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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 - MBACRT3001 - Clinical Trial and Data Management*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) | Define the Vulnerable group. | K1 (2) |
| 2) | Demonstrate the good clinical practice. | K2 (4) |
| 3) | Differentiate between Investigator bias and publication bias. | K2 (6) |
| 4) | Utilise the Clinical data management flow. | K3 (9) |
| 5) | Utilise the importance of query generation process in Clinical Data Management. | K3 (9) |
| 6) | Justify the need of clinical research and the designing of clinical studies. | K5 (10) |
| 7) | Distinguish the multicentric clinical studies and why randomization is a gold standard in these kind of studies. | K4 (12) |
| 8) | Interpret the development of CRF. Also elaborate their contents. | K5 (15) |
| 9) | Interpret the resolution of errors found after database closure. | K5 (15) |
| 10) | Elaborate the various phases of clinical research. | K6 (18) |