The Reasonable Person Standard for Research Disclosure: A Reasonable Addition to the Common Rule

Rebecca Dresser

The Common Rule is a set of United States regulations governing research involving human subjects. Federal agencies apply the Common Rule to the human studies they conduct or support; most research institutions and private sponsors also apply it to the studies they oversee. In 2017, federal officials issued the first major revision of the Common Rule since its 1991 inception.

Parts of the revised Common Rule modify the information disclosure requirements for human subject research. The revisions adopt a concept well known in law, but less familiar to the research community. The revisions direct study teams to give prospective subjects the facts that a reasonable person would want to know before making a decision to enroll.

The revision has provoked some consternation among people in the research community. Some researchers and oversight groups question whether the reasonable person standard is the right one to apply in evaluating study disclosures, while others are confused about how to apply the standard. The federal Office for Human Research Protections reports that it has received requests for guidance on the standard.[1] Presenters at a conference for Institutional Review Board (IRB) members and staff wondered who would determine what reasonable people want to know before making study decisions — would it be participants, researchers, sponsors, IRB members, or regulators?[2] In short, "[n]ot everyone is convinced ... that the reasonable person is right for the job" of guiding the research disclosure process.[3]

Worries about applying the reasonable person standard to research are understandable but in my view, overblown. The reasonable person standard has a long track record in U.S. law. During the 1970s, courts and legislatures began using it to measure the adequacy of information disclosure to patients making medical care choices. During the same period, the National Commission for the Protection of Human Subjects (National Commission) considered and recommended a version of the standard to govern disclosures in the research setting, as well.[4]

Since then, although it hasn't been formally included in regulations addressing informed consent, the reasonable person standard has had a presence in research oversight activities. I submit that study teams and IRBs often use the standard in considering the information that prospective subjects need to know. But they make their reasonable person judg-

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ments informally and unsystematically. The standard has operated under the surface, which makes it less effective and consistent than it could be.

The revised Common Rule disclosure standard is less radical than it may appear to today's research community. With some effort, the reasonable person standard can become a meaningful part of study planning and oversight. In this article, I describe Common Rule provisions incorporating the standard, legal origins of the reasonable person standard, and early U.S. policy discussions of the standard's relevance to research disclosure. I consider how IRBs have used the standard and discuss measures that could improve this effort. I close with recommendations for putting the reasonable person standard into research practice.

I. The Common Rule Revisions

The revised Common Rule adopts the reasonable person standard in two provisions addressing research disclosure. One is the provision setting forth general requirements for informed consent to study participation. To promote self-determination, study teams must give prospective participants or their legal representatives "information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information."[5]

The revised Common Rule adopts the reasonable person standard in two provisions addressing research disclosure. One is the provision setting forth general requirements for informed consent to study participation. To promote self-determination, study teams must give prospective participants or their legal representatives "information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information."

The second provision adopting the reasonable person standard applies to researchers seeking a participant's "broad consent" to future studies involving identifiable personal data or biospecimens. The revised rule requires study teams to give people considering this option "a general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted."[6]

These revisions are not the first research regulations to incorporate the concept of reasonableness in defining when human studies are permissible. The 1991 Common Rule directed study teams to disclose to prospective participants "any reasonably foreseeable risks or discomfort," as well as "any benefits to the subject that may reasonably be expected."[7] That version also required researchers and IRBs to ensure that any risks faced by study participants are "reasonable in relation to anticipated benefits."[8] The revised version retains these provisions, which means that experts and lay reviewers will continue to make these judgments. The new Common Rule requirements differ from the earlier ones in explicitly requiring the adequacy of study disclosure to be evaluated from the perspectives of ordinary people rather than those of the scientists, clinicians, and other experts who have the biggest role in designing, conducting, and reviewing human studies.

