Total No. of Pages : 1

Register Number : **7646**

Name of the Candidate :

P.G. DIPLOMA EXAMINATION DECEMBER 2013.

(CLINICAL RESEARCH AND MANAGEMENT)

120 — ETHICS, TRIAL PROCESS AND MEDICAL WRITING

Time : Three hours Maximum : 100 marks

I. Answer any TWO questions. (2 × 20 = 40)

(a) Describe ethical committee review in clinical research.

(b) List out the drug regulatory (scenario) in India.

(c) Discuss in detail the phase III clinical trial.

II. Answer any SIX questions. (6 × 10 = 60)

Write short notes on

(a) Medical monitoring.

(b) Clinical trial audit.

(c) Role of PI (principal investigator)

(d) Quality assurance matrix.

(e) The Nurembery code informed consent.

(f) Explain the major research records in a clinical trial.

(g) Stages of documentation.

(h) Medical writing styles.

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