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Writing Clinical Research Protocols: Ethical Considerations

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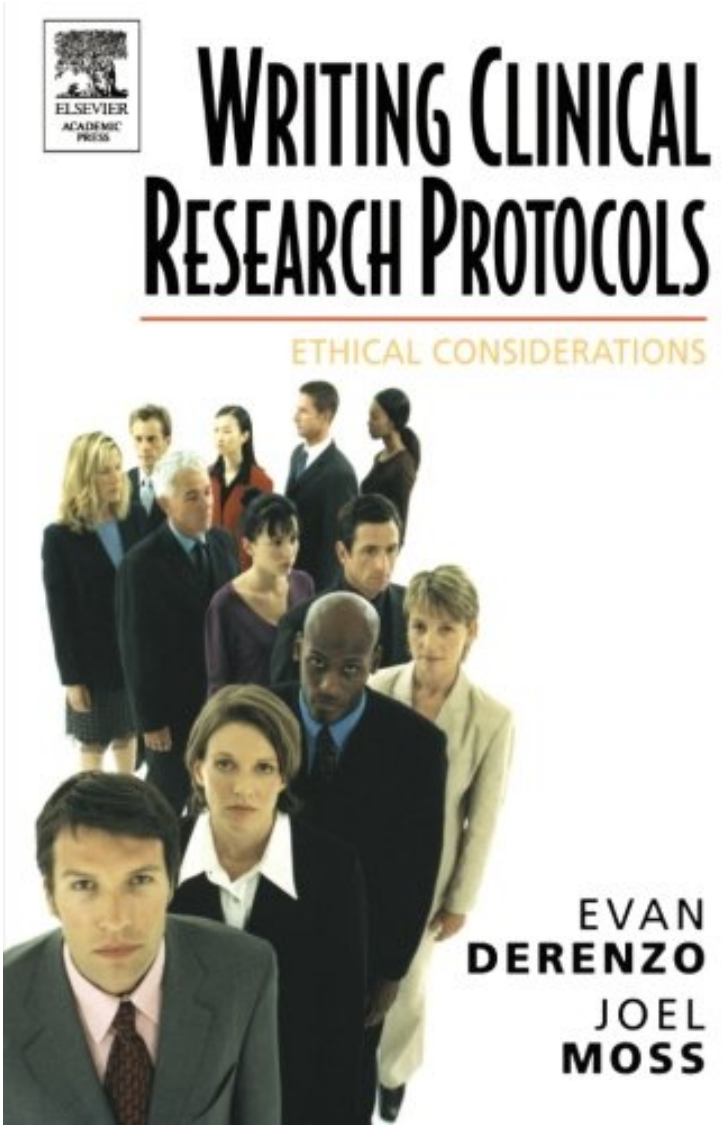

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This highly engaging guide for clinical researchers provides a foundation for improving skills in the understanding of ethical requirements in the design and conduct of clinical research. Writing Clinical Research Protocols includes practical information 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 is 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 protocolIncludes a chapter containing Case HistoriesContains information on conducting clinical research within the pharmaceutical industryAn appendix includes internet resources and world wide web addresses for important research ethics documents and regulationsChapter on 'Study Design and Methodology' purposely expanded to explicitly address biostatistical considerations

"This book will be a very useful text and reference source for students and trainees at all levels, as well as for seasoned investigators and RERB members. The continuing proliferation of formal, degree-granting masters and doctoral training programs in clinical investigation at academic centers across the country underscores the need for a book like this. These programs, and the growing acceptance and recognition of professional certification programs for clinical research professionals, are indicators that the expectations we place on investigators are greater than they were just a few years ago. Recognition that good science and good ethics are inextricably bound together in clinical research is todays reality, and this book gives real insight into why and how." --JAMA (February 2006)About the AuthorBy Dr. Evan DeRenzo and Dr. Joel MossExcerpt. Reprinted by permission. All rights reserved.A practical guide for clinical researchers that aims to improve their skills in the understanding of the ethical requirements for the design and conduct of clinical research.