THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[PHARMD 1122] NOVEMBER 2022 Sub. Code: 3825
(OCTOBER 2022 EXAM SESSION)

PHARM 'D' and PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
FIFTH YEAR (2009-2010 Regulation)
PAPER I – CLINICAL RESEARCH
Q.P. Code : 383825

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

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

1. Write the roles and responsibilities of Investigators and contract research coordinators.
2. What is Institutional human ethical committee? Give the composition, qualification required for the members. Explain the functions of the committee.
3. Write a brief note on regulatory environment in Europe.
4. Elaborate on different dosage forms in drug development process.

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

1. Write note on vulnerable subjects.
2. Importance of post marketing surveillance.
3. Write note on drug characterization.
4. ICH guidelines in clinical trials.
5. What are Source documents in clinical trial?
6. Define the following:
   (i) Blinding (ii) Randomization (iii) Good clinical practice.

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