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0805E442

Candidate's Seat No :_____

M.Sc. (Sem.-II) Examination

409

Module VI Clinical Research Operations Management

Time : 3 Hours] **May-2017** **[Max. Marks : 70**

Que. 1 Write a short note on any twoof the following **14**

a) Single Centric/ Multi centric Trial

b) Roles and Responsibilities of IRB/IEC

c) Standard Operating Procedure

d) Business Development in Clinical Trial

Que. 2 Answer any two of the following **14**

a) Roles and Responsibilities of Sponsor

b) Describe Essential Components of Informed Consent Form

c) Roles and Responsibilities of Monitor

d) Discuss Site Selection Parameters

Que. 3 Write a note on any two of the following **14**

a) Post Study Documents

b) Monitoring in Clinical Trial

c) Roles & Responsibilities of QA Personnel

d) Investigator's Brochure

Que. 4 Write a note on any two of the following **14**

a) Subject Recruitment and Retention

b) Roles & Responsibilities of CROs

c) Study Drug Accountability

d) Roles and Responsibilities of Project Manager

(P.T.O)

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Module VI Clinical Research Operations Management

14

Que. 5 Answer the following

1. Give Difference between IRB/IEC
2. Give Examples of Fundamental SOPs
3. Full Form: IDMC
4. Give composition of IRB/IEC
5. What are different forms of ICF
6. Differentiate between SOP and MOP
7. Give component of SIV
8. Audit certificate is one of the post study essential document. True/False?
9. Full Form: CDA
10. Enlist labeling requirements for IP receipt
11. If investigator fails to maintain all adequate drug inventory. FDA will issue _____ letter
12. Full Form: SWOT
13. Definition: Audit
14. Give Quorum requirement for ethics committee as per schedule Y