Name:

Enrolment No:

UNIVERSITY OF PETROLEUM AND NERGY STUDIES
End Semester Examination, May 2023
(Set-B)

Course: Good Clinical Practices **Semester: IV**
Program: B.Sc. Clinical Research **Duration: 03 hrs**
Course Code: HSCR2023 **Max. Marks: 100**

Instructions: Read each question carefully. Attempt all questions under Section A-D.

	SECTION A	**(20Q x1.5M= 30 Marks)**	**CO**
	MCQs or Fill in the blanks or single line answer-type		
Q1	The full form of CFR is ……..	**1.5**	CO1
Q2	The full form of IEC is ……	**1.5**	CO1
Q3	Document mandatory to enroll the human subject in a clinical research study is: A) Protocol B) Case Report Form C) Informed Consent Form D) Investigators Brochure	**1.5**	CO1
Q4	Preclinical studies are conducted on animals and artificial cells in labs. A) True B) False	**1.5**	CO1
Q5	To begin with a clinical research study, it is mandatory to get approval from: A) Sponsor B) Investigator C) Regulator D) Both Regulators and Ethics committee	**1.5**	CO1
Q6	Who is responsible for preparing essential documents like protocol/ investigators brochure/ informed consent form/ case report form during clinical trials? A) Investigator B) Ethics committee C) Scientist D) Sponsor	**1.5**	CO1
Q7	According to ICH GCP when should a sponsor provide an audit certificate? A) Always B) Whenever an audit has been completed successfully C) When requested D) When required by applicable law or regulation	**1.5**	CO2
Q8	According to ICH GCP who is responsible to ensure that the trial site staff assisting with the trial are adequately informed about trial procedures? A) Sponsor B) Monitor C) Ethics committee D) Investigator	**1.5**	CO2
Q9	What is the Principle 4 of GCP?	**1.5**	CO2
Q10	The full form of DSMB is _____	**1.5**	CO1
Q11	According to ICH GCP the information for clinical trial subjects should include "That the subject or the subject's legally acceptable representative will ……."	**1.5**	CO2

	A) be required to sign the consent form B) have a responsibility to inform the investigator of any change of circumstances affecting the subject's ability to participate in the trial C) be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial D) be required to maintain confidentiality regarding the trial and the subject's participation in the trial		
Q12	According to the principles of ICH GCP, what is the most important consideration when conducting a clinical trial? A) Data accuracy B) Protection of trial subjects C) Process adherence D) Statistical quality checks	**1.5**	CO1
Q13	The CIOMS was formed in: A) 1945 B) 1947 C) 1949 D) 1990	**1.5**	CO3
Q14	Prior to subject's participation in the trial, the …… should be signed and personally dates by the subject or by the subject's LAR. A) Protocol B) Clinical Trial Agreement C) IRB Approval Report D) Written Informed Consent Form	**1.5**	CO1
Q15	The federal policy requires that an IRB have at least A) 3 members B) 4 members C) 5 members D) 6 members	**1.5**	CO3
Q16	Federal law allows for human-subject research of minimal risk to be exempt from IRB review. A) True B) False	**1.5**	CO3
Q17	A clinical research aiming to carry out cross-sectional study requiring bronchoscopy following administration of methacholine should: A) Undergo a full review by IRB B) Not required any review by IRB C) Have an expedited review D) None of the above	**1.5**	CO3
Q18	The IRB is one part of the research enterprise designated to protect human subjects. A) True B) False	**1.5**	CO3
Q19	Write the full form of CIOMS?	**1.5**	CO1
Q20	The ICH was founded in the _____(year) and _____ (place).	**1.5**	CO1
	SECTION B	**(4Qx5M=20 Marks)**	**CO**
Q1	What is a clear detailed protocol? What information should be included in a study protocol?	(5)	CO3
Q2	What is Blinding / Masking in the clinical trial? What makes clinical research ethical?	(2+3)	CO1
Q3	Discuss on important ethical considerations regarding the selection of human as subject in any clinical research. What are the various responsibilities of Sponsor for the conduct of any clinical research?	(5)	CO3
Q4	What is the composition of IRB? Describe the main responsibilities of IRB.	(2+3)	CO3
	SECTION C	**(2Qx15M=30 Marks)**	**CO**

	Two case studies 15 marks each subsections *(Note. These case studies are based on the published reports)*		
Q1	***Case study A****: The drug Letrozole was approved all over the world for the treatment of breast cancer in post-menopausal women but was never authorized for any other indication in India. In 2003, Sun Pharmaceutical conducted a clinical trial of Letrozole for the treatment of inducing ovulation. The USFDA and British Authority had already labeled Letrozole as embryotoxic, fetotoxic, and teratogenic at minuscule doses. At more than 9 centers across India, approximately 300 women were enrolled in this trial without their prior knowledge or consent. The trial was conducted without any permission from the DCGI, and animal testing was also not done for a new indication. Moreover, it was conducted by an investigator who just had a diploma in gynecology.* *Question I. Was this trial ethical as per various regulatory guidelines? Justify your answer with respect to merits (if yes) or violations (if no).* *Question II. What are the various ethical violations made in this trial?* ***Case study B:*** *In 2009, many people in the Maharaja Yashwantrao Public hospital were unknowingly enrolled in the clinical trial for Tonapofylline, a drug developed by Biogen Idec. Most of the patients were poor and illiterate and were informed that some charity was going to pay for their expensive treatments. Some of the patients in this trial suffered cardiac arrest and seizures.* *Question III. Was this trial ethical as per various regulatory guidelines? Justify your answer with respect to merits (if yes) or violations (if no). Question IV. What are the various types of ethical violations made in this trial?*	**(3+4+4+4)**	CO4
Q2	***Case study A****: In 2002, Novo Nordisk conducted a large Phase III clinical trial in 32 countries, including India, for the drug Ragaglitazar, which was a treatment option for diabetes. Approximately 2,500 subjects were enrolled in the trial all over the world, including the EU and USA. However, the drug was not fully tested on animals.* Question I. Has there been a compliance with ethical guidelines. Share your opinion. Question II. Should this Phase III trial be suspended? Justify your answer. ***Case study B:*** *The Maharaja Yashwantrao Public Hospital involved a three-day-old baby, who was given a testing vaccine. The family signed a form written in English, which they did not understand and were informed that polio vaccine was being administered to the baby so, they had no idea that the doctor was giving her an experimental vaccine. The baby had seizures and bronchitis attacks after receiving the vaccine and subsequently, suffered from breathing and eating problems. The family was told that these problems were not due to the vaccine even though they probably were.* **Question III.** Was this trial ethical as per various regulatory guidelines? Justify your answer with respect to merits (if yes) or violations (if no). **Question IV.** What are the various ethical violations in this trial?	**(3+4+4+4)**	CO4
	SECTION- D	**(2Qx10M=20 Marks)**	**CO**
Q1	Discuss on the review process of a clinical research proposal by the IRB. Write a short note on the Protocol Compliance.	(6+4)	CO3
Q2	(A) What is meant by "respect for persons" and how is it most directly implemented within GCP? (B) What is meant by "justice" and how is it most directly implemented within GCP?	(5+5)	CO3