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UNIVERSITY OF PETROLEUM AND NERGY STUDIES

End Semester Examination, December 2021
(Set-A)

Course: Regulatory Aspects - Clinical Research and IPR **Semester: III**
Program: M.Sc. Clinical Research **Duration: 03 hrs**
Course Code: HSCR8005P **Max. Marks: 100**

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

	SECTION A **(Type the answers in text box)**	**(20Q x1.5M= 30 Marks)**	**CO**
	MCQs or Fill in the blanks or single line answer-type		
Q1	Which document created in 1964 forms the basis of ethical considerations in clinical research? A) Declaration of Belfast B) Declaration of Helsinki C) Declaration of Geneva D) None of the above	**1.5**	CO3
Q2	What does IRB stand for? A) Investigational Review Board B) Internal Review Board C) Institutional Review Board D) International Review Board	**1.5**	CO3
Q3	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
Q4	What does ICH stand for? A) International Convention on Homogenization B) International Conference on Harmonisation C) International Conference on Homogenization D) International Convention on Harmonisation	**1.5**	CO3
Q5	According to the ICH GCP guidelines, "Neither the investigator nor the trial staff, should ..... a subject to participate or to continue to participate in a trial" A) convince B) coerce or unduly influence C) compel D) change the opinion	**1.5**	CO1
Q6	What protects the intellectual property created by inventors? A) Copyright B) Trademarks C) Patents D) Geographical indications	**1.5**	CO4
Q7	The full form of WIPO is …….	**1.5**	CO1
Q8	What does a trademark protect? A) An invention B) A work of art C) Logos, names and brands D) A secret formula	**1.5**	CO4
Q9	The full form of IPC is …….	**1.5**	CO1
Q10	What protects the intellectual property created by artists? A) Copyright	**1.5**	CO4

	B) Patents C) Trademarks D) Registered designs		
Q11	What is CIOMS?	**1.5**	CO1
Q12	In how many phases clinical research study is conducted? A) 1 B) 4 C) 5 D) 8	**1.5**	CO1
Q13	According to ICH GCP the investigator "should be qualified by....."? A) Training and experience B) Education and training C) Education and experience D) Education, training and experience	**1.5**	CO3
Q14	In clinical research studies, conflict of interest is a risk factor for scientific misconduct. A) True B) False	**1.5**	CO1
Q15	A clinical trial must have IRB/IEC approval before it can begin? A) True B) False	**1.5**	CO3
Q16	Adverse Drug Reaction reporting is mandatory during clinical trials. A) True B) False	**1.5**	CO1
Q17	A clinical research involving the epidemiologic study of COPD with NHANES data: A) Require a full review by IRB B) Can be exempted from review by IRB C) Require an expedited review D) None of the above	**1.5**	CO1
Q18	Along with the IND application, the sponsor submits the statement of the Investigator (Investigator's undertaking) in Form number ……?	**1.5**	CO5
Q19	Define the Adverse Event (AE).	**1.5**	CO1
Q20	Define Blinding/Masking in the clinical trial.	**1.5**	CO1
	SECTION B (Scan and upload)	**(4Qx5M=20 Marks)**	**CO**
Q1	Why should we do clinical research with human beings? Why is the clinical research ethically challenging?	(2+3)	CO1
Q2	What is Blinding / Masking in the clinical trial? What makes clinical research ethical?	(2+3)	CO1
Q3	What is informed consent process? Discuss on the various challenges of the informed consent process.	(2+3)	CO3
Q4	Describe the main responsibilities of the IRB. What are the four categories of ICH guidelines, and how many guidelines are there in each categories?	(2+3)	CO3
	SECTION C (Scan and upload)	**(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:*** *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.*	**(3+4+4+4)**	CO 1-4

	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:*** *In Trivandrum, the Kerala Regional cancer treatment center conducted a clinical trial for the drug Nordihydroguaiaretic acid (NDGA) for the treatment of oral cancer during 1999-2000. The sponsor of the trial was Johns Hopkins University Hospital. The drug was administered to 26 patients before the animal safety was known; moreover, patients were not informed that they were taking part in a trial and that they can deny participation. Two patients died in this trial.* **Question III.** What are the various ethical violations made in this trial? **Question IV.** Who should be blamed for such violations?		
Q2	***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)**	CO 1-4
	SECTION- D **(Scan and upload)**	**(2Qx10M=20 Marks)**	**CO**
Q1	Discuss on the composition of the IRB. What are the types of IRB review process? Explain any one with suitable example.	(3+3+4)	CO1
Q2	Describe the organization of ICH. Discuss on the ICH process for guidelines development.	(6+4)	CO3