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Total No. of Pages: 01

Total No. of Questions: 07

M.Sc. (Clinical Research) (Sem. – 3)

CLINICAL TRIAL OPERATIONS

Subject Code: MSCR-311-18

M Code: 77011

Date of Examination : 21-12-2022

Time: 2 Hrs.

Max. Marks: 35

INSTRUCTIONS TO CANDIDATES:

1. SECTION-A is COMPULSORY consisting of FIVE questions carrying ONE mark 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. Define:

- a) Role of sponsor in CT
- b) Site master file
- c) Termination of trials
- d) Investigator brochure
- e) IAEC

SECTION-B

2. Enumerate contents of Protocol of Clinical trial.
3. Discuss contents and need of clinical study report.
4. Discuss roles and responsibilities of monitors during conducting clinical trials.

SECTION-C

5. Give the different reasons for termination of a clinical trial.
6. Enlist and discuss the contents of clinical trial agreement.
7. Mention the role of Clinical trial co-ordinator while conducting clinical trial.

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.