

[LP 1019]

OCTOBER 2019

Sub. Code: 2867

**M.Sc. BIOSTATISTICS EXAMS
SECOND YEAR
PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT**

Q.P. Code : 282867

Time : Three hours

Maximum : 100 marks

I. Elaborate on:

(2 x 20 = 40)

1. Elaborate on the detailed manner of clinical trial registration and discuss in the brief manner of Challenges in Administering a Clinical Trials Registry.
2. Describe the various statistical methods in the randomized clinical trials and elaborate the factorial design and its characteristics with examples.

II. Write notes on:

(10 x 6 = 60)

1. Method of generating randomization sequence.
2. Method of allocation concealment.
3. Blinding and masking.
4. Intellectual property rights.
5. Impact of ethics on research.
6. DCGI approval.
7. Statistical bias.
8. Preclinical research.
9. Meta analysis.
10. Clinical trial.
