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

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

Course: Ethics in Clinical Research **Semester: III**
Program: BSc Clinical research **Time 03 hrs.**
Course Code: HSCR 2006 **Max. Marks: 100**

SECTION A

Each Question will carry 1.5 Marks (not more than 150 words)

S. No.	**Question**	**CO**
Q 1	What do you mean by vulnerable population	**CO2**
Q 2	_____is a rare birth defect characterized, in most instances, by severe malformation of the extremities occurred due to thalidomide drug	**CO1**
Q 3	ICH E6 guideline discuss about Good Clinical Practices. True/False	**CO2**
Q 4	Detection, assessment, understanding and prevention of adverse effects of marketed medicine/vaccine is done which phase of clinical trial. a. Phase 1 b. Phase 2 c. Phase 3 d. Phase 4	**CO1**
Q 5	Write three major ethical principles mentioned in Belmonts report	**CO1**
Q 6	What do you understand by the term serious adverse event?	**CO2**
Q 7	What is randomization in clinical research?	**CO4**
Q 8	Define bioequivalence.	**CO2**
Q 9	How is informed consent received for a 9 years old child.	**CO2**
Q 10	In a clinical trial, half the participants are given the test treatment, other half is given the placebo. Which one of the following is correct about the trial a. Control design b. Uncontrol design c. Single arm design d. None	**CO4**
Q11	Give two important role institutional review board.	**CO3**
Q 12	What do you mean by Nocebo effect.	**CO3**

Q 13	Write 2 ways through which the remuneration can be given to a child participants in clinical trials.	**CO3**
Q 14	What is Double blinding study	**CO3**
Q 15	The Tuskegee syphilis study lead to the development of ethics in clinical trials. True/False	**CO1**
Q 16	Give full form of CDSCO.	**CO3**
Q 17	New drugs and Clinical Trial rules states that the recording should be done while taking the informed consent from the vulnerable population. True/False.	**CO4**
Q18	Mention any one ethical concern with respect to pregnant women	**CO2**
Q 19	After which Phase of clinical trial New Drug application is filled a. Phase 1 b. Phase 2 c. Phase 3 d. Phase 4	**CO3**
Q 20	Give significance of Pharmacovigilance	**CO4**
SECTION B **1. Each question will carry 5 marks (not more than 150 words)** **2. Instruction: Write short / brief notes**		
Q 1	According to ICH E11 guideline, mention the age limits for the following a. Neonates b. Infants and toddlers c. Children d. Adolescents e. Geriatric	**CO1**
Q 2	What do you understand about Placebo control trials.	**CO2**
Q 3	Discuss the ethical aspects in case of geriatric research (any 2 points).	**CO2**
Q 4	Discuss ethical implications of conflict of interest in clinical research.	**CO3**
Section C **1. Each Question carries 15 Marks.** **2. Instruction: Write long answer.**		
Q 1	Analyze the following passage and answer the following questions ART treatment interruption trials Drugs: lamivudine/zidovudine (Combivir) + tenofovir (Viread) or nevirapine (Viramune) or abacavir (Ziagen) (DART trial) Treatment: Anti-retroviral therapy (ART) Sponsors: UK Medical Research Council (MRC), Rockefeller Foundation, DfID (Uganda), GlaxoSmithKline, Gilead, Boehringer-Ingelheim Period: 2003 – 2006 (DART trial) Location: Uganda, Zimbabwe, Côte d'Ivoire	**CO3**

	Case study: The Development of Anti-Retroviral Therapy in Africa (DART) trial was an open, randomised trial to compare standard continuous therapy (CT) with structured treatment interruption (STI) of 12 weeks on and 12 weeks off anti-retroviral therapy (ART). The trial had recruited 3,300 volunteers at the Joint Clinical Research Centre (Kampala, Uganda), the MRC/UVRI Uganda Research Unit on AIDS (Entebbe), and the University of Zimbabwe College of Health Sciences (Harare). On 14 March 2006, it was decided that all patients in the STI arm of the trial would be switched to continuous therapy as interim data demonstrated they had a greater rate of clinical HIV-related disease. Critics say they had sounded alarms the year before already because of the relatively high number of fatalities in the STI arm in Uganda, but investigators replied their concerns were unfounded. Attempts to put patients whose situation deteriorated during treatment interruption back on ART failed and some of the patients died during the interruption period. There have also been complaints about enrolment of patients desperate to get free treatment, insufficient arrangements for post trial treatment access, the use of a drug regimen that is not readily available to the general population, and omission of important risks in the consent forms. Questions a. Write the unethical practices in the given trial (5 marks) b. Was there any severe outcome due to the unethical practices (3 marks) c. Do you feel it would be ethical if the trial had been a closed randomized trial (2 marks) d. After the trial is stopped in between. What should be done with the patients (5 marks)	
Q 2	Letrozole trials in India Drugs: Letrozole Treatment: Inducing ovulation Sponsors: Sun Pharmaceuticals Period: 2003 Location: India Case Study: Letrozole, which belongs to the group of aromatase inhibitors, was tested by Sun Pharmaceuticals to induce ovulation. The drug has been approved globally for the treatment of breast cancer in post-menopausal women, but it is not approved for any other use in any country. More than 400 women who had been trying in vain to conceive were enrolled in 2003 without their knowledge or consent to take part in clinical trials conducted at nine or more centres across India. a. Write the unethical practice in the trial. Give any provision through which it could have been avoided. (4 marks) b. The drug has been approved globally for the treatment of breast cancer in post-menopausal women was there a need to get an approval for the same drug for a new use. (3 marks) c. Who are the people/agencies responsible for this unethical practices (3 marks) d. Write about some special ethical aspects (general) which are important to consider for pregnant women/women who becomes pregnant during the trial (5 marks)	**CO2**
Section D **3. Each Question carries 10 Marks (300 words)** **4. Instruction: Write long answer.**		
Q 1	Mention any 4 different types of control groups. Explain any two of them.	**CO1**
Q 2	Mention some of the important points to be written in the informed consent form.	**CO4**