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Jake Greenblum
The University of Texas Rio Grande Valley

Ryan K. Hubbard

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The Common Rule's "Reasonable Person" Standard for Informed Consent

By Jake Greenblum and Ryan Hubbard

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Abstract

Laura Odwazny and Benjamin Berkman have raised several challenges regarding the new reasonable person standard in the revised Common Rule, which states that informed consent requires potential research subjects be provided with information a reasonable person would want to know to make an informed decision on whether to participation in a study. Our aim is to offer a response to the challenges Odwazny and Berkman's raise, which include the need for a reasonable person standard that can be applied consistently across IRBs and that doesn't stigmatize marginal groups. In response, we argue that the standard ought to be based in an Ordinary rather than Ideal Person conception of reasonable person and that the standard ought to employ what we call a Liberal Constraint: the reasonability standard must be malleable enough such that a wide variety of individuals with different, unique value systems would endorse it. We conclude by suggesting some of the likely consequences our view would have, if adopted.

Introduction

The revised Common Rule includes a new provision requiring that prospective research subjects or their legally authorized representatives "be provided with the

information that a reasonable person would want to have in order to make an informed decision about whether to participate" in research. [1] In a recent paper, Laura Odwazny and Benjamin Berkman raise several challenges about how to understand this new reasonable person standard.[2] Here, we will discuss Odwazny and Berkman's challenges before attempting to gesture towards a response. Our response provides several necessary conditions placed on the reasonable person standard. It is not meant to account for all necessary, let alone sufficient, conditions. We conclude by suggesting some of the likely consequences our view would have, if adopted.

We should note that while the revised rule is part of US federal law, our view is likely to interest non-American readers. As we argue in the closing section, this is because implementing our view would help yield more credible research results, which should interest Americans and non-Americans alike.

Section One

Reasonable person standards have long been prominent features of the U.S. judicial system, and indeed are already referenced in the previous version of the Common Rule. But the older references to reasonability implicitly concern institutional review board (IRB) committee members or researchers (e.g., a reasonable risk/benefit ratio), not research subjects. And this represents a challenge, for "it appears that an IRB's

[1] Code of Federal Regulations. (2017) *Federal Register* Volume 82, Number 12. Title 45, Part 46. U.S. Federal Policy for the Protection of Human Subjects.

[2] Odwazny, Laura M., & Benjamin E. Berkman. (2017). The 'Reasonable Person' Standard for Research Informed Consent. *The American Journal of Bioethics* (7): 49.

experience with the current Common Rule reasonableness assessments will not be clearly translatable to application of a reasonable person disclosure for informed consent."[3]

A related challenge concerns implementing the new reasonable person standard. Unlike a jury system – which employs the reasonableness standard within certain constraints, such as judicial precedent that allows for a shared understanding of the reasonable person in a given case – IRBs don't share previous decisions with one another. This means that each IRB is free to determine the reasonable person standard for themselves. Thus, not only will the standard fail to be consistently applied, the standard is unlikely to meaningfully exist in the first place.[4]

Another concern is that the new reasonability requirement will work to convey negative social statements towards marginalized groups. As Odwazny and Berkman put it: "It could send an unintentionally pejorative message to groups with nonstandard views."[5] For instance, if a minority group wishes to protect its members by asking for more detailed than average disclosures in the informed consent process, the minority group could be deemed unreasonable, a designation that is likely to further stigmatize the group.

Finally, Odwazny and Berkman ask who will be responsible for evaluating whether the reasonable person standard has been met. Since IRBs are typically composed of highly educated persons like researchers, it's not obvious that IRBs are best suited to perform this evaluation. Instead of entire IRBs, Odwazny and Berkman raise the

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[3] Odwazny & Berkman, op. cit. note. 2, p. 50.

[4] Ibid: 50.