II. The Reasonable Person in Law

The reasonable person standard emerged early in the development of the common law.[9] To determine when people should be legally responsible for unintentionally harmful conduct, courts considered whether defendants had behaved according to community standards for safety. It was fair, and realistic, to expect people to act with the same level of care that would be expected of a reasonably prudent community member. Those who failed to conform to the reasonable person standard behaved negligently and could be held liable for the harm they had caused.[10] Courts relied on fact finders in legal proceedings — typically juries, but sometimes judges — to interpret and apply the reasonable person standard. Because they faced similar situations in their own lives, members of the community could determine whether a defendant's behavior was acceptable or overly risky.[11]

Medical malpractice cases presented a somewhat different situation. In those cases, it was the negligence of physicians that was in question. Physicians who failed to use reasonable care in conducting surgery, diagnosing illness, prescribing medication, and other

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parts of their medical practice could be found liable for any resulting harm to patients. Similarly, when physicians failed to use reasonable care in informing patients about risks and other important facts about proposed medical interventions, they could be found negligent for any harm resulting from the failure to secure patients' informed consent to medical care.[12]

In ordinary medical malpractice cases, reasonable care was determined by professionals in the relevant medical field. Individual physician conduct was evaluated against the standard of care established by reasonably prudent physicians.[13] But the usual reliance on physicians to establish the standard of care created problems in the informed consent context. If physicians ordinarily failed to inform patients of important information about a medical intervention, then individual physicians could not be held accountable for failing to disclose that information.[14]

Despite this problem, some jurisdictions adopted what is known as the professional standard to evaluate physician disclosure. In these jurisdictions, liability depends on whether defendant physicians gave patients the treatment information that a reasonable physician would disclose. Expert witnesses testify about the information customarily disclosed by physicians in the relevant medical field. Juries or judges decide whether the standard was met in specific cases.[15]

In other jurisdictions, however, legal authorities endorsed patient-centered standards to evaluate medical disclosures. In the ground-breaking case of *Canterbury v. Spence*,[16] the judge criticized the professional standard as insufficiently protective of patients' decision-making rights. Professionals might not know or appreciate how patients think about medical procedures and their potential consequences. For patients to exercise genuine self-determination, they needed to learn the facts that a reasonable patient in their circumstances would consider relevant to the choice. Juries and judges should determine whether disclosures were sufficient to meet the reasonable patient's information needs.

Professional disclosure standards are established through collaboration among medical experts and professional organizations. It is relatively easy for physicians to find out what colleagues believe should be disclosed about particular medical interventions. The reasonable patient standard is less straightforward and can be more difficult for clinicians to ascertain. Although professional knowledge is certainly relevant to determining what reasonable patients would want to know, lay juries and judges applying the reasonable patient standard have the final say on what should be disclosed.[17]

The reasonable patient standard presents challenges for physicians, but it is not the most demanding disclosure standard. A few jurisdictions have adopted the subjective standard, which requires physicians to tailor disclosure to the individual patient's personal, perhaps idiosyncratic, values and needs. This standard recognizes that particular patients might have atypical information needs, such as a violinist's need to know about remote risks involving loss of manual dexterity. Although the subjective standard is most respectful of individual autonomy, most courts and legislatures have rejected it because it is too burdensome for physicians. Legal authorities also fear that the subjective standard could create too many opportunities for injured patients to recover in cases where physicians failed to disclose information that most patients would consider irrelevant.[18]

The revised Common Rule requirements reflect developments in medical disclosure law. But such developments are only a partial guide to applying the reasonable person standard to research disclosure. Although inadequate research disclosure can be the basis of a lawsuit, such cases are rare.[19] Unlike the retrospective inquiry that occurs in informed consent lawsuits involving injured plaintiffs, the Common Rule's disclosure provisions operate prospectively, with the aim of ensuring that subjects receive the needed information. The provisions are interpreted and applied by interdisciplinary IRBs, rather than juries and judges. And substantive differences between clinical care and study interventions affect how the reasonable person standard should operate in research. The National Commission's work on disclosure standards specifically addresses disclosure in the research context.

