

Rajiv Gandhi University of Health Sciences, Karnataka
V Year Pharm-D / II Year Pharm D Post Baccalaureate Degree Examination – 30-May-2024

Time: Three Hours

Max. Marks: 70

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. Define clinical trials. Write the requirements to conduct clinical trials as per schedule Y.
2. Explain in detail the role and responsibilities of clinical research coordinator and sponsor.
3. Explain the spontaneous reporting of adverse drug reactions with suitable examples. Write the merits and demerits of spontaneous reporting.

SHORT ESSAYS (Answer any six)

6 x 5 = 30 Marks

4. Explain different pharmacological action studies in drug development process.
5. Write a note on electronic data processing.
6. Explain about different types of observational studies.
7. Write about Fast track and Priority reviews.
8. What is IND? Enlist the different criteria for IND application.
9. Write a short note on clinical trial design.
10. Write a note on ANDA.
11. Explain the clinical trials with surgical procedures.

SHORT ANSWERS

10 x 2 = 20 Marks

12. What is the role of Uppsala Monitoring center?
13. What is ANOVA?
14. Write role of DSMB in safety monitoring.
15. Differentiate between consent and assent forms.
16. Criteria for selection of investigator.
17. What is clinical trial document?
18. Vulnerable subjects.
19. Use of placebo in clinical trials.
20. What is Nuremberg trials?
21. What is CIOMS?
