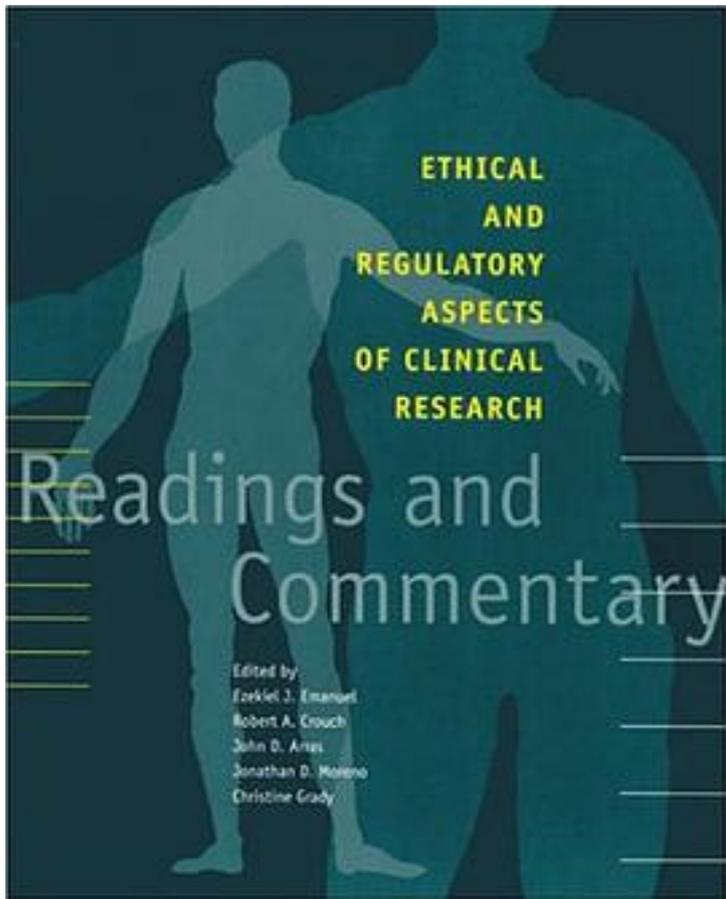


Ethical and Regulatory Aspects of Clinical Research



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出版者:Johns Hopkins Univ Pr

出版时间:2003-9

装帧:Pap

isbn:9780801878138

All investigators funded by the National Institutes of Health are now required to receive

training about the ethics of clinical research. Based on a course taught by the editors at NIH, Ethical and Regulatory Aspects of Clinical Research is the first book designed to help investigators meet this new requirement. The book begins with the history of human subjects research and guidelines instituted since World War II. It then covers various stages and components of the clinical trial process: designing the trial, recruiting participants, ensuring informed consent, studying special populations, and conducting international research. Concluding chapters address conflicts of interest, scientific misconduct, and challenges to the IRB system. The appendix provides sample informed consent forms. This book will be used in undergraduate courses on research ethics and in schools of medicine and public health by students who are or will be carrying out clinical research. Professionals in need of such training and bioethicists also will be interested.

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