III. The National Commission's Disclosure Deliberations

Decisions about research participation are different from decisions about personal medical care. Medical care is performed solely to benefit patients and delivered by physicians and other health care professionals guided by this objective. In contrast, the objective of human research is to produce knowledge. Sometimes subjects benefit from study participation, but this is uncertain and, in many studies, not even possible. These differences influenced the National Commission's deliberations on the proper disclosure standard for research.

In its influential *Belmont Report*, the Commission deemed the professional disclosure standard inadequate for research, on the grounds that the exploratory nature of research made it impossible for professionals to know and agree on the information prospective subjects should understand. Somewhat surprisingly,

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the Commissioners labeled the reasonable patient standard inadequate as well. That standard was insufficiently informative, the Commissioners declared, because "the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care."[20]

The Commissioners' preferred alternative was the "reasonable volunteer standard." Under this standard, "the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge."[21] When studies do offer a prospect of direct benefit, "subjects should understand clearly the range of risk and the voluntary nature of participation."[22]

The Commission took this position after considering scholarly papers prepared to assist its deliberations. Analyses by research ethicists Robert Levine and Robert Veatch described court decisions on disclosure in the medical setting. Both writers favored a subject-centered standard over a professional standard for research disclosure. As Veatch put it, "[I]f the objective of the consent is to promote self-determination, then it is the subject population itself which must provide the standard for determining how much information is to be transmitted in order to exercise self-determination."[23]

Veatch also supported a more individualized disclosure standard in certain circumstances. He acknowledged that some people might have individual information needs that differ from those of the general subject population. For those individuals, exercising self-determination requires going beyond the reasonable person standard. Veatch argued that if subjects express an interest in learning "more information than the reasonable citizen, then the patient's or subject's own standard of certainty must apply."[24]

Levine and Veatch both assigned to IRBs the responsibility to determine what reasonable persons would want to know about specific studies. But both also thought that laypersons were most qualified to make reasonable person judgments about what should be disclosed. Because IRBs were composed primarily of research professionals, they were ill-suited to making such judgments. Writers aware of this problem had previously proposed employing nonscientist "consent juries"[25] or subject surrogates[26] as potential remedies, but these mechanisms would be burdensome and expensive. Veatch offered his own solution — a two-committee system in which a group of professionals would apply their knowledge and values to study evaluations and a separate group of laypersons would evaluate studies based on the knowledge and values of reasonable community members. He contended that this system, or alternatively, a committee system in which professionals served in "a strictly technical advisory capacity," would be necessary to put the reasonable person standard into research practice.[27]

The laws governing medical disclosure, as well as the National Commission deliberations on research disclosure, help to explain why officials chose to make the reasonable person standard explicit in the revised Common Rule. But the analyses by Levine and Veatch also highlight IRB limitations in applying the reasonable person standard. Although IRBs attempt to consider disclosure from the reasonable person perspective, a committee dominated by research professionals will have limited success in doing so.

IV. The Reasonable Person in Research Disclosure: The Status Quo

Before it was revised, the Common Rule failed to include an explicit requirement for investigators to disclose study information a reasonable person would want to know. But even without this requirement, IRB members made reasonable person judgments about study disclosure. The literature on research oversight reveals committee efforts to adopt the ordinary layperson's perspective in evaluating the information that is presented to prospective research subjects.

Sociologist Laura Stark offers an enlightening account of this phenomenon. Stark conducted an in-depth study of IRB proceedings, observing and recording multiple IRB meetings at three different locations. In reporting her findings, she described how IRB members tried to "see like a subject" in their study evaluations. People made "claims to knowledge about participants by thinking of their friends, family members, students, neighbors, colleagues, and acquaintances."[28] Committee members — researchers and nonscientists alike — referred to "their own life experiences" in explaining how potential subjects could interpret study information.[29] Although this approach helped committees perform their study reviews, it had a negative impact, as well. As Stark points out, the "people whom board members called to mind when they imagined a research subject — a relative or a student, for example — reinforced the race, class, and gender biases of the board membership."[30]

