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The Reasonable Person Standard:
A Critical Examination of a New Requirement for Informed Consent

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Abstract

The Reasonable Person Standard: A Critical Examination of a New Requirement for Informed Consent

By Shelby I. Rhee

Background: The 2017 revisions to the Federal Policy for the Protection of Human Subjects, often referred to as the Common Rule, will, for the first time, require investigators and Institutional Review Board (IRB) to design informed consent disclosures based on what a reasonable person would want to know before making the decision to participate in the study. This requirement, called the Reasonable Person Standard (RPS), is worthy of greater exploration now that it will be supported strong arm of federal enforceability and implemented on the scale the Common Rule will require.

Discussion: In this paper, the author examines the underlying principles, requirements, and processes of the RPS, tracing its history from its origins in the legal profession to its use in research and describes the potential challenges of implementing it under the 2018 Common Rule. These challenges include understanding the conceptual underpinnings of the standard and ensuring its consistent use by groups with different regulatory responsibilities. Ideally, implementing the RPS should shift the processes of research toward power sharing, empathy, and deep respect; ultimately humanizing the research enterprise. However, questions remain if these ethical goals will be realized.

Summary: Recognizing the potential challenges and harms that may arise in applying the RPS provides an avenue for investigators, IRB members and institutions to remedy them before they arise. Ultimately, the paper advocates for an increased emphasis on training implementing parties on the potential harms and provides a value proposition for integrating community engagement strategies into early stages of the design of the informed consent process.

Keywords:
Informed consent
Research ethics
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Chapter 1: Introduction and Background

Introduction

In 1991, the Department of Health and Human Services (DHHS) and 15 other United States government agencies instituted the Federal Policy for the Protection of Human Subjects, often referred to as the Common Rule. Though each agency codified these protections in separate regulations, all committed to abide by them. DHHS promulgated the Common Rule as Section 45 of the Code of Federal Regulations Part 46 part A, and included additional regulatory provisions for vulnerable groups including women, fetuses, prisoners, and children (Office of Human Research Protection, 2016). Since then, The Common Rule has governed all human subjects research conducted with federal funding and has become the de facto standard for ethical research worldwide.

For the past 25 years, the Common Rule was left largely unaltered while the research environment changed rapidly. Technologies unimaginable when the Common Rule was first written, such as those allowing full genome sequencing and the re-identification of de-identified bio-specimens, are now routinely used in research. Multi-site, collaborative research is both increasingly possible and increasingly complex. These issues awoke new privacy concerns for participants and new administrative headaches for institutions, Institutional Review Board (IRB) members, and investigators. Taking all this into account, the Common Rule implementing agencies began the process of updating the Common Rule to strengthen protections for participants in research and reduce administrative burdens on researchers and institutions, particularly those engaged in low-risk research.

After a five-year period of negotiation between rule makers, researchers, and public interest groups, the 16 Common Rule implementing agencies issued a Final Rule in January 2017. The full text of the Final Rule received mixed reviews. Some researchers argued that

the original goals articulated in the text of the Notice of Proposed Rulemaking released in 2011, such as increasing public trust in research generally and "enhancing respect and safeguards for research participants" were not likely to be met by the Final Rule, and encouraged greater attention to the Rule's failings (Goldstein, 2017). The partial elimination of continuing review for low-risk studies was generally favored to decrease the administrative burden on investigators and IRBs (Fernandez Lynch, Cohen, & Bierer, 2017; Menikoff, Kaneshiro, & Pritchard, 2017). However, opponents expressed concern about the decrease in regular oversight (O'Rourke, 2017). Discussions of both the Final Rule's role in protecting participants and questions about how it will be implemented still continue, and will until further guidance is received from DHHS (Sugarman, 2017).

The changes to the requirements for informed consent depart significantly from the original text. The Final Rule reiterates the primacy of informed consent and attempts to institutionalize an informed consent process that better prepares people to participate in research (Field-Fote, 2017; Hodge & Gostin, 2017). One new standard mandates that a researcher must provide an organized, concise presentation of key messages in the consent form, which was included to facilitate comprehension of both the consent form and the purpose of the research. The second change requires a specific device, The Reasonable Person Standard, be used to anticipate what a reasonable person might need to know before making their decision to participate in research. Critically examining this standard is the focus of this thesis.

