

Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary



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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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