Stark's observations supplement those of IRB members. Many people serving on these committees, particularly the nonscientist and community members, see themselves as standing in and speaking for prospective research subjects.[31] But their judgments rest on speculation about subjects' perceptions. For

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example, in one set of interviews, most IRB members reported that they "had little knowledge of the values, expectations, and needs of those whom they are charged to protect."[32] Committee members, including nonscientists and laypersons, tend to be relatively well educated, financially secure, and knowledgeable about the research process. Many haven't personally experienced serious illness and thus are unfamiliar with the psychological effects that this can have on a person's decision making. These and other factors account for differences in the perspectives of prospective subjects and IRB members.

Some IRB members have participated in studies themselves, and others have close relatives with direct experience as subjects.[33] Yet these personal experiences don't necessarily qualify them to speak for the populations that will be recruited for specific studies. Moreover, the literature suggests that only a minority of IRB members have real-life experience with study participation.[34] As a result, professionals and other IRB members may be unaware of or downplay information that members of a study population would want to know.

Existing efforts to apply the reasonable person standard in research review fall short of what is needed to promote the self-determination principle underlying the informed consent requirement. Review board members look to people in their own lives as exemplars of the reasonable person, which can lead to circumscribed and biased conceptions of subjects' informational interests. Board members' judgments also lack a solid evidentiary foundation.[35]

In the current oversight system, IRBs members decide what they think prospective subjects should want to know, rather than determine what subjects actually want to know. And because most IRB members are researchers, clinicians, academics, and other experts, their reasonable person judgments don't necessarily reflect those of laypersons recruited to participate in research. The Common Rule's revised disclosure provisions call for improvements in researcher and IRB approaches to determining what prospective subjects should know about studies they are invited to join.

V. Improving Reasonable Person Judgments in Research Disclosure

As I reported earlier, people involved in research oversight are both uncertain about how to apply the reasonable person standard and skeptical of its value. But not everyone shares these negative views. One IRB administrator hopes the revised Common Rule's disclosure standard will serve as "a launching point for exploring what real people need and expect when making decisions about participation in research."[36] In the spirit of encouraging such exploration, I propose ways for researchers, IRBs, and oversight officials to develop a better sense of what reasonable people want and need to know about research.

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A. Guidance from Other Legal Contexts

Concerns about the indeterminacy of the reasonable person standard have existed since it was first adopted. Despite this, the standard has "persevered through centuries of common law development, suggesting that its benefits outweigh its costs."[37] Moreover, although the research oversight system cannot call on lay juries to determine reasonable disclosure, juries aren't essential to applying the reasonable person standard.

Juries don't actually decide most negligence cases, including those involving claims that physicians failed to provide treatment information a reasonable patient would want to know. A relatively small number of cases go to trial, and in some of those trials, judges perform the fact-finding role traditionally assigned to juries. Moreover, the vast majority of cases are settled without a trial. In such cases, lawyers, clients, and judges decide how to apply the reasonable person standard.

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Precedent helps with this effort. Previous litigation addressing facts resembling those in the case at issue can guide negligence determinations. With the accumulation of cases, "more concrete standards may begin to evolve, with the speed of their evolution depending on the frequency of litigation."[38] Building on precedent is "a way to create a shared understanding of the reasonable person view in a particular kind of case."[39]

It would be possible to develop a similar process in the research context. Written descriptions of IRB-approved study disclosures could be examined and critiqued by a variety of stakeholders, including patient advocates and members of the general public. Over time, a consensus on reasonable disclosure in different kinds of studies, such as those involving specific diseases, procedures, and investigational phases, could emerge.[40] Indeed, a new Common Rule requirement could promote this process. A provision in the 2017 regulations requires institutions and agencies to post on a publicly accessible government-created website copies of IRB-approved consent forms used in studies supported by federal agencies or conducted by agency employees.[41] This increased transparency could encourage productive conversation and build consensus on what reasonable people want to know before enrolling in research.

