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

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
School of Health Sciences

End Semester Examination, December 2021

Programme Name: B.Sc Clinical Research **Semester : IIIrd**
Course Name :Global Regulations of Clinical Trials **Time : 3 hrs**
Course Code : HSCR2009 **Max. Marks : 100**
Instructions : Attempt all the Sections

SECTION A

		Marks	
Ques	MCQs, One or two line answers, True/False, Fill in the blanks	**30**	**CO1**
1	Select the "Belmont Principle" that led to federal regulations on informed consent. a. Respect for persons b. Beneficence c. Justice d. Security	**1.5**	**CO1**
2	The Tuskegee syphilis study was ethically problematic because a. participants were exposed to a deadly contagious disease. b. the researchers made false promises that participants' disease was treatable. c. the researchers offered participants nothing in return for their participation. d. it violated the principle of informed consent.	**1.5**	**CO2**
3	Complete this statement from ICH GCP: neither the investigator, nor the trial staff, should …….or unduly influence a subject to participate or to continue to participate in a trial. a. convince b. coerce c. compel d. change the opinion	**1.5**	**CO3**
4	What comes next in the IRB/IEC for all trial subjects. • Rights • Safety • ..... a. Confidentiality b. Well-being c. Protection d. Treatment	**1.5**	**CO1**

5	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**
6	The Nuremberg Code states that human subjects must be able to withdraw from a research study at any time. **A. True** **B. False**	**1.5**	**CO3**
7	Which of the following is NOT associated with Phase 1 clinical trials? a. ~ 100 participants b. Patients with target disease c. Establishment of safety of drug in humans d. Establishment of normal human dosage	**1.5**	**CO1**
8	Complete the following sentence: James Lind usually receives credit for being the author of the first clinical trial in history, a controlled experiment that evaluated the effectiveness of citrus fruits against …….. a. Fever b. Infection c. Wound d. Scurvy	**1.5**	**CO2**
9	Match the correct answer a. E4 – 1. General Considerations of Clinical Trials b. E7 – 2. Studies in support of General Population: Geriatrics c. E8 – 3. Dose Response Information to support Drug Registration	**1.5**	**CO3**
10	…… is the European database for all interventional clinical trials on medicinal products authorized in the European Union (EEA) and outside the EU/EEA if they are part of a Paediatric Investigation Plan (PIP) from 1 May 2004 onwards. a. EudraCT b. EudraLEX c. Vigibase d. ASR	**1.5**	**CO1**
11	…….. hosted at the ICMR's National Institute of Medical Statistics, is a free and online public record system for registration of clinical trials being conducted in India that was launched on 20th July 2007. a. CTRI b. CDSCO c. ICMR d. None of them	**1.5**	**CO2**
12	The Abbreviations ANDA stands for……. NDA stands for……. IND stands for ……..	**1.5**	**CO3**

13	…… is India's national regulatory body for cosmetics , pharmaceuticals and medical devices. It serves a similar function to the European Medicines Agency of the European Union, the PMDA of Japan, and the Food and Drug Administration (FDA) of the United States.	**1.5**	**CO1**
14	Choose the correct chronological ordering of the following documents: a. Nuremberg Code, Declaration of Helsinki, The Belmont Report b. The Belmont Report, Declaration of Helsinki, Nuremberg Code c. Nuremberg Code, The Belmont Report, Declaration of Helsinki d. Declaration of Helsinki, Nuremberg Code, The Belmont Report	**1.5**	**CO2**
15	What is an "investigational new drug (IND)"?	**1.5**	**CO3**
16	The Declaration of Helsinki was developed by a. the American Medical Association b. the Nuremberg tribunal c. the government of Finland d. the World Medical Association	**1.5**	**CO1**
17	Why Placebo treatment is given during clinical trial?	**1.5**	**CO2**
18	Define 122-DAA.	**1.5**	**CO3**
19	The Schedule in Drugs and Cosmetics Act that deals with the requirements and guidelines for clinical trials, import and manufacture of new drugs is…….. a. Schedule 'O' b. Schedule 'M' c. Schedule 'F' d. Schedule 'Y'	**1.5**	**CO1**
20	What is PMDA?	**1.5**	**CO2**
	SECTION B		
Ques		**20**	**CO**
1	Discuss why clinical trial registration is important?	**5**	**CO1**
2	What is FDA? What is the role of FDA in clinical trials.	**2+3**	**CO2**
3	Identify the CFR dealing with the protection of the human subjects? What are the three basic principles for the protection of human subjects in research?	**2+3**	**CO3**
4	Discuss any five elements of Nuremberg Code.	**5**	**CO4**
	SECTION C		
		30	
1	As per ICH-GCP Guideline, Principle 12 is applied (1) through appropriate procedures to protect the privacy of the subject, and (2) by document and data control to protect the confidentiality of the subject's information. Principle 12 is also applied through the informed consent process which requires as an essential element that certain explanations be provided to the subject about the confi dentiality of the subject's records and about access to those records by monitor(s), auditor(s), the IEC/IRB, and the regulatory authority(-ies).	**15**	**CO4**

	a. What is Informed Consent Form? (3 marks) b. What is meant by "privacy" and "confidentiality"? (5 marks) c. What is IEC/IRB? Mention their functions. (5 marks) d. Who is responsible for protecting the confidentiality of the subjects' private information? (2 marks)		
2	Global Clinical Trial means any clinical trial which is conducted as part of multi-national (more than one country) clinical development for designed and development for approval of a new drug worldwide. Regulatory issues in different countries and in different regions of the world impact the conduct, efficiency, and oversight of clinical trials. a. What are the different regulatory agencies responsible for conducting clinical trials across the globe? (4 marks) b. Mention the objectives of these agencies. (5 marks) c. Which regulatory authority is responsible for the approval of vaccine in India? (1 marks) d. Why is it important to have regulations implemented for clinical trials? (5 marks)	**15**	**CO5**
SECTION D			
	Long Answer type Questions Scan and Upload (10 marks each) For 8 marks questions word limit not more than 300 words	**20 marks**	
1	What is NDA? Differentiate NDA 505(b) (1) of the FD&C Act and II and NDA 505(b) (2) of the FD&C Act. (2+8 marks) **OR** Define Adverse Drug Reaction (ADR). Discuss the importance of Pharmacovigilance. (2+8 marks)	**10**	**CO1 CO5**
2	Enlist ten main principles of Declaration of Helsinki. **OR** Define Bioavailability. Discuss FDA Safety Reporting Requirements for INDs and BA/BE Studies. (2+8 marks)	**10**	**CO2 CO3**