[5] Ibid: 50.

possibility of singular IRBs' community members serving as the evaluators, but they worry that "placing that responsibility on a single person (who might or might not have actual experience relevant to the research under review) increases the chances of the review process being unduly influenced by idiosyncratic views."[6]

Section Two

In this section, we respond to Odwazny and Berkman's challenges. To begin, it is worth mentioning that Odwazny and Berkman's first two concerns are related. Indeed, consistency is all the more difficult to realize (the second challenge) since previous reasonableness assessments are not translatable to the new reasonable person standard (the first challenge).

To address these two challenges, any plausible reasonability standard for research subjects must be substantive enough to be consistently applied across IRBs. To help ensure that the new reasonability requirement is sufficiently substantive, it is first necessary to distinguish between two different conceptions of reasonability. According to the Ideal Conception of reasonability, what is reasonable is determined by reference to the ideal person. Presumably, this person would be maximally prudent (i.e., rational) and virtuous (i.e., able to maximally follow moral imperatives). By contrast, according to the Ordinary Person conception of reasonability, reasonability is determined by reference to

[6] Ibid: 50.

the behavior or perspective of ordinary persons, i.e, to persons with typical prudential and moral limitations.[7]

We think the Ordinary Person conception of reasonability is preferable. To see why though, we must first reply to Odwazny and Berkman's challenge concerning marginalization. Recall that for Odwazny and Berkman, the new reasonability requirement is likely to further increase marginalization, at least for certain already stigmatized groups since the new requirement may lead IRBs to characterize these groups as unreasonable. To address this worry, we propose what we call the *liberal constraint*: the reasonability standard must be malleable enough such that a wide variety of individuals with different, unique value systems would endorse it. This constraint is *liberal* in the sense that it functions to accommodate divergent conceptions of the good life. Obviously, some groups – like radical scientific skeptics – nevertheless may still be deemed unreasonable even according to the liberal constraint.[8] But in practice we think it

[7] See Collins, Ronald KL. (1976). Language, History and the Legal Process: A profile of the Reasonable Man. *Rutgers-Cam LJ* 8:311; Reynolds Jr, Osborne M. (1970). The Reasonable Man of Negligence Law: A Health Report on the Odious Creature. *Oklahoma Law Review*. 23: 410; and Scalet, Steven P. (2003). Fitting the People they are Meant to Serve: Reasonable Persons in the American Legal System. *Law & Philosophy* 22 (1) (01): 75-110. for a discussion of these two conceptions.

[8] The liberal constraint, as we imagine it, is not completely analogous to the Rawlsian idea that reasonable persons must endorse moral pluralism, the burdens of judgment, and the like. Our liberal constraint clearly draws upon Rawls's idea of reasonability, but is weaker than Rawls's in that it does not require subjects to engage in the kind of internal

will be far easier to meet the liberal constraint in most circumstances, since most people accept basic rules of inference and basic moral norms, such as anti-discrimination norms, and the obligations to respect autonomy and promote well-being.

The liberal constraint recommends the Ordinary Person conception of reasonability over the Ideal conception. This is because it provides a reason to prefer the Ordinary Person conception insofar as persons with different life plans are far more likely to converge on an interpretation of the Ordinary Person conception. This is the case because the Ideal Person conception does not lend itself to the liberal constraint, for whatever counts as ideal, under the Ideal conception, will likely rely heavily on values and principles that many reject. Part of the worry here is that an Ideal conception would import the particular value system and form of the good life held by those developing the ideal. This is not so with the Ordinary Person conception. Indeed, most of us think that ordinary people are marked by their common properties, like common intelligence and the fact that they do not all agree about what the true or correct life plan is. Thus, the liberal constraint supports the Ordinary Person conception of reasonability. We are now in a position to consider what a substantive conception of the reasonable person would look like and what ought to be disclosed given this conception.

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division of labor between their public and private moralities, let alone require them to embrace the notion of moral pluralism.

