Name: **Enrolment No:**	UPES UNIVERSITY WITH A PURPOSE

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, December 2021

Course: Fundamentals of Clinical Trial Operations **Semester: III**
Program: BSc Clinical research **Time 03 hrs.**
Course Code: HSCR 2004 **Max. Marks: 100**

SECTION A

Each Question will carry 1.5 Marks

S. No.	**Question**	**CO**
Q 1	What do you mean by microdosing studies	**CO2**
Q 2	Define generic drugs	**CO1**
Q 3	What is site selection visits	**CO2**
Q 4	Which phase of clinical trial involves around 3000 participants a. Phase 1 b. Phase 2 c. Phase 3 d. Phase 4	**CO4**
Q 5	In which phase geriatric population is enrolled for the clinical trial.	**CO1**
Q 6	What do you understand by the term triple blind study	**CO2**
Q 7	Define importance of informed consent	**CO4**
Q 8	Define post marketing surveillance	**CO2**
Q 9	What do you mean by single arm design	**CO2**
Q 10	In a clinical trial, half the participants are given the test treatment, other half is given the placebo. After some weeks, first group gets the placebo and second group gets treatment. Which one of the following is correct about the trial a. Crossover design b. Uncontrol design c. Single arm design d. None	**CO2**
Q11	Give two important roles of institutional review board.	**CO4**
Q 12	A point of view or preference which prevents impartial judgment in the way in which a measurement, assessment, procedure, or analysis is carried out or reported is _____ (bias/randomization/cohort)	**CO3**
Q 13	A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject is known as _____	**CO3**

Q 14	What do you mean by follow-up study.	**CO3**
Q 15	_____ are adverse effects that cannot be explained by the known mechanisms of action of the offending agent, do not occur at any dose in most patients, and develop mostly unpredictably in susceptible individuals only	**CO1**
Q 16	Give full form of IEC	**CO3**
Q 17	What is the role of impartial witness in clinical trial for special population?	**CO3**
Q18	Mention 3 ethical principles to be followed during clinical trials	**CO2**
Q 19	Before which phase of clinical trial Investigational New Drug application is filled a. Phase 1 b. Phase 2 c. Phase 3 d. Phase 4	**CO3**
Q 20	What do you mean by interim Clinical Trial/Study Report.	**CO3**

SECTION B

1. **Each question will carry 5 marks (not more than 150 words)**
2. **Instruction: Write short / brief notes**

Q 1	Give different types of phase IV clinical trials.	**CO1**
Q 2	Write a short note on different types of auditing in clinical trials.	**CO2**
Q 3	Discuss about clinical data management for clinical research.	**CO2**
Q 4	Discuss importance of site initiation visits	**CO3**

Section C

1. **Each Question carries 15 Marks.**
2. **Instruction: Write long answer.**

Q 1	A clinical trial for a new antihypertensive drug is conducted in India. Planning for the clinical trial is being done. According to the known information in literature: Fill the information in the table below	**CO3**

Phases	Approx. Time required	Number of Participants	Multicentric (Yes/No)	Vulnerable population included	Significance
Phase 0					
Phase 1					
Phase 2					
Phase 3					

Also, mention after which phase New Drug Application if filed.

Q 2	a. Discuss about important parameters to note while enrolling clinical research subjects b. Describe factors affecting clinical research site	**CO4**

Section D 3. **Each Question carries 10 Marks** 4. **Instruction: Write long answer.**		
Q 1	Describe the difference between controlled and uncontrolled designs	**CO1**
Q 2	Explain all points which are important points to be considered during site close out visits	**CO2**