[LO 825] MAY 2019 **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 importance and requirements of various phases of clinical trials.
2. Discuss in detail about the role and responsibilities of clinical research associate.
3. Describe the clinical trial data management process and its benefits.
4. Explain in detail about essential documents of clinical research process.

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

1. Write a note on blinding and un-blinding.
2. Give a note on constitution and responsibilities of institutional review board.
3. Write a brief note on case record form.
4. Write a short note on regulatory setup in Europe.
5. Briefly write about study site audits and its significance.
6. Write a short note on informed consent process.

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