Any reasonable person standard should include a description of rational and moral capacities.[9] Given our Ordinary Person conception, we suggest that characteristics of rational capacity relative to the context of research subjects are given by generic standards of decision-making competency. These include the following abilities: ability to evidence choice, ability to understand relevant information, ability to appreciate the situation and its likely consequences, and the ability to manipulate information rationally.[10] Relevant characteristics of moral capacity include – but are not limited to – having a set of reasonable ethical values that inform one's life plan as well as the desire to act in accordance with these values. [11]

[9] See Sibley,W.M. (1953). The Rational versus the Reasonable. *The Philosophical Review* (4): 554; and Rawls, John. (1999). *Collected Papers* Harvard University Press, pg. 445

[10] See Appelbaum, Paul S., & Thomas Grisson. (1988). Assessing Patients' Capacities to Consent to Treatment. *The New England Journal of Medicine* (25): 1635; and Leo, Raphael J. (1999). Competency and the Capacity to Make Treatment Decisions: A Primer for Primary Care Physicians. *Primary Care Companion to the Journal of Clinical Psychiatry* 1 (5) (10): 131-41.

[11] Note, even though we agree with the requirement that subjects be provided with information that a reasonable person would wish to know, it does not follow that unreasonable subjects should be excluded from research, for the role of the reasonable person standard principally functions as a model of what information to provide subjects. It does not entail excluding unreasonable subjects, nor do we endorse such exclusion.

Moreover, since group identity is partially constituted by a set of values, these value sets will differ among subjects belonging to various groups. The Liberal Constraint accommodates this fact and recommends that information be provided that the subject would deem particularly significant considering her value set and would be expected to influence her decision on whether to participate in the study. Thus, information that ought to be provided may differ between subjects depending on what they deem significant. As T. M. Wilkinson notes, information regarding the researcher's views and sponsors may be relevant in this regard.[12] For example, it would be expected that a Jewish subject would want to know if the researcher or sponsors hold anti-Semitic views.

One worry here is that not all such relevant information should be provided. For example, a staunch supporter of a political party may want to know if the researcher is a member of an opposing party. While this information may influence the subject's decision and is significant regarding her values, disclosing it would be unjustified. Providing a full account of how to judge which information would be inappropriate to disclose is beyond the scope of this paper.[13] But as a preliminary response: The point of informed consent is to respect a subject's autonomy, but there are other important values that ought to be balanced with autonomy, such as privacy and fairness. In cases like our staunch supporter, the researcher's privacy clearly outweighs the value of the subject's autonomy. Keeping the balance of values in mind helps to adjudicate between appropriate and inappropriate disclosures of information.

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[12] Wilkinson, T.M. (2001). Research, Informed Consent, and the Limits of Disclosure. *Bioethics* 15 (4)(08): 341-63 pg. 346

[13] See Wilkinson ibid. for a discussion of this issue.

To reiterate: our view is that because specifying a conception of the reasonable person requires both generic and non-generic elements, there can be multiple reasonable standards, each indexed to particular, socially salient groups. But what if a minority of members within a group desires to know information that the majority would rather remain free of knowing? Is providing this information reasonable or not? And if it is reasonable, is it reasonable to also inform the majority against their wishes?

To answer these questions, it is helpful to focus on the example of cochlear implants for deaf persons. Assume that most deaf persons, like the majority of non-deaf persons, view deafness as pathological. Moreover, assume that the majority of deaf persons would prefer to forgo hearing testimony during the informed consent process from deaf persons who reject the notion that deafness is pathological. Nevertheless, following Lauren Pass and Abraham Graber, we think the reasonable person (here indexed to deaf persons) "would attach significance to the fact than many of those who best understand what it is like to be deaf view deafness not as harm, but rather as an integral aspect of their identity."[14] Therefore, on our view, not only would it be required to inform the minority who wish access to this information, it would be incumbent to inform the majority who wish to remain ignorant as well. Reasonableness would demand it, and it would demand it based on the epistemic merit of persons most intimately familiar with deafness who also reject the commonly accepted pathological view. Our

[14] Pass, Lauren and Abraham Graber. (2015). Informed Consent, Deaf Culture, and Cochlear Implants. *The Journal of Clinical Ethics* (26): 219-30. Note, Pass and Graber's discussion of cochlear implants concerns the clinical setting, but we believe their comments apply to research as well.

point here generalizes: if the minority of a socially salient group wishes to know or not know something, then, depending on the relevant reasons in favor of their request, they, along with the majority, should be granted access to this information.

