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

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

Course: Guidelines, Regulations and Ethics in Clinical Research **Semester:** I
Program: Msc Clinical Research **Time: 03 hrs.**
Course Code: HSCR7005 **Max. Marks: 100**

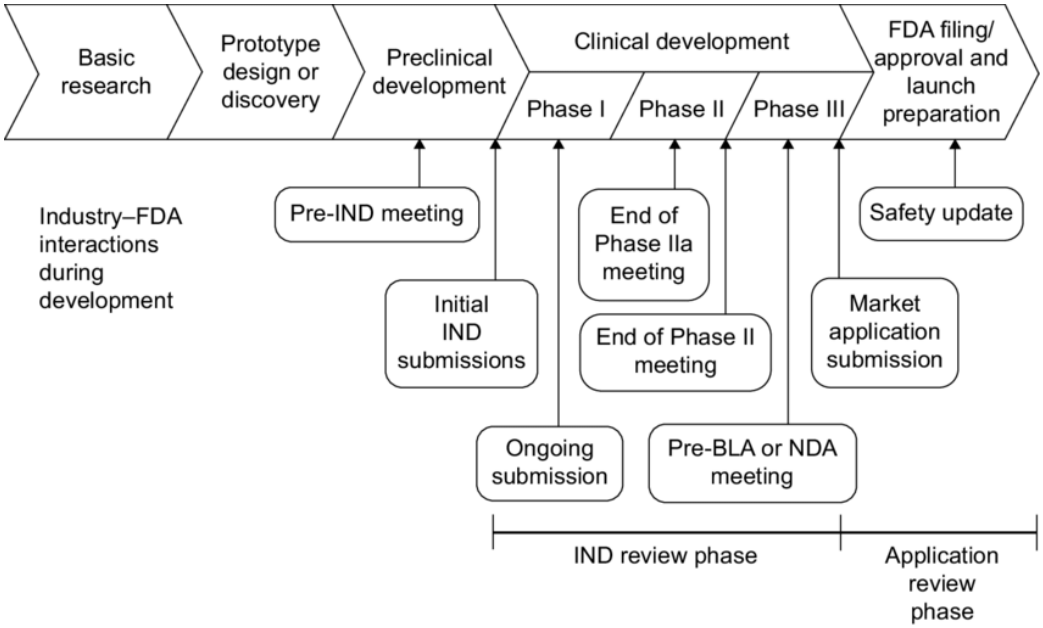
Instructions: Read question carefully.

SECTION A

S. No.	MCQ's /Fill in the blanks/ T&F (1.5 marks each)	**30 Marks**	**CO**
1	Select the option in which Good Clinical Practice (GCP) is not followed a. Phase I trial b. Phase II trial c. Preclinical trials d. Phase IV trial	**1.5**	**CO1**
2	Which of the following terms does not describe an Adverse Drug Reaction? a. Idiosyncrasy b. Anaphylaxis c. Teratogenic effect d. Placebo effect	**1.5**	**CO1**
3	Autonomy in clinical studies is defined as a. Freedom, dignity and confidentiality of the subject. b. Motive to do good to the subject and/or to the society. c. Not to do harm or put the participant at undue risk. d. Observance of fairness, honesty and impartiality in obtaining, analyzing & communicating the data	**1.5**	**CO1**
4	CFR 21 section…… permits the FDA to approve an ANDA	**1.5**	**CO2**
5	An application for a pharmaceutically equivalent drug product must be submitted under section ……	**1.5**	**CO2**
6	Good Clinical Practice (GCP) provides assurance that a. Rights and safety of participants are protected b. The rights, safety and wellbeing of research participants are protected and that research data/results are reliable. c. Results are reliable d. Safety of participant is observed and results are reliable	**1.5**	**CO1**
7	Who is the person responsible for the conduct of the clinical trial at a trial site? a. Clinical Research Coordinator b. Monitor c. Investigator d. Sponsor	**1.5**	**CO1**

