CD 03 & CD 04

I Semester P.G. Diploma in Clinical Research and Data Management Examination, July 2009
DATA HANDLING/DATA MANAGEMENT PROCESS AND GCP AND REGULATORY PROCESS

Time : 3 Hours Max. Marks : 80

SECTION – A

Answer the following questions. **(10×1=10)**

1. The International conference on harmonization has constituted standards
   a) E2A b) E2B c) E2C d) Both a and b

2. The fundamental ethical principles that guide the ethical conduct of research involving human participants include
   a) Respect for persons (autonomy)
   b) Beneficence
   c) Justice
   d) All of the above

3. For a one-to-one relationship, entity 1 and entity 2 could be
   a) Patient, Medical History
   b) Patient, Vital signs
   c) Patient, Adverse Events
   d) All of the above

4. In the medical field, the mobile computing devices used may include
   a) Tablet PC b) Digital Pen
   c) Personal Digital Assistant d) All of the above

5. In most research, ensuring confidentiality can occur by
   a) Substituting codes for identifiers or encrypting identifiable data
   b) Removing main sheets
   c) Improper disposing of computer sheets
   d) Unlimited access to identifiable data

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6. The methods used for validation include
   a) Data type checks
   b) Range check
   c) Test cases
   d) Both a and b

7. The ethical Research Ethics Board (REB) is committed to ensuring
   a) Safety and rights of research subjects
   b) Unbiased supervision of studies
   c) Studies conducted according to highest standards of ethical and clinical practice
   d) All of the above

8. A data-computerization software application allowed for
   a) Data validation
   b) Detection an deletion of all duplicate entries
   c) Breakdown of all cases pending information
   d) All of the above

9. Confirmation of review of IRB/IEC include
   a) The name and address of the investigator's or institution's IRB/IEC
   b) Non-approval of IRB/IEC document
   c) A statement obtained from IRB/IEC not operating according to GCP
   d) Protocol conversion

10. Common element of a protocol
    a) Time
    b) Title page
    c) Software testing
    d) Headers and footers

SECTION – B

Answer **any five** questions : **(5×5=25)**

1. What are the difficulties encountered in data management ?

2. What are the 3 fundamental principles made by Belmont report ? Explain.

3. Write a short note on optimal database design.

4. What are the different tools of data entry ?

5. What are the issues to be considered in internet based data entry ?

6. What are the thinks to mind while selection of participants is done ?

7. What are the roles and responsibilities of the IRB ?

8. Who is a sponsor ? What are the responsibilities in clinical research ?

SECTION – C

Answer **any three** questions : **(3×10=30)**

1. Explain the data entry platforms with necessary diagrams. (Mobile computing devices)

2. Enumerate the principles of ICH-GCP.

3. Give the description of protocol summary.

4. Taking suitable examples, explain dataset relationships.

5. Explain how data entry can be done as a part of Quality assurance, taking example tables wherever necessary.

6. Explain the types of investigative sites.

SECTION – D

Answer the following question : **(1×15=15)**

Explain with the Case Study the Quality control and data-handling in multicentric studies : the case of the Multicentric Project for clinical research.

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