

## Elements of a Research Protocol



1. General Information

2. Rationale & Background Information

3. Study Objectives

4. Study Design

5. Methodology

6. Safety Considerations

7. Follow-up

8. Data Management and Statistical Analysis

9. Quality Assurance

10. Expected Outcomes of the Study

11. Dissemination of Results and Publication Policy

12. Duration of the Project

13. Anticipated Problems

14. Project Management

15. Ethics

16. Budget

17. Supplementary Support for the Project

18. Collaboration With Other Researchers or Institutions

19. Curriculum Vitae of All Investigators

20. Other Research Activities of Investigators

21. References



# Writing Clinical Research Protocols

**Angela D. Klimaszewski**



## **Writing Clinical Research Protocols:**

**Ethical Considerations When Preparing a Clinical Research Protocol** Evan DeRenzo, Eric A. Singer, Joel Moss, 2020-06-12 Ethical Considerations When Preparing a Clinical Research Protocol Second Edition provides a foundation for improving skills in the understanding of ethical requirements in the design and conduct of clinical research It includes practical information on ethical principles in clinical research how to design appropriate research studies how to consent and assent documents how to get protocols approved special populations confidentiality issues and the reporting of adverse events The book s valuable appendix includes a listing of web resources about research ethics along with a glossary making it an invaluable resource for scientists collaborating in clinical trials physician investigators clinical research fellows and more Walks investigators and trainees through the identification of the ethical aspects of each section of a clinical research protocol Includes case histories that illustrate key points Contains information on conducting clinical research within the pharmaceutical industry Includes internet resources and worldwide web addresses for important research ethics documents and regulations Contains a chapter on Study Design and Methodology that is purposely expanded to explicitly address biostatistical considerations [9 Steps Guide on How to Write a Clinical Trial Protocol?](#) K. Ashish, Gaurav Goel, 2014-06-01 This book 9 Steps Guide On How To Write A Clinical Trial Protocol is specially designed for the Clinical Trial investigators Physicians Sponsors healthcare students and other clinical research professionals who are involved or keen to explore clinical research in future to develop skills to write protocol for clinical studies The books covers the topics Essential Clinical Trial Documents Protocol Structure Type of Research Studies Trial Design Consideration Ethical Consideration Elementary Statistics Randomization and its type Blinding Sample Sizing etc The book is designed and written in a manner so that a reader can understand overall protocol writing and the essential element involved in it We hope that the book would guide the readers to understand the overall process of protocol writing and impart essential skills involved in it *Writing Clinical Research Protocols* Evan G. DeRenzo, Joel Moss, 2006 This highly engaging guide for clinical researchers provides a foundation for improving skills in the understanding of ethical requirements in the design and conduct of clinical research It includes practical information on ethical principles in clinical research designing appropriate research studies writing consent and assent documents getting protocols approved special populations confidentiality issues and the reporting of adverse events A valuable appendix includes a listing of web resources about research ethics as well as a glossary This will be an invaluable resource for basic scientists collaborating in clinical trials physician investigators clinical research fellows research nurse coordinators residents and anyone who wants a better understanding of the clinical trials process Walks investigators and trainees through identification of the ethical aspects of each section of a clinical research protocol Includes a chapter containing Case Histories Contains information on conducting clinical research within the pharmaceutical industry An appendix includes internet resources and world wide web addresses for important research ethics documents and

regulations Chapter on Study Design and Methodology purposely expanded to explicitly address biostatistical considerations

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