Writing clinical research protocols : ethical considerations /

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Monografía

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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Descripción física: 1 online resource (xix, 300 pages)

Bibliografía: Includes bibliographical references and index

Contenido: Introduction to the art and science of clinical research -- What you need to know about clinical research ethics -- What you need to know about the regulation of clinical research -- Designing a clinical research study -- Selecting subjects for clinical studies -- Risks and benefits in clinical research -- Recruiting subjects -- Informed consent -- Privacy and confidentiality -- The "ethics" section -- Procedures and methods -- Statistics, data collection and management, and record keeping -- Use of human biological materials -- Special issues raised by evolving areas of clinical research -- Case histories : learning from experience What You Need To Know About

Research Ethics Before Deciding on What You Want To Study -- Designing a Clinical Research Study -- Writing Consent and Assent Documents -- Getting the Protocol Approved -- Conducting the Study; Special Populations -- Ethical Considerations in Genetics Research -- Ethical Considerations in Use of Tissue for Laboratory Investigations -- Ethical Considerations in Use of Stored Tissue -- Confidentiality Issues -- Research in Emergency Medicine -- Reporting of Adverse Events -- FDA -- Radiation Safety Issues -- Participation of Subjects in Multi-Site Trials -- Participation of Subjects in Multiple Studies -- Conduct of Pharmaceutical Industry Research -- Case Histories, Learning from Experience -- Appendix

Lengua: English

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