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

[LP 974] NOVEMBER 2019 **Sub. Code: 2974**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
BRANCH IV – PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH

Q.P. Code : 262974

Time : Three hours **Maximum : 75 Marks**

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

1. a) Explain the components of clinical research protocol and the process of protocol preparation.
   b) Discuss in detail about various methods used in post marketing safety monitoring process.

2. a) Define Bias. Discuss in detail about various sources of bias and methods to avoid Bias.
   b) Describe in detail about regulatory setup that governs the clinical research process in India.

II. Write notes on: **(7 x 5 = 35)**

1. Write the responsibilities of sponsor's in clinical trial.
2. Write a short note on drug discovery process.
3. List the type of audits and its importance in clinical trials.
4. Role and responsibilities of data management team in clinical trials.
5. Preparation of Informed Consent Form (ICF).
6. Explain briefly the ICH guidelines.
7. Briefly write on Case Report Form.

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