Name:

Enrolment No:

UPES

End Semester Examination, December 2023

Course: Site Management Operations **Semester: III**

Program: Int. (B.SC.+ M.Sc.) Clinical Research **Duration: 3 Hours**

Course Code: HSCC 2021 **Max. Marks: 100**

Instructions: Attempt all questions as per the marks assigned.

S. No.	Section A Short answer questions/T&F (20Q x 1.5M = 30 Marks)	Marks	COs
Q 1	Write correct sequence of a new drug reaching the consumer.	1.5	CO1
Q 2	Enlist 3 reasons of patient non-adherence for study protocol?	1.5	CO3
Q 3	Define conversion rate. Explain with its calculation.	1.5	CO2
Q 4	Give examples of 3 organizations which can sponsor a clinical trial?	1.5	CO1
Q 5	Enlist any 3 outreach resources for target audience.	1.5	CO3
Q 6	Advertisement for patient identification and recruitment must be approved by IRB. (True/ False)	1.5	CO3
Q 7	Format of case report form should be as per which regulatory guideline?	1.5	CO2
Q 8	Define good clinical practice.	1.5	CO4
Q 9	Enlist any 3 factors which may impact the recruitment rates of patients in clinical trials.	1.5	CO3
Q 10	In double blinding method both investigator and patient are unaware of IND. (True/ False)	1.5	CO1
Q 11	Differentiate between paper CRF and e-CRF.	1.5	CO2
Q 12	Randomization in assigning the subjects in clinical studies gives biased data. (True/ False)	1.5	CO1
Q 13	Name any two advanced approaches which can ease the process of patient identification.	1.5	CO3
Q 14	The inspectors for clinical trial inspection are appointed by which regulatory body?	1.5	CO2
Q 15	Schedule …….. under …….. Act provides guidelines for the conduction of clinical trials of new drugs in India.	1.5	CO2
Q 16	Define informed consent.	1.5	CO4
Q 17	Write the fullform of DCGI.	1.5	CO4

Q 18	Write an example for a well-designed and poorly designed case report form.	**1.5**	**CO2**
Q 19	Write any 3 key points for successful participant retention strategy.	**1.5**	**CO3**
Q 20	What do you understand by investigational product?	**1.5**	**CO4**
Section B (4Qx5M=20 Marks)			
Q 1	Differentiate between protocol deviation and protocol violation.	**5**	**CO2**
Q 2	Explain the advantages of working with SMOs.	**5**	**CO4**
Q 3	Briefly describe an investigator site file. Discuss the essential documents that should be placed in it?	**2+3**	**CO3**
Q 4	Is source data verification a part of case report form? If yes, explain the data that should be checked thoroughly in this process?	**1+4**	**CO2**
Section C (2Qx15M=30 Marks)			
Q 1	a) Describe case report form with special emphasis on its purpose, format & layout, header, footer and data collection. b) Case report form is used to collect information from clinical trial participants. Justify the statement by explaining the information which is collected by it.	**8+7**	**CO2**
Q 2	a) Differentiate between CROs and SMOs. b) Classify global site management organizations. c) Give a thorough overview on various services that are offered by CROs.	**5+4+6**	**CO4**
Section D (2Qx10M=20 Marks)			
Q 1	Explain funnel analysis with a well-labeled diagram. Emphasize on SWOT analysis while developing a site specific patient recruitment plan.	**4+6**	**CO3**
Q 2	Maintaining the quality of any clinical research project requires inspection from regulatory authorities. Support the above statement in terms of following: a) What are the objectives of clinical trial inspection? b) Discuss responsibilities of ethics committee in GCP. c) Enlist various members and their number required for composition of ethics committee under GCP.	**3+4+3**	**CO1**