Name:

Enrolment No:

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES

End Semester Examination, December 2022

Course: Clinical Operation **Semester : III**

Program: B. Sc. (Clinical Research) **Duration: 3 Hours**

Course Code: HSCR2004 **Max. Marks: 100**

Instructions: All the sections are compulsory

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	Define the term Hypothesis?	**1.5**	**CO1**
Q 2	What is stratification in clinical trial?	**1.5**	**CO1**
Q 3	Define AE and how is it different from ADR?	**1.5**	**CO1**
Q 4	What is placebo controlled study?	**1.5**	**CO1**
Q 5	Define randomized clinical trial? Give an advantage of it.	**1.5**	**CO1**
Q 6	Expand the term ALCOA?	**1.5**	**CO4**
Q 7	What do you understand by auditing and inspections?	**1.5**	**CO4**
Q 8	What should people consider before participating in a trial?	**1.5**	**CO1**
Q 9	What are the documents submission modes to FDA? Who will submit the docs?	**1.5**	**CO3**
Q 10	What are the objectives of an SOP document?	**1.5**	**CO1**
Q 11	Define data coding and give an advantage of data coding?	**1.5**	**CO4**
Q 12	What do understand by single-blind study?	**1.5**	**CO1**
Q 13	What are the objectives of monitoring of trial?	**1.5**	**CO3**
Q 14	Which document created in 1964 forms the basis of ethical considerations in clinical research? A. Declaration of Geneva B. Declaration of Helsinki C. Declaration of Belfast D. All of the above	**1.5**	**CO2**
Q 15	What is an informed consent? Why it is important?	**1.5**	**CO1**
Q 16	What is a source document?	**1.5**	**CO1**
Q 17	Define the term pharmacokinetic and pharmacodynamics?	**1.5**	**CO1**
Q 18	Define E-data capture?	**1.5**	**CO4**
Q 19	What do you understand by site selection?	**1.5**	**CO3**
Q 20	Define the term “therapeutic drug monitoring”?	**1.5**	**CO1**

Section B

(4Qx5M=20 Marks)			
Q 1	What is the declaration of helsinki in the research ethics?	**5**	**CO1**
Q 2	Discuss WHO key principles of good clinical practice?	**5**	**CO2**
Q 3	Describe the characteristics features of good clinical data?	**5**	**CO4**
Q 4	What is a case report form? Describe the ICH guidelines related to CRF filling?	**1+4**	**CO4**
Section C **(2Qx15M=30 Marks)**			
Q 1	Define clinical data management? Describe the data capture and data validation steps performed by investigator, monitor and CDM team.	**2+6+7**	**CO4**
Q 2	Write a note on the following: a) Site selection visit b) Close out report c) Ethical issues in genetic engineering	**5+5+5**	**CO3, CO4**
Section D **(2Qx10M=20 Marks)**			
Q 1	Discuss the various activities conducted by monitor during periodic visit?	**10**	**CO3**
Q 2	Describe the different types and phases of clinical trials?	**5+5**	**CO2**