## SHRIMATHI DEVKUNVAR NANALAL BHATT VAISHNAV COLLEGE FOR WOMEN (AUTONOMOUS) (Affiliated to the University of Madras and Re-accredited with 'A+' Grade by NAAC) Chromepet, Chennai — 600 044. M.Sc.- END SEMESTER EXAMINATIONS APRIL - 2022 SEMESTER - IV 20PBSCT4011 - Clinical Trials and Epidemiology

Total Duration : 3 Hrs.

Total Marks : 60

# Section A

Answer any **SIX** questions  $(6 \times 5 = 30 \text{ Marks})$ 

- 1. Discuss in detail the need and ethics of clinical trials.
- 2. Describe methods of randomization.
- 3. Explain the method for the dichotomous response variable.
- 4. Writes short notes on epidemiology measures.
- 5. Discuss observational and experimental studies.
- 6. Write short notes on the cross over design and hybrid design.
- 7. Explain the conduct of double-blind trials.
- 8. Write short notes on cross-sectional studies and cohort studies.

# Section B

# Part A

Answer any **TWO** questions  $(2 \times 10 = 20 \text{ Marks})$ 

- 9. Explain in detail the evaluation of patients' responses, follow up studies and GCP/ICH guidelines.
- 10. Describe statistical methods for determining trial size.
- 11. Explain the causation pie-Hil's Bradford model.
- 12. Discuss in detail the planning and epidemiological project.

## Part B

## Compulsory question $(1 \times 10 = 10 \text{ Marks})$

13. Explain phases of clinical trials.

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