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Review of *Human Subjects Research Regulation: Perspectives on the Future*

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On 19 January, 2017, the day before a new president assumed office, the Obama administration published its Final Rule for the federal policy for the protection of human subjects, the first update since 1991 of the federal ethics regulations for research on human subjects (45 CFR 46). Widely known as the Common Rule, this regulation officially governs research conducted under the auspices of eighteen federal agencies and departments, but it is influential with Institutional Review Boards (IRBs) across this country and, in various ways, around the world. The laborious process of revising the Common Rule began in 2011 when the US Department of Health and Human Services (HHS) announced possible changes to the federal regulations and initiated a period of public comment, which was extensive and contentious—more than 1,100 responses were submitted. The stakes were high for all of the usual reasons—regulated people and institutions care about any changes that could affect money, lives, and careers—but also because such changes occur infrequently. After a long delay, HHS released its proposed changes in September of 2015. This was subject to a further round of vigorous criticism in more than 2,100 responses.1

The papers in Human Subjects Research Regulation originated in a Harvard Law School conference in May 2012, a time of bureaucratic limbo when HHS was evaluating the initial public comment. In fact, the editors note that, as they were writing the book’s introduction in fall 2013, two years’ of governmental inaction led them to suspect the process had ground to a halt, and they were uncertain whether any revisions to the Common Rule would ever appear. Accordingly, they regard the book as a continuation of the conversation about how to improve the regulation of human subjects research.

Given the appearance of the NPRM in 2015 and the Final Rule in 2017, this book might seem to hold merely historical interest for people particularly concerned with human subjects research. Certainly, the resolution of the regulatory issues (for the time being) limits the urgency of these papers as they are written, but not all of the conflicts among the several authors have been settled by the Final Rule. Moreover, as a contributor observes in reference to one of the most contentious issues (regulations for access to medical data and biospecimens), “Whatever the fate of [these proposed revisions], the Common Rule’s framework . . . is a likely target for reforms in years to come” (266). The rule may be fixed for now, but not all questions are answered, and no one should be under the illusion that further changes are impossible. So there is every reason to take up this conversation and consider the arguments and proposals advanced in this book, both those one would like to see promoted and those one would like to

1 For the relevant documents, including a summary of the final changes, see https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html.
As the editors note, either cynically or dolefully, at the end of their introduction, reasoned argument does not always prevail in politics. Even so, that is no reason to abandon reasoned argument.

The book does not offer a comprehensive analysis of all issues that arise in the regulation of human subjects research. Rather it samples a broad range of opinions on the pressure points in the then-current regulatory environment. The contributors disagree on whether proposed changes are possible, necessary, desirable, or dangerous. The first chapter sketches the history of research regulation and summarizes the main areas of concern.

1. IRBs often over-review low-risk research and devote less time to high-risk studies.
2. Multi-site research often is reviewed by multiple IRBs, which is inefficient and may weaken protections.
3. Consent forms are lengthy and confusing; they may yield inadequate information to and protections for research subjects.
4. Abundant health data and bio-specimens create new threats to privacy.
5. Current regulations do not provide well for ongoing review or adverse events.
6. Current regulations protect only subjects involved in federally funded research.
7. Compliance can become burdensome when inconsistent regulatory systems apply to a single study.

Oddly, the introduction omits the seventh category. That is worth mentioning only because generally this book has been edited very carefully. One of the section introductions is rather clumsily and unclearly written, but I noticed no more than two typos in the whole text, and the several chapters regularly cross-reference one another, which is especially helpful in a book with twenty-two chapters. Not every important connection and contrast is drawn explicitly, but this is a polished group project. The papers as a whole are addressed to finding ways to improve protections for research subjects while eliminating unnecessary or counterproductive burdens on research projects.

