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1205E514

Candidate's Seat No :

P.G.D.A.C.R. Examination
Post Graduate Diploma in Advance C.R.
May-2017

Time : 3 Hours] [Max. Marks :100

Que. 1 Explain in detail on <u>any two</u> of the following 20

a) Data Entry and Remote Data Entry

b) Basic Functions, operation and procedure of IRB/IEC

c) Essential Documents in Clinical Trial

d) Schedule Y

Que. 2 Write a note on <u>any two</u> of the following 20

a) Role of QA/QC in Clinical Research

b) Project Management in Clinical Research

c) Informed Consent Form

d) Differences in various regulatory agencies with regards to:

A. Inclusion and Exclusion Criteria of Trial Subjects

B. Dispensing and Dosing of Trial Subjects

Que. 3 Write a note on <u>any two</u> of the following 20

a) Roles and Responsibilities of Investigator

b) Sulfanilamide Disaster

c) Roles and Responsibilities of IRB/IEC

d) Important Principles of Declaration of Helsinki

Que. 4 Write a note on <u>any two</u> of the following 20

a) Clinical Trial Designs

b) Investigator's Brochure

c) Standard Operating Procedure

d) Clinical Trial Monitoring and Auditing

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Que. 5 Complete the following tasks 20

1. Give full form of CDSCO
2. Define: Crossover Study
3. Phase I studies are to be done on healthy human volunteers. True/False?
4. Give full form of IPR
5. Name the drug regulatory agency of USA
6. Enlist any 5 responsibilities of a CRC
7. Define: Phase IV Trials
8. CIOMS II form is for _____
9. Give the difference between CRO and SMO
10. Define : Bioequivalence
11. SOPs are to be revised after every 3 years. True/False?
12. To take the approval of regulatory agency is the responsibility of:
    a. Sponsor
    b. Investigator
    c. Ethics Committee
13. Define: Blinded Study
14. What is the main objective of Ethics Committee?
15. Define: Protocol
16. Investigator's Brochure is to be prepared by _____
17. Give the full form of CTD
18. Enlist any 5 Essential Documents
19. Can Principal Investigator vote in the final decision of Ethics Committee?
20. Explain Replicate Study Design