

The Censor's Hand: The Misregulation Of Human-Subject Research (Basic Bioethics)



Synopsis

Medical and social progress depend on research with human subjects. When that research is done in institutions getting federal money, it is regulated (often minutely) by federally required and supervised bureaucracies called "institutional review boards" (IRBs). Do -- can -- these IRBs do more harm than good? In *The Censor's Hand*, Schneider addresses this crucial but long-unasked question. Schneider answers the question by consulting a critical but ignored experience -- the law's learning about regulation -- and by amassing empirical evidence that is scattered around many literatures. He concludes that IRBs were fundamentally misconceived. Their usefulness to human subjects is doubtful, but they clearly delay, distort, and deter research that can save people's lives, soothe their suffering, and enhance their welfare. IRBs demonstrably make decisions poorly. They cannot be expected to make decisions well, for they lack the expertise, ethical principles, legal rules, effective procedures, and accountability essential to good regulation. And IRBs are censors in the place censorship is most damaging -- universities. In sum, Schneider argues that IRBs are bad regulation that inescapably do more harm than good. They were an irreparable mistake that should be abandoned so that research can be conducted properly and regulated sensibly.

Book Information

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Customer Reviews

This is a profoundly important book. In his inimitable prose, Schneider reveals the oppression, danger, and sheer inanity of IRB censorship. (Philip Hamburger, Maurice and Hilda Friedman Professor of Law, Columbia Law School) Schneider reveals IRB regulations for what they are, a form

of censorship and prior restraint that impedes social research and undermines American universities. Let's hope that someone takes his ideas and runs with them -- to a federal court, to challenge IRBs as unconstitutional denials of free expression. (Malcolm M. Feeley, Claire Sanders Clements Professor, Jurisprudence and Social Policy Program, Boalt Hall School of Law; President of the Law & Society Association, 2007-09) IRBs are the crabgrass of academia -- destructive, unwanted, unnecessary, relentlessly expanding. In *The Censor's Hand*, Carl Schneider expertly exposes their incompetence, ignorance, lawlessness, and record of killing more people than they save. He makes me glad I no longer work in a university, subject to IRB oversight. (Howard S. Becker, author of *What About Mozart? What About Murder? Reasoning from Cases*) This is by far the most carefully researched, lucid, incisive, and cogent critique yet of the regulation of human-subject research. It should be read by anyone committed to promoting quality improvement efforts and clinical research of the highest ethical and scientific quality or a learning healthcare system that accelerates advances in healthcare, clinical outcomes, and population health. (Jon Tyson, MD, MPH, Vice Dean for Clinical Research and Healthcare Quality, University of Texas-Houston Medical School)

Carl E. Schneider is Chauncey Stillman Professor of Law and Professor of Internal Medicine at the University of Michigan. He has written *More Than You Wanted to Know: The Failure of Mandated Disclosure*, *The Practice of Autonomy: Patients, Doctors, and Medical Decisions*, and numerous other books and articles.

I have never before given a five star review. But Professor Schneider's book has earned it. He has analyzed with rigor and care what we know about what the Public Health Service of the Department of Health and Services has imposed on medical research in the name of protecting "human subjects" of research. And the results are devastating -- a bureaucracy whose costs are in the billions of dollars a year, and whose results are mainly to delay life-saving research, at the cost of thousands of lost lives a year. This book is well-researched and well-written, and reaches clear and accurate conclusion. The evidence it presents is overwhelming. It is must reading for any student of public policy who is interested in objective evidence of government failure. In the waning moments of the Obama Administration, the Office of Management and Budget approved a rule to extend the imposition of this lunatic system on both biomedical and social research. The rule pretends to limit the IRB system to federally funded research (a fatal error even if accurate), but leaves the IRB system in

place over almost all research in universities and hospitals. The time has come to see if regulatory sanity can prevail during the Trump Administration's campaign against regulatory burden. This book demonstrates what needs to be done, in objective, measured, careful, and sometimes even elegant prose.

The book was in very good condition. An excellent read.

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