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**School of Biomedical Science**  
**Bachelor of Science in Clinical Nutrition and Dietetics**  
**Mid Term Examination - May 2024**

**Duration : 90 Minutes**  
**Max Marks : 50**

**Sem II - Q1UF203T - Introduction to 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) Explain briefly the phase I clinical trial K2 (2)
- 2) What do you mean by Outsourcing? K1 (3)
- 3) What do you mean by post marketing surveillance. Analyse the importance of PMS. K2 (4)
- 4) Appraise the scope of clinical research K2 (6)
- 5) What do you mean By Investigational new drug application. Discuss the different types INDA. K3 (6)
- 6) Discuss the Informed consent process. K3 (9)
- 7) Analyze the scope and nature of patent. K4 (8)
  
- 8) Describe briefly the need and scope of ICH guidelines K4 (12)

**OR**

Describe briefly the different area/module of ICH guidelines K4 (12)