To close this section, we'll examine how our view addresses the concern about who will ensure that the reasonable person standard is met. Again, recall Odwazny and Berkman's worry: IRBs as a whole are not the best judges, since their makeup will likely be quite different from the Ordinary Person, and community members are unlikely to have the research experience needed to enable them to provide the relevant information an Ordinary Person would want in a principled manner.

In reply, we think that Odwazny and Berkman's skepticism about IRBs as a whole is well warranted, for exactly the reason they describe. But we are more optimistic about giving community members the most responsibility to ensure the reasonable person standard is met.[15] And this should come as no surprise, given our view of reasonability: Because the Ordinary Person standard directs our attention to ordinary, non-expert people, community members – as non-research specialists – are best suited to ensure ordinary persons' informed decision-making needs. [16] Moreover, were our view adopted

[15] We say the *most* responsibility because IRBs can and should have some responsibility to ensure the standard is met.

[16] An anonymous reviewer expressed the worry that community representatives may not always be able to identify the reasonable views of a small minority of a socially salient community, especially if there is wide disagreement among the community about what information should be provided. A full account of how best to implement our view is beyond the scope of this paper, but, as a tentative response we suggest that all potential

by IRBs and especially by IRBs' community members, it would provide some principled guidance about the reasonable person's content. This guidance would reduce the risk of community members' undue idiosyncratic influence.

Section Three

It is finally worth asking what the likely practical consequences of our Ordinary Person conception would be, if adopted by a majority of IRBs. First, unless a majority of IRBs have some mechanism in place to share how they actually implement this standard in particular studies, the standard is unlikely to have much impact at all. But there is reason for optimism here, since the single IRB requirement – the mandate that all NIH-funded studies must rely on a single IRB of record – is another component of the new Common Rule. And this centralization of the IRB process provides the impetus for the NIH to distribute informed consent documents and informed consent guidelines across at least the IRBs overseeing NIH-funded studies.

Second, IRBs that adopt our preferred Ordinary Person conception of reasonability subject to the liberal constraint are more likely to better facilitate subject

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participants be given the opportunity to request further information after they've received what the IRB determines is reasonable information. The IRB may decide there are reasons to reject the request for additional information, but they have the responsibility, particularly the community member, to take the request seriously and to provide reasons to the minority justifying the IRB's rejection. This would surely go some way towards ensuring that the small minority, whose views and values may not be represented, is respected.

comprehension over the Ideal Conception. Indeed, facilitating subject comprehension is one of the principal aims explicitly outlined in the Notice of Proposed Rule Making that Health and Human Services cited for the new reasonability standard.[17] Our interpretation of the reasonable person standard seems better suited to achieve this aim by directing IRBs to consider subjects as they are, not as they ideally should be.

Finally, implementing our view of reasonability is likely to make for better, more informative studies. This is because adequately informed subjects – especially in light of their values – are more likely, all else being equal, to have positive experiences participating in research, encouraging broader support for research participation. Ultimately, more research participants will yield more credible research results, something everyone has a strong interest in promoting. Thus, although the revised Common Rule is part of US law, our view is nevertheless relevant to non-American readers, since all countries have an interest promoting strong scientific research.

Conclusion

Odwazny and Berkman identify important concerns regarding the new Common Rule's reasonability standard. In this paper, we address those concerns by sketching what this standard ought to look like. Here, we suggest that the standard ought to employ a liberal constraint and be based on an Ordinary conception of reasonable person. We end

[17] Notice of Proposed Rulemaking for Revisions to the Common Rule. (2015). Federal Register Volume 80, Number 173. Retrieved March,22, 2018 from https://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf

by discussing what the likely consequences of our preferred interpretation of the standard would be, which include promoting subject comprehension and more informative studies.