Roll No. | | | | | | | | | | | | **Total No. of Pages : 02**

Total No. of Questions : 11

M.Sc. (BT) (Sem.-3)

CLINICAL RESEARCH

Subject Code : MBT-313

M.Code : 76735

Date of Examination : 21-12-22

Time : 3 Hrs. **Max. Marks : 70**

INSTRUCTIONS TO CANDIDATES :

1. **SECTION-A is COMPULSORY consisting of TEN questions carrying TWO marks each.**
2. **SECTION-B contains SEVEN questions carrying SIX marks each and students have to attempt any FIVE questions.**
3. **SECTION-C contains THREE questions carrying TEN marks each and students have to attempt any TWO questions.**

SECTION-A

Q1. Write briefly :

a) Define phase IV clinical trials.

b) Define Clinical Practice.

c) Define Intellectual Property Rights.

d) Name major ethical issues in conduct of clinical trials.

e) Enlist various phases of clinical trials and their significance.

f) Define Placebo. How does it act?

g) Define Investigator's Brochure.

h) Define protocol and protocol deviations

i) Briefly describe the composition of IEC

j) Define Good Clinical Practice.

SECTION-B

2. Describe the objectives and significance of various phases of clinical trials.

3. Differentiate between clinical research and clinical practice.

4. Describe the composition and functions of IRB.

5. Briefly describe the CDSCO guidelines for good clinical practice

6. Briefly describe the methods for post marketing surveillance.

7. Briefly describe the design of clinical trial protocol.

8. Briefly describe the history of clinical research.

SECTION-C

9. Describe in detail the national perspective of clinical trials in India.

10. Write short note on the following:

    a) Clinical Trial Market

    b) Career in Clinical Research

l 1. Briefly describe the structure of ISH and principles of ICH GCP.

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.