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### End Term Examination (December 2019)

**School:** SOM

**Program:** MSc Clinical Research

**Course:** Introduction to Clinical Research

**Course Code:** MGT549

**Semester:** I

**Max Marks:** 50

**Duration:** 2.5 hours

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Answer all of the following (2 marks each)

- 1) Define clinical research
- 2) What are different routes of administration
- 3) Define pharmacokinetics
- 4) Define investigational product
- 5) What are types of clinical trials
- 6) What is composition of ethics committee
- 7) What is peculiar about Phase 0
- 8) What is done in Phase I
- 9) What are 4 pillars of ICH
- 10) Define pharmacoeconomics
- 11) Name any 7 important documents in a clinical trial
- 12) What is done in Phase IV
- 13) Define bioavailability
- 14) Difference between clinical research and clinical practice
- 15) Describe Thalidomide tragedy
- 16) What are phases of clinical trials
- 17) Define pharmacodynamics
- 18) Difference between IRB and IEC
- 19) Which are 6 parties involved in ICH
- 20) What are important activities during Phase II
- 21) Define pharmacoepidemiology
- 22) Describe Sulfanilamide tragedy
- 23) Define clinical trial
- 24) How are Phase III carried out
- 25) Define bioequivalence study