B. Learning from Reasonable People

Researchers and IRBs can take advantage of another strategy to improve their reasonable person judgments about study disclosure. In recent years, legal scholars have endorsed the use of empirical data to improve application of the reasonable person standard in negligence determinations. They argue that information from surveys, large databases, and related sources would help courts and other decision makers develop evidence-based reasonable person judgments.[42]

Some of these proposals address disclosure rules incorporating the reasonable patient standard.[43] For example, law professor Alasdair Maclean believes that in the absence of a jury, judges applying the reasonable person standard should consult empirical studies to assist in their determinations. He contends that collecting data on what real patients need and want to know about different medical interventions would allow legal decision makers to make better judgments on appropriate physician disclosure.[44]

Consulting empirical data is a way for researchers and IRBs to develop evidence-based standards for research disclosure, too. A wealth of information about what laypersons want to know is already available. Many quantitative and qualitative studies report on what people believe is important to know about various kinds of research. Findings come from projects investigating the information preferences of the general public, members of populations that will be recruited for specific types of studies, and people with personal experience as study subjects.

Experienced research subjects are in my view the best information source. People who have been through the research experience know what important facts were missing from the descriptions they received before the study began. They can also describe what facts could have been omitted as unnecessary to their understanding. Through personal experience, these individuals have learned what reasonable people should know about studies before deciding whether to participate.

People who have never been study subjects will be unaware of at least some of this information. One experienced subject put it well: "you can't understand it until you experience it."[45] In a 2017 book, *Silent Partners: Human Subjects and Research Ethics*,[46] I describe some of what experienced subjects say they wished they had known about the studies they agreed to join. Below I offer a few of their insights.

The desire to contribute to valuable knowledge is often an important factor in a person's decision to enroll in research. Research ethicist Alan Wertheimer had this objective in mind when he volunteered for a cancer trial. Two years later, he was surprised to learn that inadequate enrollment had prevented the trial from being completed. Since unfinished studies fail to contribute useful information, Wertheimer concluded that prospective subjects should be told when noncompletion due to inadequate enrollment is a substantial possibility.[47] Other experienced subjects made a related point when interviewers asked what they thought prospective volunteers should know. Many of these subjects wanted to know whether industry-sponsored trials were being conducted for legitimate health reasons or for what they saw as less valuable objectives, such as extending a product's patent protection.[48]

Quality-of-life information is also more important to prospective subjects than experts might realize. Experienced subjects want to know how participation will affect their daily lives. Schedules, travel demands, and other logistical factors can make a big difference in prospective participants' decisions to enroll. Past volunteers often say that they weren't sufficiently prepared for these study demands, or for the stress and discomfort that they experienced as study participants.[49] As one former subject put it, "I would have liked to have a better understanding of how I was going to feel."[50]

Study disclosure is unlikely to promote subject autonomy when study teams fail to adopt subject-

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friendly disclosure processes. Experienced subjects have information on disclosure processes that would help ordinary people decide whether to enroll in research. For example, one group of researchers found that patients in trials believed that including family members and nurses contributed to more informative disclosure sessions.[51] Other prospective subjects say that having an opportunity to talk with enrolled subjects could help them understand what study participation would involve.[52]

These are just some examples of what can be learned from experienced study subjects. Up-to-date literature reviews addressing subject perspectives on disclosure in different types of studies, such as cancer trials, first-in-human trials, biobank research, and comparative-effectiveness research, would help researchers and IRBs apply the reasonable person standard. And new investigations could target areas where more data are needed. Government and private funding for such projects would advance the Common Rule's objective of promoting autonomy in research participation decisions.

