[LN 825] OCTOBER 2018 **Sub. Code: 3825**

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FIFTH YEAR
PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : Three hours **Maximum : 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. Describe the types of control and significance of using control in clinical trials.

2. Write the essential elements of informed consent form and problems in informed consent.

3. Discuss in detail about role and responsibilities of principal investigator in clinical research.

4. Explain components of ICH-GCP guidelines and write its significance.

II. Write notes on: **(6 x 5 = 30)**

1. Define randomization. Write a note on static and adaptive designs.
2. Write about functions of various regulatory divisions of US-FDA.
3. Write a short note on investigators brochure.
4. List the type of audits and its importance in clinical trials.
5. Write a note on new drug application submission.
6. Define parallel and cross over study designs of clinical research.

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