The ensuing twenty-one chapters are divided into five unequal sections. The two papers in the first section address proposals to limit review of research with minimal or negligible risk. In one, Rosamond Rhodes argues for a new category of de minimis risk, where there is no physical risk and only negligible psychological or social risk, for which informed consent would ordinarily be unnecessary. Ana S. Iltis argues against the proposed rule that there would be no continuing review of minimal risk research. She holds that new risks could emerge or mistakes in the initial review might be discovered. These two papers illustrate the type of opposition one sees in this book. Generally, one does not find diametrically opposed arguments. One finds people arguing in competing directions and with different priorities. Together the essays provide a basis for further thought much more than they provide a conclusive answer on any specific matter.

In the second section, devoted to vulnerable populations, three papers examine to research on military personnel, children, and prisoners. We are urged to want more protections for soldiers and prisoners but to conceive of children as research “partners” rather than subjects. Adam Braddock’s argument that children can be partners in participatory research concentrates on “community pediatrics,” which aims to identify and reduce “social, economic, and other environmental causes of poor child health” (79). Thus, his examples include research on drug use in a child’s environment and the merits of an online curriculum for youth with disabilities. Braddock regards children as partners because they can help with such activities as selecting research topics, recruiting participants, and collecting data. This paper instantiates one of the central questions of the book, Are the standards for regulating medical research are also appropriate for behavioral and sociological research? Authors can be found on each side of that debate.

The third section contains five papers under the heading “Redefining the Participant–Researcher Relationship and the Role of IRBs.” These are somewhat disparate, but each one proposes alternatives to
what appear to be fundamental flaws in the existing system. Michael McDonald, Susan Cox, and Anne Townsend argue that the current system focuses so heavily on compliance with IRB review that it ignores the actual outcomes for the research subjects. Seema K. Shah argues the current system and the proposed changes tend to “outsource” ethical responsibilities to the IRB review process, as if researchers and sponsors have no ethical responsibilities to research subjects beyond complying with whatever the IRB wants. She reports but is not terribly alarmed by the fact that “a significant minority” of researchers admit wrongdoing in the scientific practices of their research. Additionally, she cites a study concluding that “the vast majority of incidents of misconduct are never reported.” Shah does not lose faith in researchers, but rather asserts that “fostering a strong sense of ethical responsibility in researchers is clearly an important way to combat such behavior” (132).

Alexander Morgan Capron argues that bureaucratic adjustments to the Common Rule are inadequate because we need to recognize that we have evolved a long way from the rigorous standard of informed consent established at Nuremberg. We still pay lip service to informed consent as a sacred principle, but actual practice has shifted to reliance on IRBs to assess which risks subjects even have the opportunity to consent to. Capron speaks of the shrinking sphere of autonomy. On the one hand, willing volunteers are not permitted to take part in research if IRB review deems it too risky. On the other, vast amounts of research on health records and bio-specimens are permitted to proceed without informed consent because IRBs have established numerous exclusions, exemptions, and exceptions. Laura Stark explains that although all IRBs are governed by the Common Rule, their ethical judgments vary considerably, in part because of the importance of “local precedents,” which are the familiar cases previously decided at each IRB. Protocols under review at any given IRB are more likely to be evaluated by referencing recent precedent than universal ethical principles. Disagreement between IRBs creates obstacles for multi-site research. For example, when several IRBs review the same protocol, each may demand its own set of changes.

The fourth section, “Specimens, Data, and Privacy,” contains six papers addressing the increasingly problematic questions of how to protect confidentiality and privacy—in particular, whether informed consent is necessary for all the research that might be done on the enormous accumulation of health data and bio-specimens. One of the oddities of the current system is that a researcher who collects tissue samples from people for research purposes is engaged in human subjects research and must obtain informed consent. If personally identifiable information is removed from the samples, they may be used by other researchers. These subsequent studies are not considered human subjects research and therefore are exempt from the requirement to obtain informed consent. In one proposed change, tissue donors could give blanket consent for any and all research involving their tissues or perhaps they could provide a checklist of what sorts of research they consent to. Capron objects to coupling an empty nod to informed consent with a substantive violation of it. Obviously, one cannot give informed consent to research that is wholly unspecified and unspecifiable. Barbara J. Evans’s paper in this section offers a particularly helpful analysis of the relevant issues.

