

From Oversight to Overkill: Inside the Broken System that Blocks Medical Breakthroughs—And How We Can Fix It

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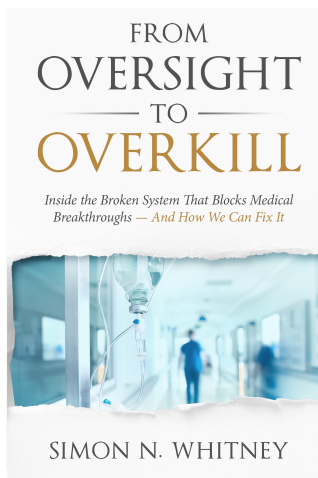
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Title: From Oversight to Overkill: Inside the Broken System that Blocks Medical Breakthroughs—And How We Can Fix It

Author: Simon N. Whitney

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Any of us conducting research involving human subjects have probably complained about institutional review boards (IRBs): the turnaround time is unacceptable, the forms are burdensome, the portals appear to have malevolent intent, and the requirements seem ridiculously finicky. It never occurred to me, however, that our IRB oversight process could lead to significant societal harms.

That is the premise of Whitney's provocative and well-spun tale of the development of our IRB system. Whitney particularly focuses on the roles of Congressional oversight and the Office of Human Research Protections (OHRP) in creating what he describes as "the shambles we have today" (p. 11).

Whitney's thesis is that "while the IRB system is not the only burden that scientists bear, its benefits are the most hypothetical, its costs the most exorbitant, and its rationalizations the most bizarre" (p. 11). Whitney is an ethicist at Baylor College of Medicine, who has been studying the OHRP and the IRB system since 2007.

The book begins with stories illustrating why a system of oversight was necessary. For example, the Willowbrook study in 1959 gave hepatitis to severely disabled children, 90% of whom were already contracting it in that facility. This research led to important guidelines for the prevention of transmission within facilities, but it raised ethical concerns (p. 39). In another example, live cancer cells were injected into patients. The extent of patients' "informed consent" was being told they would be injected as a test of their immune systems (p. 48).

Whitney describes how pioneers in research ethics, like Henry K. Beecher, began to tackle this lack of oversight. Whitney traces legislative and policy changes that expanded into the unwieldy, overreaching system we have today. One such overreach is the assumption that local IRBs must be considered infallible. The initial idea was to protect IRBs from pressure from unscrupulous medical school deans or university presidents, though there is no evidence that this ever occurred. The system devolved into "reactive hyperprotectionism," to the point where bizarre hypothetical risks became reasons to question or reject research. For example, a researcher studying the human microbiome was told he had to warn potential participants that they might get HIV or smallpox if their arm was touched with a swab that had touched another healthy person (p. 84).

Dr Whitney then illustrates his thesis with a series of examples that are baffling and occasionally infuriating. One IRB manual describes how patients in a treadmill study might fall and get a black eye. This black eye could then lead to hypothetical social, occupational, and legal problems, such as being arrested for a brutal local crime (p. 89). A much more consequential example is of a huge study on optimally treating heart attacks, which was paused for over a year because of overzealous oversight (p. 118). Whitney estimates that

6,000 lives were lost due to that unnecessary delay.

Perhaps the most upsetting study Whitney mentions is the SUPPORT trial examining optimal levels of oxygen administered to premature babies. It compared two oxygen levels that were in common use at the time. The babies given higher levels of oxygen survived at a higher rate. Ignoring the fact that babies in both arms of the study survived better than their counterparts who were not in the study, the OHRP reprimanded the researchers for a supposedly inadequate consent process. Then the media portrayed the scientists as having caused the death of premature babies, and panicked parents felt guilty about having enrolled their babies (p. 162). This had a chilling effect on researchers, institutions, and people who might otherwise have been eager to help advance the science of neonatology.

It is a testimony to Whitney's storytelling skills that what seems like a dry, academic topic could be so gripping. *From Oversight to Overkill* is a great read; it would be most valuable to anyone who conducts research or who works in medical systems where research is being conducted. I would recommend it to anyone who sits on an IRB. I served in that role in the past, but I knew nothing of the history and politics behind the system. Dr Whitney has crafted a fine book that serves both as a call for true reforms and as a guide to forging a better system. The final portion of the book is a list of recommended reforms that would help rebalance a seriously skewed system. These would balance the worthy goals of medical research with the essential rights of the patients who participate in that enterprise.