



WRITING CLINICAL RESEARCH PROTOCOLS

ETHICAL CONSIDERATIONS



EVAN
DERENZO
JOEL
MOSS

Writing Clinical Research Protocols Ethical
Considerations Author Evan Derenzo Published On
September 2005

Donald Evans, Martyn Evans



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Writing Clinical Research Protocols Evan DeRenzo, Joel Moss, 2005-09-08 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 Writing Clinical Research Protocols 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 is 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

A Decent Proposal Donald Evans, Martyn Evans, 1996-05-27 An ethical review of clinical research

Ethical Issues in Clinical Research Bernard Lo, 2010 This book teaches researchers how to resolve the ethical dilemmas that can arise at any stage in clinical research In addition to explaining pertinent regulations and laws Dr Lo helps investigators understand the gaps and uncertainties in regulations as well as situations in which merely complying with the law may not fulfill ethical responsibilities Most chapters include real life examples that the author walks through discussing the salient issues and how to approach them This book can be used in courses on research ethics that are required or encouraged by major National Institutes of Health grants in academic health centers

Ethics and Regulation of Clinical Research Robert J. Levine, 1988-01-01 The use of human subjects in medical and scientific research has given rise to troubling ethical questions How should human subjects be selected for experiments What should they be told about the research in which they are involved How can their privacy be protected When is it permissible to deceive them How do we deal with subjects such as children fetuses and the mentally infirm for whom informed consent is impossible In this book Dr Robert J Levine reviews federal regulations ethical analysis and case studies in an attempt to answer these questions His book is an essential reference for everyone members of institutional review boards scientists philosophers lawyers addressing the ethical issues involved Levine s experience as a clinician IRB chairman writer and editor of a journal devoted exclusively to issues faced by IRBS makes him uniquely qualified to bring together the legal ethical and practical dimensions The book is sophisticated but readable and should be on every IRB administrator s desk and in every medical ethics library Norman Fost M D The New England Journal of Medicine Levine is one of the foremost historians of contemporary clinical science His book is at once a guide to primary sources for the history of clinical research in the late twentieth century and a

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