The 2018 Common Rule, will, for the first time, *require* investigators and IRB members to consider what a reasonable person would want to know before agreeing to participate in a research study. The concept of the reasonable person is not new to informed consent for research, but its inclusion in enforceable regulation is "unprecedented in U.S.

federal human subjects protection regulations" (Odwazny & Berkman, 2017). Because the RPS is now required under the Common Rule, the underlying principles, requirements, and processes of this standard are worthy of greater exploration

Problem Statement

The Reasonable Person Standard is poorly explained by accompanying regulation, poorly understood by the parties charged with ensuring its proper application, and bound to cause implementation challenges for researchers, Institutional Review Board members, and those in charge of providing oversight to research programs.

Purpose Statement

The purpose of this thesis is to create a document critically examining The Reasonable Person Standard, discuss the biggest challenges investigators, Institutional Review Boards, and institutions may have in implementing the standard, and suggest further actions to minimize implementation challenges and possible harms to participants.

Chapter 2: Review of Literature

Informed Consent

Informed consent is the hallmark of ethical research. It exists within the research enterprise to promote protection for research subjects by requiring researchers to explain how participating in research may expose them to various risks of harm. The process is designed to allow prospective participants to decide for themselves whether they are willing to take on these risks. Obtaining informed consent from participants may in fact be the primary thing that makes research ethical (Capron, 2014). Informed consent works on both conceptual and practical levels to promote self-determination and autonomy, because it assumes that individuals are the best prepared to make the decisions about their own health and welfare (Brock, 2008). The consent process plays an important role for both investigators and participants, encouraging "rational decision-making" for participants and "self-scrutiny" for investigators (Brock, 2008). Practically, informed consent performs several different yet essential roles. It serves participants and institutions "as a means of respecting individual autonomy, protecting subjects' well-being, and achieving intelligent governance of research" (Capron, 2014).

Informed Consent Under the Common Rule

The principles of respect for persons, beneficence, and justice, first codified in the 1979 Belmont Report, provide the "intellectual backdrop" and moral underpinning for federal government protections (Hodge & Gostin, 2017). Each of the procedural requirements of the informed consent process under the Common Rule are built upon these moral principles. Respect for persons gave rise to the informed consent process itself, beneficence translates to requirement for balancing risks and benefits, and justice requires fair subject selection included in both the 1991 and 2018 versions of the Common Rule. The Rule lays out the requirements for informed consent clearly, many of which were crafted in response to gross

violations of the rights of human participants in research like the U.S. Public Health Service syphilis trials conducted on black share-croppers in Tuskegee, Alabama (Hodge & Gostin, 2017; Levine, 1986). The Common Rule was implemented with the goal of improving protections for participants in research, minimizing the possibility of further human rights violations, and standardizing the processes of ethical research conducted with federal funding. Additionally, informed consent benefits institutions by providing protection for researchers against liability for harm (Bierer, Barnes, & Fernandez Lynch, 2017; Hodge & Gostin, 2017).

In practice, informed consent boils down to three parts: the disclosure of materially relevant information to the prospective study participant, comprehension of that information, and a participant's willingness to participate in the research (Capron, 2008). Research ethicists give them slightly different names, information, voluntariness, and competence to make the decision, but they play out the same way (Brock, 2008). Competence is a pre-condition of informed consent, as it is necessary for autonomy in choice about whether participating in research is in a participant's interests (Brock, 2008). When a is person unable to make decisions about what is in their interests based on age or compromised decisional capacity, the ability to give consent can become a thornier issue. The Common Rule allows for a legally authorized representative to make the decision about participation, though this is not allowed in all circumstances.

Disclosure

Disclosure pertains to the type of information that must be given to participants by investigators. Generally, this includes information about the potential risks and benefits of involvement, the purpose of the research and how it will be conducted, as well as other "relevant" information (Brock, 2008). What is relevant may depend on the research study,

population, and other factors, particularly the things that matter to potential subjects. The Common Rule strictly governs what information must be disclosed to participants during the consent process. The Final Rule lists nine required "basic" elements that must be included in every consent form, and nine additional elements that must be included when appropriate (45 CFR 46.116). This includes information about the purpose and procedures of the study, the risks and benefits the participant may experience, alternatives to participation, the level of confidentiality the participant can expect from the researchers, whether or not there is the possibility of greater than minimal risk to the participant, that all participation is voluntary, whether or not the research will involve identifiable information or bio-specimens, and contact information for a member of the research team in case of questions (45 CFR 46.116).

Comprehension and Voluntariness

The next requirement for informed consent is comprehension. Giving participants a list of information means nothing if that person is unable to understand it. Research consistently finds that comprehension is low among participants in research, even after they have signed meticulously crafted consent forms (Falagas, Korbila, Giannopoulou, Kondilis, & Peppas, 2009; Lo & Barnes, 2016; Lorell, Mikita, Anderson, Hallinan, & Forrest, 2015). Promoting comprehension is consistently lauded as the primary way to increase protection. Proposed solutions to this problem include ever more complex methods of ensuring understanding, like comprehension quizzes and multimedia consent processes.