Gail Javitt identifies the central problem: the law and ethics of bio-specimens are unsettled, yet access to those materials is essential for progress in medical science. She appeals to the differential responsibilities that researchers have toward others depending on their classification as patients, subjects, or donors. She does not mention partners, probably because her review of the case law reveals that researchers, sponsors of research, and courts tend to conclude that individuals who provide valuable biological material do not retain control over it once it has passed to researchers’ hands. Javitt’s critique of legal reasoning in these cases is extremely interesting. It is worth noting that the text as a whole vacillates between referring to human subjects and to participants in research. Capron is unimpressed by the acceptance of the term participants in 2001 by the National Bioethics Advisory Commission: “As a general matter, dressing ‘subjects’ up as ‘participants’ may just lessen the felt need to prevent their suffering avoidable harm and violation of rights” (150–51).
The fifth section devotes five papers to consideration of radical reconfiguration of how we think about research on human subjects. Zachary M. Schrag summarizes the careless historical path that has led to our present problems and suggests that we should do the hard work of developing clear and coherent definitions of research and subject in ways that eliminate "IRB creep." Michelle N. Meyer argues that risk–benefit analysis should be removed from IRB responsibilities and left to potential subjects, who will evaluate it variously among themselves and differently than do IRB members. Holly Fernandez Lynch proposes reconceiving research subjects in comparison to workers and determining whether protections should be increased for subjects or decreased for employees. Greg Koski argues that we should move away from the conception of researchers as potential threats to subjects and reinforce the conception of them as professionals who are better positioned to care for subjects than are IRB members.

The fifth paper, by Heidi Li Feldman, resists efforts to liberate non-medical research from the so-called "medical model" currently used to regulate it as human subjects research. She has a robust conception of respect for persons, which leads her to conclude that informed consent regulations indicate the fundamental equality between subjects and researchers. At the same time, she does not "fetishize" consent: "Consent does not prevent injury or pain. It does not guarantee the worthiness of the researcher’s goals or her field of inquiry. Consent does, however, force notice of the separateness of persons, an ethically important fact closely associated with the exercise of autonomy" (304).

It is interesting to contrast this defense of informed consent with the degraded version of it captured in a summary remark by Suzanne M. Rivera: "Under current regulations, local IRBs are authorized to permit the re-use of specimens or data without re-consenting the subjects/donors only when it is determined that such use would not pose more than minimal risk" (251). The use of re-consent as a transitive verb where the agent is the researcher rather than the one consenting could be dismissed as an inconsequential bit of careless writing or a clumsy medical obfuscation. Or one might see in it a genuine indication of how some researchers think about consent. Far from being a moral transaction in which the researcher acknowledges his or her subordination to the moral agency of the potential subject, “consent” becomes something the researchers do to the subject: poke the patient and draw out consent, more or less like bloodletting—call it consent-letting. On this view, consent is of no moral significance, but it might be required for regulatory compliance. It is just another item extracted from patients or subjects and stored.

This book lets the reader juxtapose radically conflicting ethical standards for human subjects research. For that reason, this is a valuable resource for ethics professionals, and advanced students perhaps could profit from it with the guidance of a teacher. It would not make a good introduction to the ethics of human subjects research because one needs to know how to read beyond the text to evaluate its contents. It should also be noted that some of these contributions are shortened versions of more extensive arguments published elsewhere. Roughly one-third of the contributors are lawyers and professors of law, while the remainder are medical or ethics professionals serving in academic and non-academic roles. In my judgment, the value of a book like this lies not in recording the winners and losers of the wars over regulatory revision, but rather in expressing the divergent ways people think about the good that might be done and the harm that might be incurred when we pursue scientifically informed medicine.