Name: **Enrolment No:**	UPES UNIVERSITY OF TOMORROW

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

Course: **MSc. Clinical Research** **Semester : 3rd**
Program: Regulatory Aspects of Clinical Research and IPR **Duration : 3 Hours**
Course Code: HSCR8005 **Max. Marks: 100**

Instructions: All questions are compulsory

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	Under which type of agreement royalties paid on the basis of sale? a. Mining b. Patent c. Copyright d. licensing	**1.5**	**CO4**
Q2	Which of the following is not the infringement of copyright? a. Copy the software to another computer by educational institution b. Copy the software to another computer by company c. Copy the software to another computer d. To make backup copies	**1.5**	**CO4**
Q3	Patent can be granted for ……? a. Process b. Ideas c. Product d. Both product and process	**1.5**	**CO4**
Q4	What is meant by a blind subject? a. The subjects do not know which study treatment they receive b. Patients injected with placebo and active doses c. Fake treatment d. Signed document of the recruited patient for the clinical trial procedures	**1.5**	**CO2**

Q5	Which one of the following will perfectly fit on the marked place?  a. Investigator selection b. Patient recruitment c. Statistical Analysis d) Data filed and registration	**1.5**	**CO1**
Q6	What is informed consent in a clinical trial? a. The subjects do not know which study treatment they receive b. Patients injected with placebo and active doses c. Fake treatment d. Signed document of the recruited patient for the clinical trial procedures	**1.5**	**CO1**
Q7	Which one of the following will perfectly fit on the marked place?  a) Investigator selection b) Patient recruitment c) Statistical Analysis d) Data filed and registration	**1.5**	**CO2**
Q8	Who is responsible for WHO international drug monitoring Program? a. Uppsala monitoring centre b. WHO drug dictionary c. PVPI d. Contract research Organization	**1.5**	**CO1**
Q9	How many people will be selected for phase II trial? a. The whole market will be under surveillance b. 300-3000 people c. 20-300 people d. 0-50 people	**1.5**	**CO1**
Q10	The most adopted method for reporting of ADR is - a. Expedited reporting. b. Longitudinal electronic patient records	**1.5**	**CO2**

	c. Spontaneous reporting. d. Suspected reporting		
Q11	Patent application can be filed in India by a. True and First Inventor b. Assignee of the inventor c. Legal representative of the inventor d. All the above	**1.5**	**CO2**
Q12	Which of the following is NOT included in the ICH quality guidelines? a. Stability studies b. Reproductive toxicity studies c. Impurity testing d. Good manufacturing practice (GMP)	**1.5**	**CO3**
Q13	Which of the following sources does NOT provide Individual Case Safety Reports (ICSRs)? a. Pharmaceutical companies b. Clinical Research Organizations c. Individual patients d. Regulatory agencies	**1.5**	**CO4**
Q14	Which of the following patients are at the highest risk of suffering from an adverse drug reaction? a. An 8 month year old infant receiving a prescription for an antibiotic. b. A 22 year old patient with asthma receiving prescriptions for inhalers to relieve and prevent their asthma. c. A 48 year old patient who has hypertension and receives a prescription for an ACE Inhibitor. d. A 68 year old patient who has oedema receiving a prescription for a diuretics	**1.5**	**CO1**
Q15	Which of the following is NOT one of the principles of Good Clinical Practice (GCP)? a. The well-being of subjects is of highest priority. b. Trials should have a clear, defined protocol. c. Informed consent of subjects must be obtained. d. The protocol is approved by the trial organization.	**1.5**	**CO2**
Q16	What is meant by "compliance" in a randomized clinical trial? a. Flexibility in assignment to treatment groups. b. The degree to which study subjects adhere to an assigned treatment protocol.	**1.5**	**CO3**

	c. An inter-institutional agreement for a multi-center study. d. Benefits for people who enroll in the study.		
Q17	How many members should an Ethics Committee have? a. At least 3 b. At least 5 c. At least 7 d. There is no specification	**1.5**	**CO4**
Q18	I am the lowest concentration of drug in the systemic circulation at which it can produce a therapeutic effect. a. Therapeutic dose b. Therapeutic Threshold c. Minimum Effective Concentration d. Tolerance	**1.5**	**CO1**
Q19	I am an annual report containing all safety information for a product which is in development. a. IND b. NDA c. IMPD d. DSUR	**1.5**	**CO1**
Q20	What is the following the definition of? "The specific project goals, deliverables, features, functions, tasks, deadlines, and ultimately costs of a project" a. Project Plan b. Project Scope c. Project Definition d. Project Objective	**1.5**	**CO1**
Section B (4Qx5M=20 Marks)			
Q 1	Describe four basic principles of Belmont Report.	5	CO1
Q2	Discuss the steps in INDA filing	5	CO4
Q3	Write a brief note on regulatory aspects of clinical trials	5	CO1
Q4	Elaborate the components of Orphan Drugs Application	5	CO3
Section C (2Qx15M=30 Marks)			
Q 1	Write a detailed note Council for International Organizations of Medical Sciences (CIOMS)	15	CO2

Q2	Elaborate the role of IPR and its types in safeguarding inventor/creator	15	CO4
Section D (2Qx10M=20 Marks)			
Q 1	Write a note on composition and responsibilities of IRB	10	CO2
Q2	Briefly explain the principles of medical ethics relevant to the protection of prisoners against torture.	10	CO1