Opponents argue that complete comprehension, at least in the sense of a participant being able to regurgitate the list of disclosures, is not necessary to achieve an ethical level of protection for participants as long as other forms of protection and oversight are present (Sreenivasan, 2003). This includes a review by the IRB and a participant's free decision not to participate. However, gaps in comprehension about the purpose of research like the

therapeutic misconception, where a participant is unable to "appreciate the difference between research and treatment" (Henderson et al., 2007), are not only possible but also well-documented in clinical research. Research ethicist Gopal Sreenivasan argues that if perfect comprehension is required for an ethical consent process, any participant with the therapeutic misconception is unfit to participate. He argues that the modern obsession with comprehension disadvantages the research enterprise because enforcing the exclusion of any participant on this basis "would bring enrollment in many valuable and otherwise ethical clinical trials near to a halt" (Sreenivasan, 2005). He proposes that researchers should take "reasonable steps" like writing in "clear, non-technical language, at an appropriate reading level, in the prospective participant's mother tongue; providing opportunities to ask questions throughout the trial; and using short consent forms" to achieve a sufficient baseline of comprehension (Sreenivasan, 2003). Beyond that, voluntariness should be the primary consideration.

Voluntariness is at the core of the logic of legal doctrine of informed consent, and should not be distorted or displaced to by the current fixation on comprehension. As mentioned above, participants must know and agree to the procedures of the study, but full and complete comprehension of the study may not be necessary to freely, ethically agree to join the project (Sreenivasan, 2003). A participant may not fully understand the minutiae, but can still give valid consent. Researchers are responsible for ensuring that consent to join the study is freely given, not obtained through coercion or undue influence. Outright coercion, such as an implicit or explicit threat that they will be made worse off if they don't participate is "no doubt rare" (Brock, 2008). More commonly, voluntariness is undermined by undue influence, such as offering outsized incentives or conducting research among populations where the researcher has near total control.

The Reasonable Person Standard

The Final Rule introduces the reasonable person in the Common Rule using the following language: investigators must provide "the information that a reasonable person would want to have in order to make an informed decision about whether to participate" and the opportunity to discuss that information (45 CFR 46 .116(a)(4)). This is the first time such language exists in the U.S. Federal Regulatory scheme. It is important to note that while the 2017 Final Rule enshrines the RPS in federal regulation for the first time, the concept of the reasonable person has a long history in the legal profession, where it is used as a comparative standard to determine the appropriateness of an individual's action or to determine liability for harm.

The Reasonable Person in Law, Medicine, and Research

The legal standard of the reasonable person can be traced back to 1837. From its inception, the reasonable man of "ordinary prudence" has served as a "personification of a community ideal of reasonable behavior, determined by the jury's social judgment" (Peterson, 1999). Consideration of the reasonable person has been used in tort, criminal, discrimination, and sexual harassment lawsuits. It is applied primarily to render judgement over an individual's actions, based on what an imagined reasonable person would do in the given circumstances. It is important to remember that the reasonable person does not refer to a specific individual. Instead, s/he is a depersonalized figure that seeks to strike a balance between objectivity— "some fixed dimension"—and subjectivity— an individual's "particular qualities and attributes"—to judge what is appropriate in a given situation (Moran, 2010). While its wide application may lead the uninitiated to believe that the reasonable person standard is well-defined and universal, the truth is that, as a test, the reasonable person "is characterized by a lack of clarity about the exact nature of the subjective and objective characteristics" (Moran, 2010). Thus, the standard is highly contextually dependent.

Clinical medicine also brings insight into the application of the reasonable person. Unlike its legal test, the reasonable person is used in medicine as a prospective step in the informed consent process rather than a retrospective judgement about behavior. A clinician may consider a "reasonable patient" when deciding what information is materially relevant to present about a procedure that would help a patient make the right decision for their own care. Because some clinical research feels familiar, like a doctor visit, clinicians may have more of a sense of what kinds of information are likely to be pertinent to the decision to participate in research. This is not a perfect analogue, especially in light of the therapeutic misconception. Most patients do not understand what they want or even need from a clinical encounter, much like most research participants understand little about what want or need out of participating in a research study. Considering physician- patient counseling, then, gives some insight into what might be considered reasonable when building a consent form, but still carries risks of harm from a basic misunderstanding between experts and non-expert.

