NG ESSAY (Answer any Three) **3 X 10 = 30 Marks**

1. Write a note on clinical trial protocol. Explain Phase III studies.
2. Explain the responsibilities of sponsors, CRO and investigator in ethical conduct of clinical research.
3. Enumerate the application procedure for approval of NDA 505 (b) (1).
4. Explain the principles of ICMR Ethical Guidelines for Biomedical Research

SHORT ESSAY (Answer any Nine) **9 X 5 = 45 Marks**

5. Write a note on Phase 0 studies.
6. Define and explain ethical principles of informed consent process.
7. Write a note on role of placebo in clinical trials.
8. Explain clinical trial protocol.
9. Write a note on ANDA and its approval procedure.
10. Explain regulatory requirements of BA/BE studies.
11. Discuss on EU Directives 2001.
12. Enumerate the Indian GCP guidelines.
13. Write a note on 21 CFR Part 312 (IND Application)
14. Add a note on FDA Med Watch. Explain about 21 CFR Part 822

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