Name: **Enrolment No:**	

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

Course: Clinical Trial Management **Semester: IV**
Program: B.Sc. (Clinical Research) **Time : 03 hrs.**
Course Code: HSCC2024 **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.	IND application is filed a) Before clinical trial b) After clinical trial b) Before preclinical trial d) After post-marketing	1.5	CO1, CO4
2.	Sponsor in a clinical is responsible for a) Reviewing the documents b) Initiating the study b) Funding the study d) Both b & c	1.5	CO2
3.	Site-initiation visit does not include the following personnel. a) Sponsor b) Investigator c) Monitor d) Data manager	1.5	CO1
4.	The ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, is a critical activity completed by the Sponsor prior to the start of a study.	1.5	CO1
5.	The ,,,,,,,,,,,,,,,,,,,,,,,,,,,,, is the person who dispenses medicine	1.5	CO2
6.	The ,,,,,,,,,,,,,,,,,,,,, is the first meeting conducted before starting the clinical trial.	1.5	CO1
7.	Reason for participating in a clinical trial include a) Lack of availability therapy b) Improved medical care c) Lack of health insurance d) All of the above	1.5	CO4
8.	Which of the following is not reason of patient drop-out in clinical trial a) Adverse effect b) Lack of benefit c) Lack of medicine	1.5	CO4

	d) Lack of transportation		
9	Phase I clinical trials are conducted exclusively on patients. The statement is a) True b) False	1.5	CO4
10.	Cross-sectional study is conducted over a long time period. The statement is a) True b) False	1.5	CO4
11.	Which ICH guidelines deals carcinogenicity and genotoxicity?	1.5	CO3
12.	What do you understand by sub-investigator and co-investigator?	1.5	CO2
13.	Which responsibilities could be common between sponsor and investigator?	1.5	CO2
14.	What is NDA and when it is filed?	1.5	CO1, CO4
15.	Mention the first step in patient recruitment.	1.5	CO4
16.	Name at least one strategy for patient retention.	1.5	CO4
17.	Mention one development strategy for emerging market.	1.5	CO5
18.	What do you understand by supply chain and life cycle management?	1.5	CO5
19.	What is the meaning of Justice in Belmont report?	1.5	CO3
20.	What is a probability sampling?	1.5	CO4
	Section B	**(4Qx5M=20 Marks)**	CO
Q	Attempt all the questions		
1.	Write down about site qualification visit briefly.	5	CO1
2.	Elaborate about post-marketing surveillance and its significance.	5	CO4
3.	Discuss about the principles of Belmont report.	5	CO3
4.	Mention the role of contract research organization.	5	CO2
	Section C	**(2Qx15M=30 Marks)**	

Q	Attempt all the questions (Case studies)		CO
1.	**Background:** A rhesus rotavirus tetravalent (RRV-TV) vaccine was licensed in the US after 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 (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
2.	**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	CO1
	Section D	**(2Qx10M=20 Marks)**	
Q	Attempt all the questions		CO
1.	Discuss all the principles of ICH-GCP guidelines.	10	CO3
2.	Mention the roles and responsibilities of various personalities (sponsor, investigator, study coordinator, monitor) in a clinical trial system.	10	CO2