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School of Biomedical Science**Master of Science in Healthcare and Clinical Research
Mid Term Examination - Nov 2023****Duration : 90 Minutes
Max Marks : 50****Sem I - Q1PM104T - Ethics and Ethical principles in Clinical trial**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 Adverse Event. K2 (2)
- 2) Illustrate the Adverse drug reaction. K1 (3)
- 3) Demonstrate the five criterias of SAE. K2 (4)
- 4) Describe the responsible conduct of research. K2 (6)
- 5) Apply the Data acquisition, management, sharing and ownership. K3 (6)
- 6) Utilise the Terms of reference and Criteria for selection of members of an EC. K3 (9)
- 7) Conclusion of ethical review procedure in Special situations. K4 (8)
- 8) Distinguish the types of review. K4 (12)

OR

- Distinguish the role and responsibilities of ethics committee members and their tenures. K4 (12)