

Name:	
Enrolment No:	

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

Course: Site Management Operations	Semester: 3rd
Program: Integrated B.Sc + M.Sc. Clinical Research	Duration: 3 Hours
Course Code: HSCC 2021	Max. Marks: 100

Instructions:

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1			
1	State any two uses of randomization in CT's.	1.5	CO 1
2	Define SMO.	1.5	CO 1
3	Define the concept of blinding in CT's.	1.5	CO 1
4	State the importance of protocol in CT's.	1.5	CO 1
5	State any two uses of CRF.	1.5	CO 1
6	Report the basic requirements for a CT.	1.5	CO 1
7	Consent form filling is mandatory in CT. Is it true or false?	1.5	CO 2
8	Identify any two requirements for validation of reports in CT's.	1.5	CO 2
9	Following of GCP gives a sense of reliability. Is it true or false?	1.5	CO 2
10	Report the importance of quality management in clinical trials.	1.5	CO 2
11	Select the therapeutic segments of global site market.	1.5	CO 2
12	Identify the components of clinical trial.	1.5	CO 2
13	Classify different aspects of pharmacovigilance.	1.5	CO 2
14	Write the importance of spontaneous reporting in CT's.	1.5	CO 3
15	Write any two benefits of archiving of data of CT's.	1.5	CO 3
16	Interpret the importance of survey in pharmacovigilance.	1.5	CO 3
17	Write about importance of reporting an adverse event in CT.	1.5	CO 3
18	Interpret any two uses of unsolicited reports.	1.5	CO 3
19	Illustrate importance of ethical clearance for conduction of any trial.	1.5	CO 3
20	Give two roles of investigator in CT's.	1.5	CO 3

Section B

(4Qx5M=20 Marks)			
Q 1			
1	State in detail about CRF's.	5	CO 1
2	Illustrate the intricate part played by site management operations in CT's.	5	CO 3
3	Memorize about the importance of accuracy and reproducibility of data during any trial.	5	CO 1
4	Appraise the various functions performed by CRO's.	5	CO 4
Section C (2Qx15M=30 Marks)			
Q 1			
1	Write in detail about the responsibilities shared by personnel involved in CT's.	15	CO 3
2	Appraise about good clinical practices.	15	CO 4
Section D (2Qx10M=20 Marks)			
Q 1			
1	Discuss the challenges associated with multiple site clinical trial organizations.	10	CO 2
2	Contrast the interventions and key geographies in relation to global site management organization.	10	CO 4