

1. Record Nr.	UNINA9910784640803321
Autore	DeRenzo Evan G
Titolo	Writing clinical research protocols [[electronic resource]] : ethical considerations // Evan G. DeRenzo and Joel Moss
Pubbl/distr/stampa	Burlington, MA ; ; London, : Elsevier Academic, c2006
ISBN	1-280-63341-7 9786610633418 0-08-045420-8
Edizione	[Second edition.]
Descrizione fisica	1 online resource (321 p.)
Altri autori (Persone)	MossJoel
Disciplina	615.50724
Soggetti	Clinical trials Medical protocols
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	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.
Sommario/riassunto	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