

## School of Biomedical Science

Bachelor of Science Honours in Healthcare and Clinical Research  
Semester End Examination - Aug 2024

Duration : 180 Minutes  
Max Marks : 100

### Sem I - Q1UE101T - Introduction to Clinical research

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*

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|-----|---|--------|
| 1)  | Illustrate the objective of phase III clinical trial  | K1(2)  |
| 2)  | Distinguish between Bioavailability and Bioequivalence  | K2(4)  |
| 3)  | Discuss the informed consent process.   | K2(6)  |
| 4)  | Discuss the role and responsibilities if contact research organization  | K3(9)  |
| 5)  | Discuss the different types of Clinical Trial Design  | K3(9)  |
| 6)  | Distinguish between randomization and blinding. Discuss the scope of randomization and blinding in clinical trail | K5(10) |
| 7)  | What is ICH GCP. Discuss the vision and mission of ICH  | K4(12) |
| 8)  | Discuss different types of Intellectual property right  | K5(15) |
| 9)  | Discuss the the scope different types bioavailability and bioequivalence studies.                                 | K5(15) |
| 10) | Discuss the role and responsibilities of different stakeholders of clinical reaserh                               | K6(18) |