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School of Biomedical Science
Master of Science in Clinical Nutrition and Dietetics
Semester End Examination - Nov 2023

Duration : 180 Minutes
Max Marks : 100

Sem III - MBACNT3008 - Regulatory Affairs and Ethics in 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 Inspection and monitoring. K2 (4)
- 3) Differentiate between MHRA and EMA. K2 (6)
- 4) Utilise the Information exchange process during ICF Process. K3 (9)
- 5) Utilise the documents retrieval and archival process. K3 (9)
- 6) Evaluate the components of investigator brochure. K5 (10)
- 7) Distinguish the components of essential documents in clinical trial. K4 (12)
- 8) Interpret the elements of informed consent. K5 (15)
- 9) Interpret the European Agency for Evaluation of medicinal Products. K5 (15)
- 10) Elaborate the various phases of clinical research. K6 (18)