Rajiv Gandhi University of Health Sciences, Karnataka

V Year Pharm-D/II Year Pharm-D (Post Baccalaureate) Degree Examination – June 2014

Time: Three Hours **Max. Marks: 70 Marks**

CLINICAL RESEARCH

Q.P. CODE: 2874

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 are the roles and responsibilities of sponsor and of investigator in clinical research?
2. Discuss about designing of inform consent form for clinical study?
3. Write about data management and its components in clinical drug development.

SHORT ESSAYS (Answer any six) **6 x 5 = 30 Marks**

4. Write a short note on methods of post marketing surveillance.
5. Explain phase II and phase III clinical trials.
6. Explain how bioequivalence study is conducted.
7. Explain a short note on schedule Y.
8. Explain various pharmacological & toxicological approaches to drug discovery.
9. Roles and responsibilities of auditors in clinical research.
10. What are the responsibilities of EMEA?
11. Explain the significance difference between ICH GCP and Indian GCP.

SHORT ANSWERS **10 x 2 = 20 Marks**

12. What is Belmont report?
13. When did ICH come in to existence and which are countries involved.
14. What do you mean by Site close out visit/
15. Uses of Med watch FDA From 3500A and Med Watch FDA From 3500.
16. Functions of DCGI.
17. What are Form 44 and From12?
18. Composition of IEC.
19. What is IND
20. Name different types of clinical trials.
21. Define "Blinding" in clinical trials.

*****