

**Instruction: Kindly write Part A and Part B in separate sheets**

**HIT 709 - Regulatory Aspects in Healthcare IT - A**

**Short Questions (6 marks each, do any 5)**

**6 x 5 = 30 marks**

1. What do you understand by medical negligence? What are the elements of medical negligence? What are the types of medical negligence?
2. What is medical consent? What are the types of consent? When is consent not required?
3. What is meant by medical ethics? What are its principles? How & by whom is it implemented?
4. What is HIPAA? What is PHI and what are its permitted disclosures and uses?
5. What are clinical trials? How are these controlled?
6. What is Electronic Health Record management and how is it done?
7. What is HITECH Act and what are its implications?
8. What is DISHA Act and what are its implications?

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

**1 x 5 = 5 marks**

- a) Electronic record management must include (all except)
  - i. Tracking and storing records
  - ii. Appropriate classification of the records
  - iii. Retention and purging policies / procedures
  - iv. User access charges
- b) HITECH Act
  - i. Requires patients to be notified of any unauthorised access or disclosure of their data
  - ii. Specifies the eHealth standards to be followed
  - iii. Makes it compulsory for healthcare institutions to maintain all health records in digital format
  - iv. Physicians & hospital must pay the govt for using eHealth data
- c) Indian Code of Medical Ethics
  - i. Allows Euthanasia
  - ii. Allows signing of certificates by doctors
  - iii. Allows a doctor to advertise his services
  - iv. Allows a doctor to sell medicines to the public
- d) FDA Regulations for clinical trials cover (all except)
  - i. Drugs
  - ii. Vaccines
  - iii. Medical devices
  - iv. Software
- e) HIPAA was necessitated by
  - i. Medical / healthcare insurance
  - ii. Patient demand
  - iii. Software vendors
  - iv. Demand from Medical staff

1. What are the components of Health Technology Assessment? Write the steps involved (brief) what are the steps you will take to perform HTA of a medical device (example digital Stethoscope, or defibrillator or insulin pump) and health technology (example mobile app or CDSS ). Take one device and one technology to explain your answer. **20 marks**

2. **Read the paper given (source: Health and Quality of Life Outcomes 2008, 6:96 doi:10.1186/1477-7525-6-96) and answer the following checklist questions 15 marks**

**Checklist for Article on Health Relate Quality of Life Article**

**I. Are the recommendations valid?**

Primary guides:

- \_ Have the investigators measured aspects of patients' lives that patients consider important?
- \_ Did the HRQL instruments work in the way they are supposed to?

Secondary guides:

- \_ Are there important aspects of HRQL that have been omitted?
- \_ If there were trade-offs between quality and quantity of life, or an economic evaluation, have they used the right measures?

**II. What were the results?**

- \_ What was the magnitude of effect on HRQL?

**III. Will the recommendations help in the clinical practice?**

- \_ Will the information from the study help me inform my patients?
- \_ Did the study design simulate clinical practice?