The research community would benefit from including more experienced subjects in study planning and review, as well. Researchers designing study consent forms and procedures could consult with people who previously participated in similar studies. Community engagement and patient–centered research efforts give research teams opportunities to communicate with experienced subjects. Research institutions could make a concerted effort to appoint experienced subjects as IRB members and advisors, too. Such members could be particularly helpful in considering proposed disclosures for studies under review. Measures like these would promote efforts to apply the reasonable person standard to research disclosure.[53]

VI. Conclusion

The reasonable person standard puts the spotlight where it belongs: on prospective participants' actual information needs. I don't mean to suggest that vigorous application of the reasonable person standard is all that is needed to remedy the problems associated with research decision making. But the standard could be an incremental step toward promoting informed choices about research participation.

Over the years, the reasonable person standard has influenced what prospective subjects hear and read about the studies they are invited to join. But the standard has operated in the background, without the necessary rigor to make it effective. Now that the Common Rule explicitly includes the reasonable person standard, researchers and the oversight system must develop a stronger foundation for its application. This will require learning from a new group of experts — ordinary people who know what it's like to make potentially life-altering decisions based on the new and often confusing information researchers have conveyed to them. Input from these individuals will be crucial to creating a defensible basis for disclosures that allow reasonable people to make informed choices about research participation.

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References

1. Federal Policy for the Protection of Human Subjects: Six Month Delay of the General Compliance Date of Revisions While Allowing the Use of Three Burden-Reducing Provisions During the Delay Period, 82 *Federal Register* 28497, 28500-01 (final rule, June 19, 2018).
2. J. Gearhart, "The Reasonable Person: A Character of Interest in the New Common Rule," *Quorum Review*, June 13, 2018, *available at* <https://www.quorumreview.com/reasonable-person-character-interest-new-common-rule> (last visited March 20, 2019).
3. *Id.* See also J. Gearhart, "OHRP Sheds a Little Light on the Revised Common Rule," *Quorum Review*, April 4, 2018, *available at* <https://www.quorumreview.com/ohrp-answers-about-revised-common-rule> (last visited March 20, 2019).
4. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, U.S. Department of Health, Education, and Welfare, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Bethesda MD: National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978): 5-6.
5. Federal Policy for the Protection of Human Subjects, 82 *Federal Register* 7149, 7265 (final rule, January 19, 2017).
6. *Id.* at 7266.
7. *Id.*
8. *Id.* at 7264.
9. See generally S. Stern, "*R. v. Jones* (1703): The Origins of the 'Reasonable Person,'" in P. Handler, H. Martin, and I. Williams, eds., *Landmark Cases in Criminal Law* (Oxford, UK: Hart Publishing, 2017): at 59-79.
10. O. Ben-Shahart and A. Porat, "Personalizing Negligence Law," *New York University Law Review* 91, no. 3 (2016): 627-688, 628 (reasonable person standard "requires people to behave in the prudent way that … the ordinary, typical member of the community observes").
11. A. Rose, "The 'Reasonable Investor' of Federal Securities Law: Insights from Tort Law's 'Reasonable Person' and Suggested Reforms," *Journal of Corporation Law* 43, no. 1 (2017): 77-118, at 104 (juries seen as competent to make general negligence determinations because personal experience allows them to apply realistic judgments to situations they are familiar with).
12. See N. King, "The Reasonable Patient and the Healer," *Wake Forest Law Review* 50, no. 2 (2015): 343-361, at 346-347.

