

## **"Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009"**

**By Zachary M. Schrag, 2010, 245 pages, Johns Hopkins University Press, \$24.95**

**Review by Norman M. Goldfarb**

"Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009" tells the story of how the human subjects protections developed for medical and psychological research have been misapplied to the social sciences.

In a nutshell, human subjects protections have principally been created to prevent abuses in medical and, to a lesser extent, psychological research. In such research, people participate in scientific experiments that might cause them physical or mental harm. The same rules and principles have then largely been applied to social science research, which employs interviews, surveys and observation, i.e., activities that are likely to leave the study subjects unaffected. (However, these methods can raise issues of privacy, and participants might not want to discuss certain topics with researchers.) Also, while medical studies are usually designed, for example, to test the safety and effectiveness of a new treatment against a placebo per a pre-specified protocol, much social science research is observational and somewhat unstructured. For example, an interviewer might ask open-ended questions and follow up in unanticipated directions.

The book includes numerous horror stories, such as the following:

Music educator Linda Thornton and a colleague at another university wanted to survey music education majors at the 26 top university programs to ask why they had chosen music education as a profession — an innocuous question that should have been granted swift exemption from review. Instead, an IRB forbade the researchers from interviewing students at their own institutions and required them to seek permission from the IRBs at the remaining 24 universities they wanted to study. Nine of the 24 accepted the proposal as approved by Thornton's IRB, including one that noted it had a reciprocity agreement in place. Of the remaining 15, several imposed burdensome requirements, ranging from small changes in the informed consent letter (which then needed to be reapproved by the original IRB) to the requirement that the instructor at the local institution, who was just going to distribute and collect questionnaires, be certified in human subjects research. Application forms varied from two pages to eight. At least one IRB demanded to know the exact number of music education majors in every school to be surveyed. The result was that the researchers dropped many of the schools they hoped to study, cutting their sample from several thousand to 250.

The recent amendments to the Common Rule take some small steps to address the issues. It categorizes scholarship, criminal justice data collection, and activities in pursuit of national security objectives as "not research." It also classifies educational studies, behavioral assessments, and public benefit program reviews as research, but "exempt" from the Rule's application.

While IRB review of social science research does not directly affect clinical researchers, it does have the indirect effects of consuming IRB member time and cluttering their minds with social science expertise. A proper reform of the rules for social science might also affect the rules for observational medical research.

The book includes 10 chapters:

- Introduction
- Ethics and Committees
- The Spread of Institutional Review
- The National Commission
- The Belmont Report
- The Battle for Social Science
- Détente and Crackdown
- The Second Battle for Social Science
- Accommodation or Resistance?
- Conclusion

### **Reviewer**

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