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## "The Censor's Hand: The Misregulation of Human-Subject Research"

**Carl E. Schneider, 2015, 257 pages, The MIT Press, $35.00**

**Review by Norman M. Goldfarb**

"The Censor's Hand: The Misregulation of Human-Subject Research" is a wide-ranging and persuasive critique of the institutional review board (IRB) system. Most clinical research professionals accept IRBs as an indispensable element of clinical research that, despite its flaws, is the only viable alternative for protecting the safety and welfare and study participants. This book argues strongly against that assumption.

This book has been selected for

**The First Clinical Research Bookshelf**

Essential reading for clinical research professionals

According to the author, the fundamental problem with IRBs is the system of "event licensing," in other words, requiring approval of every study involving human subjects — even exempt studies that must be reviewed to confirm they are exempt. Event licensing is extremely time consuming. Imagine having a contract review board (CRB) analyze every clinical trial agreement (CTA), pointing out clauses that are poorly worded, understate their significance, or give one side an unfair advantage? Then, before the study sponsor and investigator can sign the agreement, they must redraft it and resubmit it to the CRB for approval.

The result is an IRB system that lacks the due process of the courts, administrative proceedings, or even arbitration. For example, discussions are conducted secretly, with no opportunity to contest anecdotal "evidence" from the life experience of board members, and no opportunity to appeal. Most IRB members have limited expertise on the regulatory requirements, to say nothing of the scientific or medical aspects of a study. IRBs do not even trust one another, as evidenced by inconsistent and sometime contradictory decisions on multicenter studies. If IRBs don't trust one another, why should anyone else trust them?

IRBs impose substantial costs on the research enterprise that could be invested more productively if a more efficient process could be found to ensure participant safety and welfare. Further, IRB reviews delay the availability of medical treatments to the public, costing thousands of lives, orders of magnitude more than those that IRBs save. Such substantial costs require substantial benefits.

What is the alternative? The author argues that IRBs should play a much more limited role, with adequate due process. Far more people die from deficient clinical care than from deficient clinical research, but society allows the medical profession to employ a system based on professional licensing, medical-board discipline, malpractice insurance, legal and governmental sanctions, professional reputation, employment, and pre-review of certain high-risk procedures. Why can't clinical researchers use the same system?

*Reviewer's note:* Imagine certifying proven investigators to conduct certain types of research without IRB review. Imagine accrediting proven sites to conduct certain types of research without IRB review. Imagine certifying proven experts who can vouch for a study, putting their reputations and finances on the line? Imagine removing the "learned intermediary" doctrine that insulates study sponsors from most legal liability when a study participant is injured? A few new paragraphs in the Code of Federal Regulations could make any of these possible.

The following extracts illustrate the breadth and width of the author's argument:

> Instead of evidence and argument, regulationists use "justification by scandal." They invoke a few emblematic disgraces to show that research subjects are abused. Even as the principal scandals of their rhetoric recede into the past, even as their system moves into scandal-free areas of research, regulationists recite the litany of shame.
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> Levine concluded: "On the basis of all the empirical evidence" he knew, "the role of research subject is not particularly hazardous… [A]ttempts to portray it as such and arguments for policies designed to restrict research generally because it is hazardous are without warrant." Recent literature reviews concur. Burns and Moss report that harm from research misconduct is "apparently very rare." Saver says, "the Advisory Committee on Human Radiation Experiments' comprehensive review of federally funded research...determined that most studies posed only minimal risks of harm."
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> Abbott and Grady "could not identify one study that evaluated the effect that IRB review has on the protection of human subjects."
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> IRBs are easily alarmed because they substitute speculations for research on risks, speculations distorted by errors like overweighting single cases, scanting base rate information, and consulting salience, not probability.
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> Multisite studies continue to report flagrant inconsistencies. Some contradict each other… One thought vitamin A supplements necessary and another thought them unethical. Similarly, faced with Stair's study of inhaled fluticasone supplementing standard emergency asthma treatment, one IRB said all patients should receive it while another thought it "hazardous and therefore unethical.
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> The IRB rejection of the rule of law is so complete that even convicts are better treated than researchers. Parolees are convicted criminals with only conditional liberty, but when accused of violating parole conditions, they get a prompt inquiry near the scene by an uninvolved arbiter. They must be told of the hearing, its purpose, and its charges. Parolees "may appear and speak" and "bring letters, documents or individuals." Ordinarily, witnesses must be "available for questioning" in the parolee's presence. A hearing summary is made; decisions must rest on the evidence and be explained. Then parolees are entitled to a second hearing in a reasonable time to determine what the facts are and whether they justify revoking parole. Parolees must be allowed to show that parole was not violated or should not be revoked. Again, they receive written notice of charges, disclosure of evidence, a chance to be heard in person, to cross-examine adverse witnesses, "neutral and detached" arbiters, and a written statement of the "evidence relied on and reasons for revoking parole."
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> We have just seen that IRBs use few of the procedures government agencies use to discipline decisions. Nor could they afford to. The system is already crushingly cumbersome and costly, and good procedures would make it much more so. Event licensing of all human-subject research…already overloads IRBs… The IRB system's structure, in short, makes fair procedures and sound decisions unaffordable.
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> No rules are entirely comprehensive or comprehensible and so gain meaning through the accretion of precedents that generate broader principles. This is how, for two centuries, the Supreme Court has given meaning to the Constitution's Delphic provisions and the state courts have nurtured the "common law" of torts, property and contracts. But, since IRBs do not write opinions and since their decisions cannot be appealed within the agency nor reviewed by courts, IRBs cannot benefit from this way of developing and refining rules.

> Beecher, whose article regulationists eagerly invoke, opposed "formal, codified rules" for research and thought "an 'intelligent, informed, conscientious, compassionate and responsible investigator offered the best protection for human research subjects."

The book consists of seven chapters:

- Research Risk and Regulationist Stereotypes
- Cost Is No Object
- Arbitrary and Capricious Decisions
- The Misshapen Ideology of the IRB System
- The Rule of Law: The Lessons of Due Process
- Censorship in a System of Free Expression
- Conclusion: The Imperial IRB

The book is available in bookstores.

**Reviewer**

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