Ethics and Regulation of Clinical Research: Second Edition

By Robert J. Levine

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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 pioneering secondary source about that history.”—Daniel M. Fox, *Bulletin of the History of Medicine*
“You will be charmed by the [book’s] elegance and lucidity and. . . persuaded of its relevance to doctors in any country.”—Alex Paton, *British Medical Journal*
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