

**QP CODE: 114332**

**Reg. No:.....**

**First Semester M.pharm Degree Examinations March 2019**

**M.Pharm (Pharmacy Practice)**

**Paper IV: Clinical Research (MPP 104T)**

**Time: 3 Hours**

**Total Marks: 75**

- Answer all Questions.
- Draw Diagrams wherever necessary.

**Essays**

**(3x10=30)**

1. What is clinical trial. Explain the various phases, planning and execution of clinical trials.
2. What is institutional review board. Explain the constitution and functions of the institutional review board.
3. What is audit in clinical trials. Explain the types, process and follow up of audit

**Short Notes**

**(9x5=45)**

4. Discuss the case control and cross sectional study.
5. What is informed consent form. Discuss the process of informed consent.
6. Electronic data capture systems.
7. Define and explain the preparation of source document.
8. Procurement and storage of investigation product.
9. Roles and responsibilities of investigator.
10. What is clinical trial data management. Explain the data transfer and database lock process.
11. Briefly explain: ICH - good clinical practice.
12. Discuss about the essential documents for conducting clinical trial.

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