

Rajiv Gandhi University of Health Sciences, Karnataka
V Year Pharm-D (II Year Pharm D Post Baccalaureate) / V Year Pharm-D Degree
Examination – 24-Oct-2024

Time: Three Hours

Max. Marks: 70 Marks

CLINICAL RESEARCH (RS & RS2)

Q.P. CODE: 2874 / 2890

Your answers should be specific to the questions asked
Draw neat, labeled diagrams wherever necessary

LONG ESSAYS (Answer any two)

2 x 10 = 20 Marks

1. What is institutional review board (IRB)? Detail the constitution and function of the institutional review board (IRB).
2. What is clinical trial document? Explain the various trial documents involved in the clinical trial.
3. What is IND Application? Detail the process of IND Application.

SHORT ESSAYS (Answer any six)

6 x 5 = 30 Marks

4. Challenges in the implementation of ICH GCP guidelines.
5. Roles and responsibilities of study coordinator.
6. Briefly describe about various phases of clinical trial.
7. Regulatory environment in USA.
8. What is clinical trial audit? Briefly describe the types of audit.
9. Quality control and quality assurance in clinical data management.
10. Various approaches to drug discovery.
11. Methods of post marketing surveillance.

SHORT ANSWERS

10 x 2 = 20 Marks

12. What is ICH GCP?
13. List the members of institutional ethical committee.
14. What is Randomization?
15. What is drug development process?
16. What is pre-study visit?
17. Define investigator's brochure.
18. What is CRF?
19. What is site close-out visit?
20. What is fraud and misconduct in clinical trial?
21. Define archival of study documents.
