Writing Clinical Research Protocols: Ethical Considerations

Evan DeRenzo, Joel Moss

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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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