Record Nr. UNINA9910817238103321 Autore Tereskerz Patricia M **Titolo** Clinical research and the law / / Patricia M. Tereskerz; consulting clinical editors, Robert Edelman, Ross McKinney, Jr Chichester, West Sussex, : John Wiley & Sons, 2012 Pubbl/distr/stampa **ISBN** 1-299-31371-X 1-118-27216-1 1-118-27215-3 1-118-27218-8 Edizione [1st ed.] Descrizione fisica 1 online resource (282 p.) Altri autori (Persone) EdelmanRobert <1936-> **McKinneyRoss** Disciplina 344.04/196 Soggetti Biology - Research - Law and legislation - United States Medicine - Research - Law and legislation - United States Clinical trials - Law and legislation - United States Human experimentation in medicine - Law and legislation - United States 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. Research malpractice & negligence -- Duty of care : understanding the Nota di contenuto legal differences between medical treatment and medical research --Establishing standard of care & violation of standard of care --Informed consent in clinical research -- Liability issues for institutional review boards (IRBs) and data safety monitoring boards (DSMBs) --Legal aspects of financial conflicts of interest in clinical trials --Disclosure of clinical trial information: legal ramifications of withholding study results -- Clinical trials & insider trading -- Clinical trials and criminal law -- Clinical trial contracts. Sommario/riassunto This book provides a comprehensive resource for medical professionals on the various legal aspects involved in conducting clinical research. It encompasses legal and ethical issues such as duty of care, research malpractice and negligence, standards of care, informed consent, liability issues for Institutional Review Boards (IRB), conflicts of interest,

insider trading and the disclosure and withholding of clinical trial

results. It will also provide legal guidance on research contracts, setting up clinical trials and common legal pitfalls encountered in medical research.