In research, the ultimate goal of using the RPS is to guide decision-making about which information investigators need to disclose in the consent form. Imagining what a reasonable participant would want to know before joining a study should lead investigators to an appropriate level of disclosure about the procedures, risks, and benefits of the study. In practice, using the RPS should follow this procedure. When designing the consent processes, a research team will have to make assumptions about what a prospective participant in their project would want or need to know to make an informed decision about joining the study. These assumptions could be informed by anything—the investigators previous work, primary or secondary information the researcher has on the population, etc. These assumptions may have nothing to do with the participants' circumstances or interests, but may fundamentally form the language of the consent document. After the protocol is submitted, it will come before the IRB. The reviewers, then, may take one of two paths. First, they may trust the

writer's assumptions and approve the proposal, or, second, they may interrogate the consent form more deeply, questioning why the investigators believe a reasonable person would need that information specifically. At that point, the research team may amend the content of the form with or without any meaningful contribution from the prospective participants themselves. Thus, the success of the entire process hinges on several levels trust in how well the researchers understands the needs of their subject population.

Using the reasonable person standard, then, can theoretically provide increased protection for participants by improving the understanding between researchers and subjects. Research ethicist Robert Levine, one of the writers of the Belmont Report, was advocating for the reasonable person standard as the determinant of the minimum amount of information that a researcher should provide to a research participant as early as the writing of the Belmont Report. After meeting the reasonable person standard as a baseline, investigators would engage in a "consent negotiation" to determine what more a participant would want to know before deciding to join the study (Levine, 1986). Robert Veatch, another famous research ethicist, advocated for disclosing more than a reasonable person might require if an individual participant requires more information in order to exercise their own self-determination (Veatch qtd. in Odwazny & Berkman, 2017). In each case, the reasonableness of a participant is highly relied upon to determine whether information should be disclosed. Determining what is reasonable, however, requires discernment and a thorough knowledge of the prospective participant. Scholars affirm the value of reasonableness, but questions remain about how the baseline should be met.

Gaps in Research

Tracing its history shows that the reasonable person standard has been used in research before. However, it has never been used on the scale the Common Rule will require,

or with the strong arm of federal enforceability. There is very little evidence tracking the use of the Reasonable Person Standard by research institutions. A thorough search of multiple public health and medical databases revealed only one commentary paper and no research on this topic. Thus, it is important to dive deeply into the what instituting the RPS will mean for institutions, investigators, and IRBs who play a vital role in protecting participants and reducing the potential harms of misusing this standard.

Chapter 3: Methods

This project was inspired by the Common Rule Implementation and Informed Consent Workgroups at the Centers for Disease Control and Prevention. These workgroups were commissioned by CDC's Human Research Protections Office to identify the agency's top implementation priorities after the Final Rule was released. One meeting of this group focused deliberating the new standards for informed consent, including the Reasonable Person Standard. It was determined that the general level of knowledge about this concept was low and a deeper analysis would be valuable.

I analyzed the language of 45 CFR 46, where the Reasonable Person Standard is codified in the regulatory text. Then I performed a thorough review of the literature in both the legal and research ethics traditions, utilizing databases such as JSTOR, CINAHL, PubMed, and SCOPUS. These sources were instrumental to exploring the evolution of understanding of the reasonable person. However, this wide search revealed little previous research on this topic, and only one short commentary examining the RPS in light of the Common Rule revisions. Based on this analysis, I identified potential implementation challenges and harms from poorly applying the Reasonable Person Standard, and made suggestions for how institutions can minimize some of these harms by integrating community engagement strategies in the early stages of a study and creating RPS-specific training for IRB members that can be added as a supplement to informed consent trainings currently offered by implementing institutions.

Chapter 4: Conclusions and Implications for Global Health

A major force behind the revision of the Common Rule was to better protect participants in research. As the field of global health relies heavily on research to inform its practice, understanding the problem of the RPS is vitally important. Changing informed consent requirements, including the addition of the RPS, is an important step. Significant power imbalances exist within individual research studies and the larger field— between investigator and participant, funding organizations and research teams, and researchers and IRB members, and even investigators from different research methods and paradigms (Edwards, 2013; Giampapa, 2011; Lunde, Heggen, & Strand, 2013). This is especially problematic in some global health research. Relying on these changes alone, however, will ultimately fail because they pay no explicit attention to remedying those power dynamics. In fact, over-reliance on a single standard may even exacerbate these problems. This has great implications for public health research.

