“Human Subjects Research Regulation: Perspectives on the Future”
Glenn Cohen and Holly Fernandez Lynch, editors, 2013, 2014 pages, MIT Press, $66.00

Review by Norman M. Goldfarb

“Human Subjects Research Regulation: Perspectives on the Future” provides a broad-ranging discussion of issues raised by the U.S. Department of Health and Human Services (DHHS) 2011 Advanced Notice of Proposed Rulemaking (ANPRM) to revise the Common Rule. Three years on, it’s unclear whether this effort to revise the Common Rule is still alive, but this volume confirms that there are good reasons to update the Common Rule in fundamental ways. As Luke Dunphy, the noted social commentator, would ask, can we make the impossible unimpossible?

The following excerpt from Seema Shah’s essay illustrates the content of the book:

**What Ethical Obligations Do the Regulations Overlook?**

By addressing investigator and sponsor responsibilities only minimally and primarily focusing on compliance with IRB review, the regulations and proposed revisions fail to recognize that investigators have important ethical responsibilities. In his seminal 1966 article bringing to light several examples of unethical research, Henry Beecher noted the importance of informed consent in protecting against such abuses, but went on to say that “there is the more reliable safeguard provided by the presence of an intelligent, informed, conscientious, compassionate, responsible investigator” (Beecher 1966, 1354-60). Since Beecher’s article was published, IRBs have become an increasingly integral part of the research enterprise. Even assuming an IRB could take over some of these obligations for the investigator, an investigator’s ethical obligations cannot and should not be fully outsourced for several reasons.

First, IRB review still allows for considerable discretion for investigators. IRB review occurs before a study begins, and then no less than annually, depending on the level of risk (45 CFR 46.109(e) (2011)). IRBs do not directly review the ongoing conduct of research. In fact, IRBs could not effectively police the conduct of the large volume of research they review because they lack capacity to do so (DuBois 2004, 390).

Second, unexpected events often occur in the course of research, including new research findings, disruptive behavior by participants, or changes in the environment of the research institution. If any of these events have implications for participant welfare or study design, an investigator must consider what to do and whether to inform the IRB. Because the IRB must rely on investigators to report adverse events, protocol violations, and lapses in behavior by the parties involved, and there will be a time lag in obtaining the IRB’s answer, the investigator will have to recognize her ethical obligations and, in some cases, temporarily address them.

Finally, scholars have argued that some ethical obligations arise from the investigator-participant relationship. Steven Joffe and Frank Miller have argued that investigators have duties to pursue beneficent purposes, minimize the number of participants, minimize risks and burdens, respect participants, satisfy obligations of justice, provide ancillary care, and help participants transition back to care post-trial (Joffe and Miller 2008, 37-38). Applying these duties to the example at the beginning of the chapter suggests that the investigator should give more thought to her ethical obligations. The investigator’s plan to refer mothers back to HIV care immediately
after delivery seems unlikely to result in a smooth transition. During that hectic time, mothers may simply fail to obtain the treatment they need. If the investigator planned instead to allow participants to receive study treatment for a few weeks after delivery and then transition to care outside the study, this would be a better way to fulfill her ethical obligations. Yet the Common Rule provides little room or encouragement for ethical reflection of this sort.

As currently controversial duties become increasingly widely accepted and acknowledged, it seems important for the regulations to address them. Yet not only does the Common Rule fail to acknowledge that these duties are relevant to investigators, but its structure also implies investigators or sponsors should not be concerned with these duties.

The book consists of 22 essays by 33 contributors:

- Setting the Stage: The Past and Present of Human Subjects Research Regulations
- *De minimis* Risk: A Suggestion for a New Category of Research Risk
- Risk Level, Research Oversight, and Decrements in Participant Protections
- Classifying Military Personnel as a Vulnerable Population
- Children as Research Partners in Community Pediatrics
- Back to the Future? Examining the Institute of Medicine’s Recommendations to Loosen Restrictions on Prisoners as Human Subjects
- Toward Human Research Protection That Is Evidence Based and Participant Centered
- Outsourcing Ethical Obligations: Should the Revised Common Rule Address the Responsibilities of Investigators and Sponsors?
- Subjects, Participants and Partners: What Are the Implications for Research as the Role of Informed Consent Evolves?
- Democratic Deliberation and the Ethical Review of Human Subjects Research
- IRBs and the Problem of “Local Precedents”
- Biospecimen Exceptionalism in the ANPRM
- Biobanking, Consent and Certificates of Confidentiality: Does the ANPRM Muddy the Water?
- Mandating Consent for Future Research with Biospecimens: A Call for Enhanced Community Engagement
- Take Another Little Piece of My Heart: Regulating the Research Use of Human Biospecimens
- Reconsidering Privacy Protections for Human Research
- In Search of Sound Policy on Nonconsensual Uses of Identifiable Health Data
- What Is This Thing Called Research?
- What’s Right about the “Medical Model” in Human Subjects Research Regulation
- Three Challenges for Risk-Based (Research) Regulation: Heterogeneity Among Regulated Activities, Regulator Bias, and Stakeholder Heterogeneity
- Protecting Human Research Subjects as Human Research Workers
- Getting Past Protectionism: Is It Time to Take off the Training Wheels?

The book is available in bookstores.
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