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"The Ethics Police? The Struggle to Make Human Research Safe"

Robert Klitzman, 2015, 422 pages, Oxford University Press, $36.00

Review by Norman M. Goldfarb

"The Ethics Police? The Struggle to Make Human Research Safe" is an essential resource for any human subjects protection program interested in improving its processes and results. The book provides numerous insights into the world of IRBs, probably too many to digest in a single reading. The book might best be used to open minds and provide context when addressing a specific issue, such as conflict of interest management, IRB-member training, or researcher relationships.

The book is based on dozens of in-depth interviews. The author approaches the topic from multiple perspectives:

> As a researcher, I was initially wary of IRBs. In my years of conducting studies, they had delayed investigations — in my view, often unnecessarily — that many colleagues and I had sought to conduct. These committees had forced us to spend weeks and months of our time completing bureaucratic forms and awaiting replies. But as a doctor and as a son, I had witnessed firsthand the need to protect vulnerable patients. The interviews I conducted for this book helped me to see that, while the system certainly needs to be improved, neither side is entirely right or wrong. I now appreciate these committee members' perspectives and dedication far more than I did before; but I can also see more clearly the challenges they face and the unintended consequences of their actions, both good and bad. The problems and potential solutions are more complex than I had suspected.

The author found wide variation in IRB practices:

> Of 21 hospitals participating in one minimal-risk study, the amount of time to receive IRB approval ranged from 12 to 960 days, with none of these institutions changing the basic study. In other cases, IRBs at different institutions have altered the same study in different ways that have made the comparison of the results between the sites difficult, thus impeding the science. In a study of 37 IRBs reviewing an identical protocol, 16 required no changes, while 21 required alterations and four IRBs' hurdles seemed so insurmountable that the investigators at these institutions decided not to conduct the study at all. IRBs can also require researchers to spend weeks, if not months, filling out extensive forms that divert limited resources from conducting experiments. For one study reviewed by 52 IRBs, each committee made an average of five changes, 76% of which involved only differences in institutional language. No committees made substantial changes to the research. But the cost of the 52 separate reviews was over $100,000…
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> IRBs often say that differences result because of variations in their local community values, but, in fact, discrepancies occur even within a single institution in a single community! Many institutions have more than one IRB, and these committees can disagree. In one academic medical center, multiple scientists may be participating in the same study, yet each may submit it to different IRBs within the same institution, which then evaluate it differently…

> Few interviewees here admitted that their decisions were in any way open to different interpretations by others. They tend to see their job as applying the regulations correctly, and appear to feel that, ultimately, there is one absolute "right way" for their board to do so. Though ethical debate, consensus and standards continue to evolve, committees tend to think that, at any one point, their decisions are right and justified…
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> The fact that many of these interviewees displayed little concern for these inconsistencies, or awareness of the consequent costs to researchers, is striking… Inconsistencies cannot be wholly eliminated, but they emerge here as wide and of many types, and can and should be reduced; and far more efforts are needed to do so. At several institutions with more than one IRB, the chairs meet periodically to try to harmonize the decisions of the committees in their institution. But even here they often don't succeed — though all located in the same community. A few chairs may seek uniformity in response to a particular protocol that more than one board within their institution happens to review, but such efforts are needed on a much more systematic, ongoing basis for all studies where individual, idiosyncratic committee attitudes may prevail. Such consensus, meetings, and conferences could be established at national levels. This indifference fuels critics' desires for more centralized IRBs. Yet almost all of the interviewees here opposed such centralization.

The book discusses numerous elements of IRB activity, such as the following:

> **"Curbside Consults" with Researchers**
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> Though federal regulations originally made IRBs local bodies so that these committees would reflect local standards and laws, additional, unintended benefits emerged — under the present arrangement, PIs can interact with their IRB both formally and informally, thereby potentially facilitating the process. Knowing the local "gatekeeper" (i.e., the IRB) has advantages. As Jack argued, "I don't think it was the intent, but the practical outcome of local IRBs is that PIs bounce stuff off me all the time." IRB members can interact with PIs informally and in person, rather than through the constraints of formal memos back and forth. Such informal 10-minute verbal communication can allow researchers to present possible approaches (e.g., "What if I did X?"), get immediate feedback, and then make better decisions as a result. Such conversations can significantly shape studies early on, clarifying what research the IRB may find ethically problematic. Informal local feedback has the advantage, too, of being readily available, whereas an exchange of memos might take weeks, or even months.
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> **Pre-reviews by IRB Members**
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> To facilitate assessments, many committees have established various forms of IRB "pre-review," though these range considerably in nature, extent and effectiveness, having different costs and benefits to different stakeholders. Some IRBs have their own members or staff conduct these pre-reviews, which can be very cost effective — such a pre-review can avoid requiring a whole committee to reconsider a protocol multiple times. IRBs may, in fact, require or encourage reviewers, before presenting protocols at meetings, to speak in advance to PIs to try to address any questions. Such prior discussions with PIs can be very helpful. "We can head off issues," Kevin, the chair, said, "and help PIs with the IRB red tape." Such informal openness and availability can reduce the time to get approval. It is, however, by no means universal.

Pre-review also carries with it a different sort of risk: A full IRB assessment may identify problems that didn't arise in the pre-review, incensing researchers who assumed their protocol would go through. Elaine said:

> We quit corresponding with the investigators ahead of time, because they would say, "Well, they didn't catch this during the pre-review." That's why a committee has all these different people. I can catch some stuff, but not everything.

Remedial Education

IRBs may also require that a researcher undergo additional training. For minor offenses, IRBs might require merely online training. "We don't shut that person down," Dwayne said, "but make them retake an online tutorial." Yet, such responses may not be very effective. PIs may speed through an online educational module, giving it little heed. "I don't see a big impact from formal training," Dwayne confessed. "The IRB training we require is an 'online, honesty policy.' You could whisk through it, and basically not pay attention."

Ethics lectures alone don't always fix the problem. As Olivia said, "It's very easy to take an online test, and not internalize what you learn." Courses also do not teach how to interpret and apply ethical principles to one's own research. Indeed, courses usually teach these principles as objective entities — not as being open to differing interpretations in complex situations.

The fact that researchers may still make errors even after taking federally mandated online training courses raises further questions about the effectiveness of this education.

To make the learning process active, not passive, committees may require that investigators who undergo remedial training also have to present newly acquired knowledge to others. Kevin, the health care provider and chair, said:

> "Sanctions" is not a nice word. But we have required that a PI who has significantly over-enrolled or altered protocols without informing the IRB go back to school — take an educational module, and then present the information in a lecture to their own research group. We aim at education of the culprit, if you will, and his or her staff.

The book consists of 14 chapters:

- Protecting the People We Experiment On
- "Inside the Black Box": Becoming and Being IRB Members
- Weighing Risks and Benefits, and Undue Inducement
- Defining Research and How Good It Needs to Be
- What to Tell Subjects: Battles over Consent Forms
- From "Nitpicky" to "User-Friendly": Inter-IRB Variations and Their Causes
- Federal Agencies vs. Local IRBs
- The Roles of Industry
- The Local Ecologies of Institutions
- Trusting vs. Policing Researchers
- Bad Behavior: Research Integrity
- Researchers Abroad: Studies in the Developing World

- Changing National Policies
- Conclusions: Other Changes

The book is available in bookstores.

Reviewer

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