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

[PHARMD 0423] **APRIL 2023** **Sub. Code: 3825**

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

Q.P. Code: 383825

Time : Three hours **Answer ALL Questions** **Maximum : 70 Marks**

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

1. Explain briefly about Ind application and drug characterization.
2. Explain Safety monitoring in clinical trial.
3. Discuss in detail the overview of regulatory environment in Europe and India.
4. Explain the contents in Abbreviated New Drug Application submission.

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

1. Institutional review board.
2. Ethical guidelines in clinical research.
3. In clinical trials, what are the responsibilities of Auditors?
4. Explain briefly about protocol.
5. Write note on Sponsor.
6. Discuss the challenges in the implementation of Good Clinical Practice guidelines.

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