IIHMR UNIVERSITY

**School of Pharmaceutical Management**

**Master of Business Administration**
**Pharmaceutical Management**
**Batch-9th (2017-2019) Second Year**


**Clinical Research and Development**
**Term Examination**

**Time - 3 Hour** **MM-70**

The question paper contains 1 printed page.
Each question carries equal marks
Attempt any five questions.

Q. 1. What do you mean by drug development process (DDP). Describe the role of Clinical Research in DDP with its different phases of trials.

Q.2. What is the role of Ethics committee in clinical research? Give its responsibilities and compositions as per ICH-GCP requirement.

Q.3. What is the signal detection in pharmacovigilance? Describe periodic safety update reporting (PSUR).

Q.4. Define bioavailability/bioequivalence. Give advantage of parallel designs over cross-over designs.

Q.5. What are source documentation and give examples of different source documents for clinical trials. Enumerate the list of essential documents required before the trial start.

Q. 6. How Pharmacovigilance is important in clinical research. Describe about the role of Pharmacovigilance Program in India (PvPi).

Q.7. Write short note on any two.
1. Essential Documentation
2. Outsourcing of clinical trials
3. Medical Report Writing