were new from foreign countries and were not available in the market, so they had to take it from the hospital. The patients were also told that a charity foundation was funding their treatment cost. The whistle-blower *saw thumbprints on consent forms that were written in English. The doctors of this hospital chose poor, illiterate, and ill patients who were in need of medicine. From all these trials, a total of 81 patients, including 18 children, suffered from serious adverse events while 35 patients died.* **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.** State the various ethical violations made in this trial? ***Case study B:*** *In another case of the Maharaja Yashwantrao Public Hospital involved a three-day-old baby, who was given a testing vaccine. The family signed a form written in English, which they did not understand and were informed that polio vaccine was being administered to the baby so, they had no idea that the doctor was giving her an experimental vaccine. The baby had seizures and bronchitis attacks after receiving the vaccine and subsequently, suffered from breathing and eating problems. The family was told that these problems were not due to the vaccine even though they probably were.* **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.** State the various ethical violations 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