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2012

Behind Closed Doors: IRB's and the Making of Ethical Research

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Recommended Citation

Zhang, Xiaomeng. Review of Behind Closed Doors: IRB's and the Making of Ethical Research, by L. Stark. Law Lib. J. 39 (2012): 594-6.

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Stark, Laura. *Behind Closed Doors: IRBs and the Making of Ethical Research*. Chicago: University of Chicago Press, 2012. 229p. \$27.50.

Reviewed by Xiaomeng Zhang

¶44 In the late 1700s, English physician Edward Jenner intentionally exposed his infant son to swinepox and an eight-year-old boy to cowpox in order to observe whether they would become immune to smallpox, a related disease. While the modern history of human experimentation can be traced back to the eighteenth century, the topic did not engage significant public attention until 1946, when the Nuremberg trials disclosed horrific medical experiments carried out by Nazi scientists. Now, almost all research involving human subjects is subject to prior review and ongoing monitoring by institutional review boards, or IRBs. *Behind Closed Doors: IRBs and the Making of Ethical Research*, a new book from Wesleyan University sociologist Laura Stark, seeks to shed light on the closed-door decision-making processes employed by IRBs and to describe the historical developments that made the IRB and the group-review model the primary mechanisms governing research involving human subjects.

¶45 There are currently about 5660 registered IRBs located across the country.²⁵ The deliberations of each of these boards are guided by a collection of Health and Human Services regulations often called the Common Rule²⁶ and by “three moral principles—respect for persons, beneficence, and justice” (p.11). For her study of IRBs, Stark interviewed twenty board chairs and sat in on the proceedings of three different IRBs situated at three separate universities. Drawing on this invaluable data, part 1 of Stark’s book presents a picture of how IRBs actually make decisions. Stark describes a process in which IRB members seek shared decisions through *warranting*. “Warrants are reasons or justifications that people give for their views” (p.22), and warranting is a mechanism used by deliberative groups to “reach[]

25. Ivor A. Pritchard, *How Do IRB Members Make Decisions? A Review and Research Agenda*, J. EMPIRICAL RES. ON HUMAN RES. ETHICS, June 2011, at 31, 31 (citing data maintained by the Department of Health & Human Services’ Office for Human Research Protections).

26. The Common Rule is separately codified as a regulation by fifteen different federal agencies, each of which follows the Department of Health and Human Services version found at 45 C.F.R. pt. 46 (2011). See also *Policy for the Protection of Human Subjects* (‘Common Rule’), HHS.GOV, <http://www.hhs.gov/ohrp/humansubjects/commonrule> (last visited Aug. 17, 2012).

consensus by deciding whose recommendation [is] based on the most relevant knowledge” (p.23). Stark identifies three general types of warrants—“matters of fact, private experience, and professional experience” (p.26)—and finds that, for IRBs, professional experience warrants generally prevail.

¶46 As an administrative mechanism, the use of IRBs has been sharply criticized for decision-making variability; when faced with similar—or exactly the same—research protocols, different IRBs frequently reach contrary conclusions. Some scholars theorize that “uneven material resources” (p.46) explain such “uneven decisions” (*id.*). Based on her observations and interviews, Stark suggests instead that differences in the “conceptual resources” (*id.*) of individual IRBs account for much of the variability. She points out that IRBs tend to establish their own local precedents and to follow them consistently when later reviewing similar research protocols. Stark’s explanation cannot fully explain why IRBs develop different precedents in the first place, but her observations may help researchers isolate further factors that contribute to the variability of IRB decisions, such as the impact of board members’ personal experiences and the role of vague federal guidelines that leave too much room for interpretation.

¶47 While the data gleaned from Stark’s firsthand observation of IRB deliberations and her interviews with board chairs add significant value to her analysis, additional observations involving research proposals from the social sciences would have enhanced this study. Each of the three IRBs observed by Stark focused on reviewing medical research proposals. IRBs addressing social science research protocols may weigh the risks and benefits of experimentation differently or consider important general values, such as freedom of speech, when reviewing human subject research proposals.

¶48 In part 2 of the book, Stark shifts her focus to historical analysis. She takes her readers back to the 1940s through 1960s—decades when the public, media, and government in the United States first began to scrutinize human subject research, and offers an insider perspective on the federal government’s evolving oversight of experimental activities. Her discussion illustrates how, in response to public and congressional pressure, National Institutes of Health (NIH) leaders and the research community itself worked to develop the modern group-review model. Stark demonstrates that the IRB concept, which grew out of the expert-review model employed at the NIH Clinical Center in the 1950s, balanced competing stakeholder interests—protecting the rights of human subjects and preserving researchers’ autonomy while shielding the NIH and other government entities from any potential liability.

¶49 As a whole, *Behind Closed Doors* makes a significant contribution to the scholarship on human subject research. Stark’s ethnographic research data on IRB operations and decision making—processes that are not otherwise open to public scrutiny—are invaluable, while her lively account of the historical development of IRBs provides important insight into the current group-review model and background information that will enrich any future discussions of IRB reform. Although the book lacks in-depth analysis of the laws and regulations governing human subject research, it will prove helpful as a secondary resource for those researching legal issues related to IRBs. *Behind Closed Doors* is recommended for law school and

general academic libraries, as well as for any library serving patrons with a strong interest in the IRB or in research ethics more generally. The book will also be of interest to all researchers whose work is or will be subject to IRB review.