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13. J. Berg, P. Appelbaum, C. Lidz, and L. Parker, *Informed Consent: Legal Theory and Clinical Practice* (New York: Oxford University Press, 2d ed. 2001): 133.
14. *Id.* at 46-47.
15. *Id.* at 46-49.
16. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).
17. Berg et al., *Informed Consent*, *supra* note 13, at 49.
18. See Berg et al., *Informed Consent*, *supra* note 13, at 50; King, "The Reasonable Patient," *supra* note 12, at 351-352.
19. See King, "The Reasonable Patient," *supra* note 12, at 353-54 (important ethical implication of reasonable person standard is not its impact in lawsuits, which look at cases retrospectively, but how it shapes what clinicians disclose in their interactions with patients).
20. National Commission, *Belmont Report*, *supra* note 4, at 5.
21. *Id.* at 5-6.
22. *Id.* at 6.
23. R. Veatch, "Three Theories of Informed Consent: Philosophical Foundations and Policy Implications," *Appendix II: The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Bethesda MD: National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978): 29.
24. *Id.* at 32. The revised Common Rule's adoption of the reasonable person standard should not discourage researchers from supplying individual prospective subjects with the additional information they seek. Indeed, the Common Rule provision establishing the reasonable person standard directs researchers to give prospective subjects "an opportunity to discuss the study information" that is disclosed. Such discussions can open the door to additional questions from individuals with particular information needs. Federal Policy for the Protection of Human Subjects, 82 *Federal Register* 7149, 7265 (final rule, January 19, 2017).
25. The consent jury would be composed of nonscientists considering study information presented by "expert advocates" arguing for and against disclosure of each anticipated study risk. The jury would then decide which risks should be disclosed to prospective subjects. See R. Levine, "The Nature and Definition of Informed Consent in Various Research Settings," *Appendix II: The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Bethesda MD: National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978): 20-21.
26. This approach would involve assembling a group of laypersons with backgrounds similar to those of prospective subjects, presenting them with a hypothetical protocol resembling a specific proposed study, then interviewing them to elicit their comments and questions about the protocol. N. Fost, "A Surrogate System for Informed Consent," *JAMA* 233, no. 7 (1975): 800-803.
27. Veatch, "Three Theories of Informed Consent," *supra* note 23, at 30-31. See also R. Veatch, "Human Experimentation Committees: Professional or Representative?" *Hastings Center Report* 5, no. 5 (1975): 31-40.
28. L. Stark, *Behind Closed Doors: IRBs and the Making of Ethical Research* (Chicago: University of Chicago Press, 2012): 15.
29. *Id.*
30. *Id.* at 14. See also L. Odwazny and B. Berkman, "The 'Reasonable Person' Standard for Research Informed Consent," *American Journal of Bioethics* 17, no. 7 (2017): 49-51.
31. C. Lidz et al., "The Participation of Community Members on Medical IRBs," *Journal of Empirical Research on Human Research Ethics* 7, no. 1 (2012): 1-8, 6; S. Sengupta and B. Lo, "The Role and Experiences of Nonaffiliated and Non-Scientist Members of Institutional Review Boards," *Academic Medicine* 78, no. 2 (2003): 212-218.
32. A. Cook, H. Hoas, and J. Joyner, "The Protector and the Protected: What Regulators and Researchers Can Learn from IRB Members and Subjects," *Narrative Inquiry in Bioethics* 3, no. 1 (2013): 51-65, 60.
33. R. Dresser, "Personal Knowledge and Study Participation," *Journal of Medical Ethics* 40, no. 7 (2014): 471-474.
34. *Id.* See also E. Anderson, "A Qualitative Study of Non-Affiliated, Non-Scientist Institutional Review Board Members," *Accountability in Research* 13, no. 2 (2006): 135-151.
