

**International Institute of Health Management Research (IIHMR)**

**NEW DELHI**

**Health care IT/IM Batch- 2017-2019**

**Regulatory Aspects and Control in Healthcare IT**

**Total Marks 70**

**Please answer any four (10 marks each)**

**10 x 4 = 40 marks**

1. Describe the salient features of The Clinical Establishment Act including the offences and punishments under the act. Give a critical analysis of the positive and negative features of the act.
2. What are the Indian and FDA regulations that need to be followed for conducting Clinical Trials in India?
3. Explain the essential requirements of a proper Informed Medical Consent. What are the situations where medical consent is required / not required? What are the types of Consent? What is Invalid consent?
4. What are Medical Ethics and what are the regulations for this?
5. What is the importance of Health Records? What are the regulations related to this?
6. What is HIPPA? What are the essential components of compliance to HIPAA?
7. Medical Negligence is covered under which legal regulations? What are the safeguards for protection of medical staff from Medical Negligence suits?

**Write short notes on any four (5 marks each)**

**5 x 4 = 20 marks**

1. BMW Act and Rules
2. Contract Act and rules
3. MLC
4. Major laws that apply to a Pharmacy and the key requirements of compliance to them.
5. PCPNDT Act & MTP Act
6. Sale of Goods Act

**Multiple Choice Questions (1 mark each)**

**2 x 5 = 10 marks**

- a) IPC 80 relates to
  - i. Accident in doing a lawful act
  - ii. Kidnapping
  - iii. Illegal abortion
  - iv. Murder
- b) IPC 197 relates to
  - i. Giving false evidence
  - ii. Destruction of evidence
  - iii. Issuing or signing false certificates
  - iv. Sale of spurious drugs

c) IPC 269 relates to

- i. Negligent act likely to spread infection of disease dangerous to life
- ii. Negligent conduct with respect to poisonous substance
- iii. Culpable homicide
- iv. Attempt to commit suicide

d) IPC 274 relates to

- i. Adulteration of drugs
- ii. Act done in good faith
- iii. Culpable homicide
- iv. Forged document or electronic record

e) IPC 304A relates to

- i. Murder
- ii. Causing death by negligence
- iii. Abetment of suicide
- iv. Causing miscarriage