1904N300

Candidate's Seat No :_____

M.Sc Semester-2 Examination

409

Clinical Research

Time : 2-30 Hours] **April-2024** **[Max. Marks : 70**

Instructions:

- **Attempt all questions from question.1 to question.4.**
- **Attempt any fourteen questions in question.5.**

Que. 1 Describe the following :

a) Explain in detail Investigator Selection. 07

b) Explain in brief Site Selection Criteria. 07

OR

Que. 1 Describe the following:

a) Explain SOP and give one sample SOP. 07

b) Write a Note on Single centric & Multi centric trials. 07

Que. 2 Describe the following:

a) Explain in Brief the composition, function, and procedures of IRB/IEC. 07

b) Explain in Brief R & R of Auditor. 07

OR

Que. 2 Describe the following:

a) Role & Responsibility of Monitor. 07

b) Explain Elements of Clinical Trial Protocol 07

Que. 3 Describe the following:

a) Short Note: Standard TMF. 07

b) Write a note on essential components of Informed consent form. 07

OR

Que. 3 Describe the following:

a) Explain Roles & Responsibilities of Sponsor. 07

b) Explain Roles & Responsibilities of CRO. 07

Que. 4 Describe the following:

a) Explain in brief Investigational Brochure. 07

b) Elaborate Roles & Responsibilities of Clinical Research Coordinator. 07

OR

Que. 4 Describe the following

a) Explain Roles & Responsibilities of QA and QC. 07

b) Write a note on Essential Documents in CRF. 07

(P.T.O)

N300-2

Module VI Clinical Research Operations Management

Que. 5 Answer the following (write any 14 out of 17) **14**

1. Give full form of CTA_____
2. Give the difference between consent form and assent form.
3. Sponsor is responsible for assuring that the IRB being used for a study is properly constituted. True/False?
4. Define: Investigator undertaking.
5. Define: Baseline Parameters
6. Give full form of CDA_____
7. Will there be a sign of Ethics Committee Chairperson on Study Protocol. Yes/No.
8. Define Monitoring Report.
9. Define End Points.
10. Define Exclusion Criteria.
11. Define Query Resolution.
12. Define: Source Document
13. Name two documents provided from Sponsor to CRO during study initiation.
14. Define: IP accountability
15. Mention two post study documents.
16. Give full form of CAPA _____
17. Give full form of NCS_____