[LE 825] **APRIL 2014** **Sub. Code: 3825**

DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

FIFTH YEAR

PAPER I – CLINICAL RESEARCH

Q.P. Code: 383825

Time: Three Hours **Maximum: 70 marks**

Answer All questions

I. Elaborate on: **(2 x 20 = 40)**

1. a) What is clinical research and why do we need to conduct research?
   b) What are the different stages of drug development process?

2. a) Roles and responsibilities of contract research organizations in clinical research.
   b) Define Investigator's brochure and describes about its components.

II. Write notes on: **(10 x 3 = 30)**

1. Good clinical practice and its principles.
2. Informed consent process.
3. Central drug standard control organisation and food and drug administration.
4. Various ethical guidelines in clinical research.
5. Safety monitoring in clinical trials.
6. Source documents in clinical trial.
7. Vulnerable subjects.
8. Roles and responsibilities of Investigator in clinical trial.
9. What are the responsibilities of regulatory authority in clinical research?
10. Define the followings:
    a) Case report form (CRF).
    b) Impartial witness.
    c) Schedule-Y.

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