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

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, December 2022

Course: Fundamentals of Clinical research **Semester: III**
Program: Integrated B.Sc.+M.Sc. (Clinical Research) **Time : 03 hrs.**
Course Code: HSCR2013 **Max. Marks: 100**

Instructions: Attempt all the questions

Q.No	Section A Short answer questions/ MCQ/T&F	(20Q x1.5M= 30 Marks)	COs
Q	Attempt all the questions		CO
1.	Sponsor in a clinical is responsible for a) Reviewing the documents b) Initiating the study c) Funding the study d) Both b & c	1.5	CO1
2.	IND application is filed b) Before clinical trial b) After clinical trial c) Before preclinical trial d) After post-marketing	1.5	CO3
3.	Which of the following is/are the limitation/s of biomarker? a) Complex analysis process b) Time consuming c) Expensive d) All of the above	1.5	CO2
4.	Which of the following studies are conducted in preclinical studies? a) Teratogenicity b) Carcinogenicity c) Mutagenicity d) All of the above	1.5	CO1
5.	Case-control study calculates a) Rate ratio b) Risk ratio c) odd ratio d) Prevalence ratio	1.5	CO1
6.	Which of the following is not a type of Information bias a) Observer bias	1.5	CO3

	b) Recall bias c) Misclassification bias d) Overdiagnosis bias		
7.	Which of the followings is not a type of Probability sampling? a) Simple random sampling b) Cluster sampling c) Stratified sampling d) Convenience sampling	1.5	CO3
8.	Which of the following sampling method is the easiest to conduct? a) Simple random sampling b) Systematic random sampling c) Cluster random sampling d) Startified random sampling	1.5	CO3
9.	What is the Declaration of Helsinki statement?	1.5	CO3
10.	Post-marketing surveillance comes under which phase of clinical trial?	1.5	CO5
11.	Define an Interventional study.	1.5	CO3
12.	Which 3 regions are the members of ICH?	1.5	CO3
13.	Which guideline of ICH deals about Pharmacopeia?	1.5	CO4
14.	What do you understand by Quality control?	1.5	CO2
15.	What's your understanding about Essential Documents for the conduct of a Clinical Trial?	1.5	CO3
16.	What is the difference between Audit and Investigation?	1.5	CO2
17.	What do you understand by Emerging market in Pharmaceutical Industry?	1.5	CO5
18.	What is prevalence ratio?	1.5	CO3
19.	What is the meaning of Justice in Belmont report?	1.5	CO4
20.	What is the role of FDA and where it is located?	1.5	CO4
	Section B	**(4Qx5M=20 Marks)**	CO
Q	Attempt all the questions		

1.	Mention the roles and responsibilities of Contract Research Organization.	5	CO1
2.	Write down the characteristics of an ideal biomarker.	5	CO2
3.	Differentiate between Cross-sectional and Cohort study.	5	CO3
4.	Discuss about the principles of Belmont report.	5	CO4
	Section C	**(2Qx15M=30 Marks)**	
Q	Attempt all the questions (Case studies)		CO
1.	**Background:** • The prevalence of prostate cancer has increased in your country over the last 5 years. • You want to examine the association between calcium intake and prostate cancer risk. • You have limited time and funding to conduct this study. **Questions:** 1. What type of study would you conduct? 2. Why would you conduct that specific type of study? 3. What is the measure of association to calculate for this study?	5+5+5=15	CO3
2.	**Background:** A rhesus rotavirus tetravalent (RRV-TV) vaccine was licensed in the US after randomized-controlled trial? (RCT) in developed countries showed 60% efficacy in preventing diarrhea. However, shortly after FDA approval, the vaccine was withdrawn from US market because of a cluster of cases of intussusception (adverse drug reaction) (risk~1 in 10,000). A similar RCT was being planned in developing countries at the time. **Questions:** 1. Is it ethical that the trial be allowed to proceed in developing countries? 2. Is it possible by any mean to reintroduce the vaccine in US? 3. What could be the other ethical options to minimize the ethical violations? (Note: About 600,000 kids died of rotavirus diarrhea in developing countries in spite of ORS)	5+5+5=15	CO3
	Section D	**(2Qx10M=20 Marks)**	

Q	Attempt all the questions		CO
1.	Write the details of ICH objectives, members, and committees? Discuss one guideline each from safety, quality, efficacy, and multidisciplinary category.	10	CO4
2.	Write down brief notes on the following. a) IRB b) Investigator c) Sponsor d) Clinical trial protocol e) Pharmacovigilance	2*5=10	CO2