Name:

Enrolment No:

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES

End Semester Examination, December 2022

Course: Clinical Research **Semester : III**

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

Course Code: HSCR2006 **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	What is an intervention?	1.5	CO1
Q 2	How unanticipated risks are identified during the course of a study?	1.5	CO3
Q 3	Within GCP, what is the investigator's responsibility for the medical care of research subjects?	1.5	CO2
Q 4	Give the full form for the followings: EMA …….. USFDA ……	1.5	CO1
Q 5	Who is responsible for reviewing the benefit-risk profile of the investigational product(s) while the study is proceeding?	1.5	CO2
Q 6	Enlist three cardinal principles of belmont report?	1.5	CO1
Q 7	Why should clinical trials be regulated ?	1.5	CO1
Q 8	What should be done if the benefit-risk profile of a study becomes unfavourable?	1.5	CO2
Q 9	What are the objectives of Phase 1 clinical trial ?	1.5	CO1
Q 10	Define human subject?	1.5	CO1
Q 11	Is it ethical to include subjects who are unable to consent?	1.5	CO1
Q 12	What is research misconduct and how it can be avoided?	1.5	CO2
Q 13	Who is responsible for compliance with the protocol?	1.5	CO2
Q 14	When should a risk/benefit determination be performed?	1.5	CO2
Q 15	What "information" should be given to study subjects for clinical trial in accordance with GCP?	1.5	CO1
Q 16	What is the purpose of Good Clinical Practice?	1.5	CO1
Q 17	What is meant by "freely given" consent or "voluntary" participation in an investigation?	1.5	CO1
Q 18	Within GCP, what is meant by "prior" opinion by the IEC/IRB?	1.5	CO1

Q 19	Investigational projects should be manufactured, handled, and stored in accordance with applicable_____. A. GCP B. GMP C. ACRP D. IRB	**1.5**	**CO1**
Q 20	Who should have access to clinical trial records?	**1.5**	**CO2**
	Section B **(4Qx5M=20 Marks)**		
Q 1	Discuss the ethical aspects of trial samples for genomic studies?	**5**	**CO2**
Q 2	What is conflict of interest in research ? Discuss the COI at the level of investigators?	**5**	**CO2**
Q 3	Explain the Tuskegee Syphilis Experiment?	**5**	**CO1**
Q 4	Write a short note on indemnity and insurance for participants in clinical trial?	**5**	**CO3**
	Section C **(2Qx15M=30 Marks)**		
Q 1	Define informed consent? What are the legal and ethical components of informed consent and why it is important? Outline the informed consent process?	**2+6+2+5**	**CO1**
Q 2	What do you understand by 'Ethics in Research'? Discuss the ethical aspects of tissue engineering and gene therapy?	**1+7+7**	**CO2**
	Section D **(2Qx10M=20 Marks)**		
Q 1	Discuss the ethical aspects in research question and study design in clinical trials?	**5+5**	**CO2**
Q 2	What is ICH? Explain the purpose and core principles of ICH-GCP.	**1+2+7**	**CO1**