35. The controversy over the SUPPORT study is an example of problems with the existing approach to ascertaining what prospective subjects would want to know. Much of the debate involved researchers and bioethicists voicing competing claims about the risks that should have been disclosed to parents considering study participation. The claims relied on experts' assumptions about what should be disclosed to parents, rather than on information about what parents in similar situations would want to know. See B. Furlow, "SUPPORT Controversy's Lessons for Informed Consent," *Lancet Respiratory Medicine* 3, no. 12 (2015): 928-929.
36. Gearhart, "Reasonable Person," *supra* note 2, at 3. See also J. Greenblum and R. Hubbard, "The Common Rule's 'Reasonable Person' Standard for Informed Consent," *Bioethics* 33, no. 2 (2019): 274-277; J. Sugarman, "Examining Provisions Related to Consent in the Revised Common Rule," *American Journal of Bioethics* 17, no. 7 (2017): 22-26.
37. Rose, "'Reasonable Investor' of Federal Securities Law," *supra* note 11, at 103.
38. Berg et al., *Informed* Consent, *supra* note 13, at 49.
39. Odwazny and Berkman, "'Reasonable Person' Standard for Research," *supra* note 30, at 50.
40. See H. Lynch, E. Largent, and D. Zarin, "Reaping the Bounty of Publicly Available Clinical Trial Consent Forms, *IRB: Ethics & Human Research* 39, no. 6 (2017): 10-15; C. Coleman, "Rationalizing Risk Assessment in Human Subject Research," *Arizona Law Review* 46, no. 1 (2004): 1-51.
41. Federal Policy for the Protection of Human Subjects, 82 *Federal Register* 7149, 7267 (final rule, January 19, 2017). See also Greenblum and Hubbard, *supra* note 36, at 4 (new regulatory requirement for centralized single IRBs will increase IRB members' awareness of other institutions' consent forms and guidelines).
42. See for example Ben-Shahart and Porat, "Personalizing Negligence Law," *supra* note 10 (courts considering negligence should be permitted to "subjectify" the standard of care, based on information available through advanced information tools).
43. See A. Porat and L. Strahilevitz, "Personalizing Default Rules and Disclosure with Big Data," *Michigan Law Review* 112, no. 8 (2014): 1417-1478.
44. A. MacLean, "Giving the Reasonable Patient a Voice: Information Disclosure and the Relevance of Empirical Evidence," *Medical Law International* 7, no. 1 (2005): 1-40. See also B. Main, A. McNair, and J. Blazeby, "Informed Consent and the Reasonable-Patient Standard," *Journal of the American Medical Association* 316, no. 9 (2016): 952-953.
45. R. Kost et al., "Assessing Research Participants' Perceptions of Their Research Experiences," *Clinical and Translational Science* 4, no. 6 (2011): 403-413, 409.
46. R. Dresser, *Silent Partners: Human Subjects and Research Ethics* (Oxford: Oxford University Press, 2017).
47. A. Wertheimer, "Non-Completion and Informed Consent," *Journal of Medical Ethics* 49, no. 2 (2014): 127-130.
48. Cook et al., "Protector and Protected," *supra* note 32, at 61.
49. A. Motluk, "Diary of a Lab Rat," *New Scientist* 196, no. 2633 (2007): 38-41; K. Cox, "Enhancing Cancer Clinical Trial Management: Recommendations from a Qualitative Study of Trial Participants' Experiences," *Psycho-Oncology* 9, no. 4 (2000): 314-322.
50. A. Cook and H. Hoas, "Trading Places: What the Research Participant Can Tell the Investigator about Informed Consent," *Journal of Clinical and Research Bioethics* 2, no. 8 (2011): 1-7, 5.
51. C. Behrendt et al., "What Do Our Patients Understand about Their Trial Participation? Assessing Patients' Understanding of Their Informed Consent Consultation about Randomized

The Journal of Law, Medicine & Ethics, 47 (2019): 194–202.

Clinical Trials," *Journal of Medical Ethics* 37, no. 2 (2011): 74-80, at 78.

52. See M. Eder et al., "Improving Informed Consent: Suggestions from Parents of Children with Leukemia," *Pediatrics* 119, no. 4 (2007): e849-59; Y. Unguro, A. Sill, and N. Kamini, "Experiences of Children Enrolled in Pediatric Oncology Research: Implications for Assent," *Pediatrics* 125, no. 4 (2010): e876-83.

53. For more on this topic, see Dresser, *Silent Partners*, *supra* note 46; R. Dresser, "Research Information for Reasonable People," *Hastings Center Report* 48, no. 6 (2018): 3-4; R. Dresser, "Experimentation without Representation," *IRB: Ethics & Human Research* 40, no. 4 (2018): 3-7.

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