

School of Biomedical Science

Department of Biomedical Science

Mid Term Examination

Exam Date: 04 Oct. 2023

Time : 90 Minutes

Marks : 50

Sem III - MBAMTT3008 - Regulatory Affairs and Ethics in Clinical Research

Your answer should be specific to the question asked

Draw neat labeled diagrams wherever necessary

- 1) Define the Adverse Event. K2 (2)
- 2) Illustrate the Adverse drug reaction. K1 (3)
- 3) Demonstrate the five criteria of SAE. K2 (4)
- 4) Describe the Thalidomide study. K2 (6)
- 5) Explore the Nuremberg code. K3 (6)
- 6) Utilise the ICH GCP Principles. K3 (9)
- 7) Conclusion of declaration of helsinki. K4 (8)

- 8) Distinguish the belmont report and syphilis study. K4 (12)

OR

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