

Name:

Enrolment No:



UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
School of Health Sciences

End Semester Examination, December 2020

Programme Name: M.Sc. Clinical Research
Course Name : Management of Clinical Trials
Course Code : HSCR7004

Semester : Ist
Time: 3 hour
Max. Marks: 100

Instructions : Read all questions carefully

SECTION A

Each Question will carry 5 marks		Marks	
Instructions: Complete the statement/Select the correct answer(s)			
1.	Define the following terms: (a) Clinical Trials (b) ICH	5	CO1
2.	Write two difference between Prospective study and Retrospective study.	5	CO2
3.	The important steps in site selection criteria of clinical trials are	5	CO3
4.	Define (a) "Phase 0" trial in Clinical Research. (b) Surrogate biomarkers	5	CO4
5.	How will you calculate Incidence and Prevalence rate in observational studies?	5	CO3
6.	Enlist the functions of CROs.	5	CO3

SECTION B

1. Each question will carry 10 marks 2. Instruction: Write short / brief notes			
7.	Discuss the requirements for new drug development process	CO1	10
8.	Explain the different phases of Clinical Trials.	CO1	10
9.	Discuss the physiological changes occurs during pregnancy.	CO3	10

10.	Enlist life threatening diseases and write in brief about translation medicine.	CO2	10
11.	Discuss the Clinical Trial Study Design (observational and interventional) protocol.	CO2	10
12.	Define SMO's? Describe the site selection parameters for clinical research. Or Explain CRF, Format and Sponsor Needs, guidelines related to CRF filling Research ethics and research audits.	CO4	20
			20