

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

[AHS 0122]

**JANUARY 2022
(OCTOBER 2021 EXAM SESSION)**

Sub. Code: 2867

**M.Sc. BIOSTATISTICS
SECOND YEAR (From 2011-2012 onwards)
PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT
Q.P. Code : 282867**

Time: Three hours

Answer ALL Questions

Maximum: 100 Marks

I. Elaborateon:

(2 x 20 =40)

1. Write in detail about Sequential and Group Sequential Designs in Clinical Trials.
2. Explain in detail about randomized control trial and its applications.

II. Writenoteson:

(10 x 6 =60)

1. Blinding in clinical trials
2. Preclinical Research
3. Who can participate in a clinical research study?
4. Difference between an observational clinical research study and a clinical trial.
5. Informed consent.
6. Interim analysis
7. Crossover trials
8. Multiple testing in clinical trials
9. Trial data and data management principles.
10. Essential Documents in Clinical Trials.
