

GUJARAT TECHNOLOGICAL UNIVERSITY
PHARM.D. –YEAR-5/ PHARM.D(PB) YEAR-2 EXAMINATION – SUMMER - 2024

Subject Code: 858801/828901**Date: 29/04/2024****Subject Name: Clinical Research****Time: 02:30PM TO 05:30PM****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) With schematic representation, discuss drug development process. | 06 |
| | (b) Write a note on informed consent process. | 04 |
| | (c) Discuss the responsibilities of clinical data manager. | 04 |
| Q.2 | (a) Discuss various phases of clinical trials. | 06 |
| | (b) Write a note on ANDA submission. | 04 |
| | (c) Describe protocol amendment in clinical research. | 04 |
| Q.3 | (a) Explain the components of ICH-GCP. | 06 |
| | (b) Explain ethical guidelines in clinical research. | 04 |
| | (c) List the type of audits and its importance in clinical trials. | 04 |
| Q.4 | (a) Discuss the composition and responsibilities of IRB/IEC. | 06 |
| | (b) Write a note on electronic data capturing system and its role in clinical research. | 04 |
| | (c) Describe the methods and benefits of post marketing trials. | 04 |
| Q.5 | (a) Define serious adverse event in clinical trials and the role of investigators in reporting them. | 06 |
| | (b) Enlist the clinical study documents. Explain its importance. | 04 |
| | (c) Discuss randomization in clinical trials. | 04 |
| Q.6 | (a) Write a note on overview of regulatory environment in India. | 06 |
| | (b) Discuss data migration and archiving. | 04 |
| | (c) Define the following terms:
a) Vulnerable subjects b) Comparator c) Blinding d) Good clinical practices. | 04 |
| Q.7 | (a) Define investigator's brochure and describe its components. | 06 |
| | (b) Write a note on schedule Y. | 04 |
| | (c) Explain the following terms:
a) Impartial witness b) PSUR c) Placebo d) Candidate drug. | 04 |
