

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

**[PHARMD 1023]**

**OCTOBER 2023**

**Sub. Code: 3825**

**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**

**Answer ALL Questions**

**Maximum : 70 Marks**

**I. Elaborate on:**

**(4 x 10 = 40)**

1. Describe the composition and functions of IRB.
2. Discuss the different stages of drug development process.
3. Explain the clinical trial data management process and its benefits.
4. Discuss in detail the roles and responsibilities of investigator in clinical research.

**II. Write notes on:**

**(6 x 5 = 30)**

1. Types of audit and its significance in clinical research.
2. Investigator's brochure.
3. Case Report Form.
4. Contract Research Coordinators.
5. Vulnerable subjects.
6. Safety issues of investigational new drug.

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