

School of Biomedical Science**Master of Science Clinical Research
Semester End Examination - Jun 2024****Duration : 180 Minutes
Max Marks : 100****Sem II - Q1PN202T - Clinical Trial Designing***General Instructions**Answer to the specific question asked**Draw neat, labelled diagrams wherever necessary**Approved data hand books are allowed subject to verification by the Invigilator*

- | | | |
|-----|---|--------|
| 1) | Define audit. | K1(2) |
| 2) | Explain the selection of site. | K2(4) |
| 3) | Explain the observational study. | K2(6) |
| 4) | Illustrate the documents retrieval and archival process. | K3(9) |
| 5) | Illustrate the epidemiological studies. | K3(9) |
| 6) | Examine the reason for terminating the clinical studies. | K5(10) |
| 7) | Analyze the NDCT 2019 implementation and India's regulatory evolution in clinical research. | K4(12) |
| 8) | Examine the Subject Recruitment and Advertisement process. | K5(15) |
| 9) | Examine the elements of informed consent. | K5(15) |
| 10) | Elaborate the various phases of clinical research and its importance. | K6(18) |