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## Ethics and Regulation of Clinical Research: Second Edition

*Robert J. Levine*

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#1770231 in Books 1988-07-27 Original language: English PDF # 1 9.02 x .95 x 5.981, 1.43 #File Name: 0300042884480 pages | File size: 67.Mb

**Robert J. Levine : Ethics and Regulation of Clinical Research: Second Edition** before purchasing it in order to gauge whether or not it would be worth my time, and all praised Ethics and Regulation of Clinical Research: Second Edition:

3 of 3 people found the following review helpful. a classic, or ought to be By a reader This is not an easy read, but there is a good reason it is still in print from 1988 - it is a classic, or ought to be. I am a mid-level institutional administrator and had to read it for a class in research management, and unlike many in the class, I actually read it cover to cover

once I became engaged with it being history as much as philosophy. Meaning it turns out to be more concrete than abstract. The best parts are about the creation and workings of the National Commission for the Protection of Human Subjects, back in the day, and about the emergence of the Belmont Report from the nothingness of a really crummy prior human subject history combined with the usual messiness of committee-style group process. I think, and Dr. Levine thinks too, that the Belmont Report is a beautiful thing. It turns out to be pretty interesting where it came from, how it got there. This is what I recall the book to be mostly about, or at least most engagingly about.

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 [books] elegance and lucidity and. . . persuaded of its relevance to doctors in any country. Alex Paton, *British Medical Journal* Should be of wide interest to those keen to see advances in medical research brought into general medical practice. Gilbert Omenn, *Issues in Science and Technology*