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

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

Course: Good Clinical Practice: Conducting Clinical Trials **Semester: II**
Program: M.Sc. (Clinical Research) **Time: 03 hrs.**
Course Code: HSCR7010 **Max. Marks: 100**

Instructions: All the sections are compulsory

SECTION A

1. Each Question will carry 1.5 Marks
2. Instruction: Answers all the 20 questions.

S. No.	Type the answer/True or False /MCQ/Fill in the blanks Questions.	**30 Marks**	**CO**
1	Define Good Clinical Practice……	**1.5**	**CO1**
2	The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment is known as…….	**1.5**	**CO2**
3	Write any two significance of good clinical practice in clinical trials.	**1.5**	**CO3**
4	Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research is known as…….	**1.5**	**CO1**
5	Clinical trial monitor is third party personnel who is not directly involved in clinical trials. A. True B. False	**1.5**	**CO1**
6	21 CFR Part 312 is related to…….and 21 CFR Part 56 is related to……	**1.5**	**CO2**
7	Write down the perfect way of clinical trial have reported in media?	**1.5**	**CO3**
8	……prepare and maintain case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation.	**1.5**	**CO1**
9	According to ICH GCP what are the absolute minimum requirements for essential documents at site before IMP can be sent to the site. (A) CV of investigator and Clinical Trial Authorisation (CTA) (B) Ethics Committee Approval and signed protocol (C) CTA and Ethics Committee Approval	**1.5**	**CO2**

	(D) CTA, Ethics Committee Approval and signed protocol		
10	What C is missing from this statment in ICH GCP: The sponsor should provide insurance or should indemnify (legal and financial XXXXX) the investigator against claims arising from the trial, except for claims arising from malpractice and/or negligence? (A) Compensation (B) Coverage (C) Costs (D) Compliance	**1.5**	**CO3**
11	Prior to subject's participation in the trial, the _____should be signed and personally dates by the subject or by the subject's LAR.	**1.5**	**CO1**
12	According to ICH GCP the investigators should be qualified by _____ to assume responsibility for the proper conduct of the trial. (A) Training and experience (C) Education, training and experience (B) Education and experience (D) Education and training	**1.5**	**CO2**
13	What does ICH stand for?	**1.5**	**CO3**
14	Give any two examples of inclusion criteria for human subjects for enrollment in clinical study.	**1.5**	**CO1**
15	Clinical study report does not include the data of patients who discontinued during trial. A. True B. False	**1.5**	**CO2**
16	Which of the following is not the part of title page of clinical study report? (A) Name of the sponsor (C) Name of investigational product (B) Protocol identification code (D) Study center(s)	**1.5**	**CO3**
17	According to ICH GCP the investigator should be qualified by.....?	**1.5**	**CO4**
18	Section 6 of ICH GCP states the protocol should generally include stopping rules for individual subjects, parts of trials and entire trial. What other term does it specify in addition to Stopping Rule? (A) Interim Analyses (C) Endpoints (B) Termination Criteria (D) Discontinuation Criteria	**1.5**	**CO4**
19	A clinical trial must have IRB/IEC approval before it can begin?	**1.5**	**CO4**
20	We know that clinical research is necessary to establish the safety and effectiveness of specific health, medical products and practices. A. True B. False	**1.5**	**CO4**
SECTION B			
Q	**Short Answer Type Question (5 marks each) Scan and Upload 4 questions 5 marks each.**	**20 Marks**	**CO**
1	How is identification of risks and benefits implemented within GCP and where may information about risks and benefits be obtained?	**5**	**CO1**
2	What is GLP (Good Laboratory Practice) and what is the relationship between GLP and GCP Principle?	**5**	**CO2**

3	Who is responsible for determining that the risk/benefit profile of a study is acceptable or unacceptable?	**5**	**CO3**
4	How is compliance with the protocol ensured and documented within GCP?	**5**	**CO4**
SECTION C			
Q	**Two case studies 15 marks each subsection**	**30 Marks**	**CO**
1	**Case Study 1:** FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic. As per new guidelines answer the following questions: (i) Suppose your company is the NDA holder of an FDA-approved drug for a non-COVID-19 indication and is also the sponsor of an IND for the same drug being investigated to treat COVID-19. If you receive a spontaneous report of a serious adverse event that occurred with the approved drug being used in clinical practice for treatment of COVID-19, do you report that event to the IND for the COVID-19 investigational use? (5) (ii) Suppose you are a study monitor and you are unable to conduct on-site monitoring visits due to the COVID-19 public health emergency. May I remotely perform the site monitoring visit? What recommendations does FDA have for how I can remotely perform source document review? (5) (iii) How can the sponsor ensure proper disposal of unused investigational drug product if the participant cannot return to the study site? (5)	**15**	**CO1**
2	**Case Study 2:** With reference to January 2021, updated revised FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency Guidance for Industry, Investigators, and Institutional Review Boards answer the following questions. (i) COVID-19 patients are hospitalized and thus they fall in category of vulnerable population. Thus, as per guidelines audio- video consent should be taken from them. But it is observed that only written informed consent is being taken. Comment on this? (5) (ii) What are some of the key factors that a sponsor should consider when deciding whether to suspend or continue an ongoing study or to initiate a new study during the COVID-19 public health emergency? (5) (iii) The rapid changes in clinical trial conduct that may occur due to the COVID-19 public health emergency, including multiple deviations to address patient safety, what is the best way for sponsors and investigators to capture these data? (5)	**15**	**CO2**

	SECTION- D		
Q	Long Answer type Questions Scan and Upload (not more than 500 words for each question).	**20 Marks**	**CO**
1	Explain about the IRBs and Multi-Site Research.	**10**	**CO3**
2	Discuss in detail about total 13 WHO Principles of GCP.	**10**	**CO4**