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

[M.PHARM 0823] **AUGUST 2023** **Sub. Code: 3003**
(APRIL 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER III – CLINICAL RESEARCH REGULATIONS

Q.P. Code: 263003

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

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

1. Discuss the clinical research regulations in India.

2. Explain the Regulatory Guidance on Efficacy and Safety ICH Guidance.

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

1. Differentiate the ICH GCP and Indian GCP guidelines.
2. What are the General Biostatistics principles applied in clinical research?
3. Write a note on CFR 21 part 312 and 314 of USFDA Guidance document.
4. Write in brief about EU Directives 2001.
5. Write a note on ISO 14155.
6. Write in brief GHTF study groups.
7. Write notes on informed consent form.

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