Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

PHARM.D YEAR-5 / PHARM.D (PB) YEAR-2 EXAMINATION – SUMMER - 2025

Subject Code: 858801/828901 **Date: 02-05-2025**

Subject Name: Clinical Research

Time: 02:30 P.M. TO 5:30 P.M. **Total Marks: 70**

Instructions:

1. **Attempt any five questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

Q.1	**(a)**	Explain in detail about IND application.	**06**
	(b)	Brief about pre-clinical evaluation of drug during development process.	**04**
	(c)	Define ICF. Discuss designing of Informed consent form.	**04**
Q.2	**(a)**	Make a detail note on the designing of the protocol for clinical study.	**06**
	(b)	Brief role and responsibilities of followings (A) Regulatory authority (B) Investigators	**04**
	(c)	Short note on various phases of clinical trials.	**04**
Q.3	**(a)**	Define Sponsor. Explain sponsor's responsibilities.	**06**
	(b)	Discuss ethical guideline requirements during clinical research.	**04**
	(c)	Define Toxicity. Brief about toxicological studies conducted during drug development process.	**04**
Q.4	**(a)**	Discuss ICH-GCP guideline in accordance with good clinical practice.	**06**
	(b)	Brief on the role and responsibilities of the Auditors during clinical studies.	**04**
	(c)	Explain in detail about Informed Consent Process.	**04**
Q.5	**(a)**	Discuss the process of ANDA submission.	**06**
	(b)	Brief about methods of the post marketing surveillance.	**04**
	(c)	Make a note on role and responsibilities of the clinical research coordinator.	**04**
Q. 6	**(a)**	Brief the composition of IRB. Explain in details about responsibilities of members.	**06**
	(b)	Describe the procedure of the IEC for the approval of the protocol.	**04**
	(c)	Define CRF. Explain in detail about its designing.	**04**
Q.7	**(a)**	Compare and overview of regulatory requirements in USA, Europe and India.	**06**
	(b)	Discuss challenges in the implementation of the different guidelines.	**04**
	(c)	Define followings: Dosage form, Drug Characterization	**04**

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