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

Total No. of Questions : 07

M.Sc. (Clinical Research) (Sem.-3)

CLINICAL TRIAL OPERATIONS

Subject Code : UC-MSCR311-20

M.Code : 79935

Date of Examination : 21-12-22

Time : 2 Hrs. **Max. Marks : 35**

INSTRUCTIONS TO CANDIDATES :

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

SECTION-A

1. Answer the following briefly

a. What is clinical trial master file?

b. What is significance of informed consent form?

c. What is considered as the» single most important reason for delay in clinical trial completion?

d. What should be qualifications of principal investigator?

e. Clinical trial report is prepared according to which guidelines?

SECTION-B

2. Describe the site close out activities.

3. What steps are involved in site selection?

4. How will you plan for the unexpected situations during conduct of clinical trial?

SECTION-C

5. What are the merits and demerits of single site and multiple sites? What are challenges in selecting/dealing international site?

6. What are the different broad recruitment strategies for subject enrolment in a clinical study?

7. Describe roles and responsibilities of principal investigator and sponsor.

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