Q.P. Code: 201340 **Reg. no.: ……**

Second Pharm D Post Baccalaureate Degree Examinations, August 2015

Paper I – Clinical Research

Time: 3 Hours **Total Marks: 70**

- Answer all questions
- Draw diagrams wherever necessary

Essay: **(3x10=30)**

1. What is informed consent. Explain the informed consent process in a clinical trial.

2. Explain the composition and procedure of institutional review board in detail.

3. Define clinical trial. Explain various phases of clinical trials.

Short notes: **(8x5=40)**

4. Roles of clinical research associate as per international conference on harmonization good clinical practice.

5. Regulatory environment in India for clinical trial.

6. Investigational new drug application.

7. Designing of case report form.

8. What is abbreviated new drug application (ANDA), add a note on abbreviated new drug application submission
9. Pharmacological approaches to drug discovery.

10. Data monitoring in clinical trail.

11. Importance of safety monitoring in clinical trial.

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