

GUJARAT TECHNOLOGICAL UNIVERSITY
PHARM.D YEAR-5 / PHARM.D (PB) YEAR-2 EXAMINATION – WINTER - 2025

Subject Code: 858801/828901**Date: 13-11-2025****Subject Name: Clinical Research****Time: 10 : 30 AM TO 1 : 30 PM****Total Marks: 70****Instructions:**

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

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|-------------|-----|--|-----------|
| Q.1 | (a) | Explain in detail the process and importance of designing the study protocol in clinical trial | 06 |
| | (b) | Enlist various phases of Clinical trial. Mention objective of each phase. | 04 |
| | (c) | Illustrate schematic representation of integrated drug development process | 04 |
| Q.2 | (a) | What is IND? Enlist different criteria for IND. | 06 |
| | (b) | Define Ethics. Discuss ethical issues of clinical research involving children. | 04 |
| | (c) | Explain Belmont Report and Nuremberg trial | 04 |
| Q.3 | (a) | Explain designing of CRF with suitable example | 06 |
| | (b) | Explain the challenges in implementation of guidelines in clinical trials | 04 |
| | (c) | What is significance of Post marketing surveillance? Explain | 04 |
| Q.4 | (a) | Write a note on CDSCO guidelines for clinical research | 06 |
| | (b) | What is ANDA? Explain review process of ANDA | 04 |
| | (c) | Explain the roles of DSMB | 04 |
| Q.5 | (a) | Describe composition and responsibilities of IEC | 06 |
| | (b) | Enlist principles of ICH GCP guidelines | 04 |
| | (c) | Write roles and responsibilities of Clinical Research Associate in clinical trial | 04 |
| Q. 6 | (a) | Describe pharmaceutical regulations with regard to clinical trials in European union | 06 |
| | (b) | Explain roles and responsibilities of Investigator | 04 |
| | (c) | Explain Informed Consent Process in detail | 04 |
| Q.7 | (a) | Give an overview of regulatory environment for clinical trial in USA | 06 |
| | (b) | Describe the procedure of communicating Periodic Safety Update Reports (PSUR). | 04 |
| | (c) | Explain components of data management in clinical trial | 04 |
