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School of Biomedical Science**Master of Science in Healthcare and Clinical Research
Semester End Examination - Nov 2023****Duration : 180 Minutes
Max Marks : 100****Sem III - MBACRT3003 - Operational Aspects Of 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*

- 1) Define the Vulnerable group. K1 (2)
- 2) Demonstrate the Query resolution. K2 (4)
- 3) Differentiate between efficacy and safety. K2 (6)
- 4) Utilise the recruitment advertisement procedure and the role of sponsor and Ethics committee. K3 (9)
- 5) Utilise the documents retrieval and archival process. K3 (9)
- 6) Evaluate the guidelines for conduct of bioavailability and bioequivalence study . K5 (10)
- 7) Distinguish the ICMR Principles. K4 (12)
- 8) Interpret the establishment procedure of ethics committee. K5 (15)
- 9) Interpret the feasibility and feasibility questionnaire before clinical research. K5 (15)
- 10) Elaborate the various phases of clinical research. K6 (18)