

"Behind Closed Doors: IRBs and the Making of Ethical Research"

Laura Stark, 2012, 229 pages, University of Chicago Press, \$27.50

Review by Norman M. Goldfarb

"Behind Closed Doors: IRBs and the Making of Ethical Research" is actually two books in one. The first is a revelatory look at how institutional review boards (IRBs) actually operate in practice, based on the author's experience watching three IRBs meet and deliberate for a year.

The second is a startling analysis of the origin of the first ethics review board, the National

Institutes of Health (NIH) Clinical Research Committee, and the spread of IRBs, starting in 1966, to other research institutions.

This book has been selected for
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Essential reading for clinical research professionals

In 1953, the NIH opened the Clinical Center, an in-patient research facility, in large part to house healthy volunteers for the Normal Volunteer Patient Program for long periods of time, in some cases, years. Churches recruited "volunteers" as an alternative to compulsory military service. The program was based on a similar military program in World War II that, among other things, exposed healthy volunteers to dangerous levels of radiation in "Guinea Pig Units," as the churches actually called them.

One volunteer in the NIH program participated as a normal control in studies to assess the intensive use of LSD for treating schizophrenia. After she, herself, was diagnosed with schizophrenia, the NIH discharged her from the Clinical Center, but then allowed her to remain as a participant in the non-healthy arm of other schizophrenia studies.

IRB review and signed informed consent forms are obvious ethical protections today, but this was not always the case. In fact, in 1953, the NIH Clinical Center established the Clinical Research Committee, the first ethics review board, as a group process working behind closed doors, in large part to resolve several dilemmas. First, testing medical treatments on healthy subjects was not covered by the medical code of ethics for physician/patient relationships. Second, each NIH institute had its own culture regarding clinical research ethics. Third, the NIH was very concerned about legal liability for itself and for individual researchers. Fourth, and incomprehensibly to us today, many NIH researchers stubbornly opposed mandatory written informed consent, believing the consent process should be left to the researcher. For example, rather than relying on legally authorized representatives, as we do today, many researchers considered themselves the best judge of whether patients would have consented if they were competent to do so, and enrolled them accordingly.

The author coins the term "local precedents" to explain how 10 qualified IRBs can arrive at 10 different conclusions as to how a protocol must be changed to gain approval:

Surveys agree: when different boards are presented with the same standard protocol to review, the boards will unfailingly arrive at different judgments about how the protocol needs to be changed before they will approve it. Survey results, however, have fallen short in explaining why this happens. Authors of these studies tend to view variable decisions as the product of uneven resources across boards. They suggest that with larger staffs, more time, and better training, all boards would arrive at the "correct" decision about a protocol.

Locating the source of uneven decisions in uneven material resources does have some merit, [but t]hese are only partial explanations... This is because the differences between IRBs rest not only with their material resources but with their conceptual resources... Each board imprints the studies they review with their common knowledge and experiences as a group. Boards treat many reviews as routine encounters with familiar cases that they know how to handle... By drawing on local precedents, board members can read new protocols as permutations of studies that they have previously debated and settled... The result is that IRBs tend to make decisions that are locally consistent over time...

The important feature of IRBs' local precedents is that they tend to be idiosyncratic to each board but reasonably stable within them, which explains how two well-supported, fully functioning IRBs can arrive at different decisions about the selfsame protocol.

The book describes how IRB members justify their opinions about studies during board meetings, why some justifications are more persuasive than others, and why meeting minutes are not necessarily a record of the actual deliberations.

The book includes seven chapters:

- Everyone's an Expert? Warrants for Expertise
- Local Precedents
- Documents and Deliberations: An Anticipatory Perspective
- An Ethics of Place
- The Many Forms of Consent
- Deflecting Responsibility
- The Making of Ethical Research

The book is available in bookstores.

Reviewer

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