8	An application which is a duplicate of a listed drug and eligible for approval under section 505(j) cannot be submitted as 505 (b)(2) a. True b. False	**1.5**	**CO2**
9	According to the principles of ICH GCP what should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification? a. Data entered into the case report form b. Source information c. All clinical trial information d. Essential documents	**1.5**	**CO3**
10	What are Good Clinical Practices? a. Regulations set in place by Government that how clinical trials are supposed to be managed. b. Clinical practices that adhere to the best standards of care. c. Widely accepted standards of practice during clinical trials d. The FDA's requirements for how trials are conducted and documented	**1.5**	**CO3**
11	According to the principles of ICH GCP, which of the following is the most important consideration while conducting a clinical trial? a. Data accuracy b. Protection of trial subjects c. Process adherence d. Statistical quality checks	**1.5**	**CO3**
12	Under 21 CFR 312 FDA accept foreign clinical trials a. True b. False	**1.5**	**CO2**
13	The Federal Food, Drug, and Cosmetic Act (1938) established the quality standards for - Statement I: Food, drugs, and cosmetics manufactured and sold in the United States Statement II: Medical devices manufactured and sold in the United States a. Statement I is Correct b. Statement II is correct c. Both the statement is correct d. Statement I is correct and II incorrect	**1.5**	**CO2**
14	The comparison of bioavailability between two dosage forms is refereed as_____ a. Bioavailability b. Biopharmaceutics c. Biologicals d. Bioequivalence	**1.5**	**CO4**
15	An "investigational new drug (IND)" means a new chemical or biological entity or substance that has not been approved for marketing as a drug in any country a. True b. False	**1.5**	**CO3**
16	Audit in clinical trial is a a. Study related activities to determine consistency with the protocol b. Study data to ensure that there are no contradictions on source documents. c. Compliance with the adopted Standard Operating Procedures d. All of the above	**1.5**	**CO3**
17	Bioavailability and Bioequivalence requirements are laid down in the title …… of Code of Federal Regulation under section..…….	**1.5**	**CO4**
18	The timeline for disposal of an application for conduct of clinical trial and BA / BE study is …… working days from the date of receipt of application	**1.5**	**CO4**

19	The new section of ISO 14155 adds GCP principles in alignment with ICH E6(R2) and the Declaration of Helsinki a. True b. False	**1.5**	**CO4**
20	ISO 14155:2020 standard focus on a. Medical device b. Treatment c. Animal Study d. All of the above	**1.5**	**CO4**
SECTION B (5 marks each question)			
Q	Short Answer Type Question (5 marks each) Scan and Upload 4 questions 5 marks. Word limit (100-120)	**20 Marks**	**CO**
1	Explain the regulatory requirements for conducting Clinical Trial in India.	**5**	**CO2**
2	Explain the procedure how a company design and submit the post-market surveillance plan to FDA?	**5**	**CO4**
3	Briefly describe the Section 5 of ICH GCP E6 guidelines.	**5**	**CO3**
4	Control groups are essential in experimental design. Justify your answer.	**5**	**CO3**
SECTION C 30 marks			
Q	**Two case studies 15 marks each subsections**	**30 Marks**	**CO**
1	Case Study 1 (Word limit-250-300) **Read the below paragraph carefully and answer the questions:** A Ministry of Health has requested for a prevalence/behavioral surveillance study for sexually transmitted disease (STD) among female sex workers. Participants in this study will be tested for three common STDs. They will be participating in an interview with the researchers. Participants will receive a card with a number linking them to their blood sample and will have the option of presenting their cards to get the results of the STD tests. They will also have a report of complete blood count (CBC). Those with positive results for any of the three infections will be consider as participants. They will have offered free treatment for a tenure of six months. In addition, all participants will receive a small gift in return for their participation. The target population will go through an education counselling to know the details of study. Prior to initiating the research, a researcher meets with all the population and ask permission to participate in the study. During the meeting, all of the women showed their willingness to participate in the study. The protocol of the study was approved by the ethical committee. **a.** What steps can the researchers take to ensure that informed consent is freely given by all participants? **b.** If a woman chooses not to participate in the study, what can be done to protect disapproval? **c.** If you believe that the women will not be able to give voluntary informed consent, what alternatives could you suggest to the Ministry of Health?	**15**	**CO1**

2	Case Study 2 (Word limit- 250-300)  **a.** Identify the phases of FDA approval for a new drug mentioned in the above image? **b.** Classify the different categories of FDA filling? **c.** Where you can find out the requirements for the format and content of the IND application? **d.** Organize all the necessary documents required for New Drug Application as per code of federal regulations title 21.	**15 (1+2+1 +11)**	**CO4**

	SECTION- D 20 marks		
Q	Long Answer type Questions Scan and Upload (10 marks each) Word limit 200-250	**20 Marks**	**CO**
1	**a.** The company SEPU, Dehradun seeking for the permission to import and /or manufacture of new drugs for sale. Where the company will ask for the permission? **b**. If the company willing to undertake clinical trial, under which schedule, rule and form it can be done? **c.** Describe briefly the schedule for requirements and guidelines.	**(1+1+8)**	**CO2**
2	**a.** Describe the ethical principles in biomedical research involving human beings. **b.** Write down the ICMR Ethical Guidelines for Biomedical Research.	**(4+6)**	**CO 3**