In their role as experts, investigators must wield their power appropriately and respectfully in order to reduce the possibility of harm to participants. This cannot be an empty ethical goal. The distinct challenge in applying the RPS is the seduction of the standard. In short, this would be defaulting to what investigators find reasonable and then believing that because *a* reasonable person standard has been met that the requirement was fulfilled. If an investigator bases the consent form disclosures on what they themselves would reasonably expect to be told, they may be committing to a far lower bar of disclosure, or to one that pays insufficient attention to the interests and circumstances of the prospective participants. IRB members may compound the problem by making the same error. Both parties can affirmatively answer the question, *is this reasonable?* However, this is neither the point nor purpose of the RPS. Allowing a generic standard to prevail reaffirms a deeply

ingrained hierarchy where participants are afforded the least authority to determine the reasonableness of informed consent disclosures. All the while, researchers and IRB members believe they have increased protections for participants because they asked themselves about reasonableness. This changes nothing and undermines the work that went into changing the Common Rule. To avoid falling for the seduction, investigators can use many tools. There is an increased focus on qualitative and community-based participatory action research (CBPAR), particularly in the field of public health. These methods are being used to better understand and protect the needs of participants and communities during the research process. Instituting a few principles from community engagement during the implementation of the RPS will help improve the researcher/ participant relationship and decrease the likelihood of unintended harms.

Communities are an essential part of public health systems and research (South & Phillips, 2014). Community engagement (CE) is a blanket term used to refer to a range of practices researchers employ to build, maintain, and strengthen relationships with participants in research and public health interventions. CE focuses on eliciting what is important to stakeholders in research projects, with a specific aim of understanding the complex relationships among competing priorities, potentially mutually incompatible goals, and non-obvious desires that make up a person's interests. Utilizing the tools of CE like community advisory boards, public meetings, and informant interviews can strengthen the individual consent process by virtue of its broader understanding of individuals as parts of communities. Having at least a baseline knowledge of the scope of participants' interests is vital to appropriately understanding what is reasonable to a person or population. There is no better way to determine what a reasonable member of a community would do in given situation than to ask. An investigator can fulfil the requirements of the RPS by translating a community's actual beliefs into those of the standard's reasonable person. The only way to

do this is in some form of relationship with members of the community (King, Kolopack, Merritt, & Lavery, 2014).

How will this work? Before writing a consent form, a research team should form relationships with the potential participant community and set up some system for soliciting their interests. This should continue at least until non-obvious interests have been identified among the participants. Prospective participants may refuse to join an experimental drug trial out of fear that the packaging of the medication they bring home may link them to having a stigmatized disease. Researchers can then ensure that the method of dispensing treatment will not expose the participant's condition to household members. Solving this problem benefits both the study and the participants. More generally, involving CE strategies will allow investigators will see trends that will help understand what a reasonable person in that community would want to know about a study. Once interests are known, it is nearly impossible to default to a generic standard. Further along in the process, IRBs will read the consent form and protocol and recognize that investigators are not defaulting to the standard disclosures because they have specific knowledge of the participant community.

This is far from the first time that integrating CE into consent processes has been proposed. There is a long history of discussion about who is best qualified to write ethical consent forms and the correct parties to make judgements about the quality of the consent process. Robert Levine, co-writer of the original Common Rule, believed that the individuals who generally serve on IRBs were not the best people to make the decision. He favored a system of surrogacy, whereby a member of the research population unable to participate in the study would review the consent form and examine whether or not the disclosures were reasonable. Finding this surrogate may be difficult, but it is important not to let challenges get in the way of accomplishing the ethical goals set forth in the Final Rule.

A second suggestion is for institutions to create additional training opportunities for their staff focused solely on the reasonable person. This could be added to the informed consent training required for investigators and IRB members before they are allowed to engage in research. Intermittent training is already required for investigators and researchers, but this is an especially good time to reacquaint investigators, researchers, and others with the basics of informed consent while introducing the new standards. This is an excellent opportunity for institutions to communicate what will be expected from investigators and IRB members in regards to the Reasonable Person. Because no further guidance on using the standard has been released by the Common Rule agencies, institutions are grappling with how to use RPS more or less by themselves. For example, CDC, in its trainings on informed consent under the Final Rule, is advising its researchers to show consideration of the RPS by conducting primary or secondary research on their subject population to determine what are reasonable disclosures. IRB members are being taught to ask specifically what investigators knew about subject population that led them to the consent form disclosures. Understanding and practice are necessary for the RPS to take root in institutions. Beginning now with training can only help change the research environment for the better.

Thoughtfully applying the Reasonable Person Standard carries promise and great power. In the right hands, it can guide researchers to a better understanding of the interests and needs of participants, to fulfill the ethical goals of the Final Rule, and reduce unintended harms to participants from the research enterprise. In order for its potential to be realized, however, the RPS must be understood and used consistently by all implementing parties. There will be challenges ahead, but approaching these challenges with sincerity, openness, and a determination to better understand those willing to accept personal risk for benefit of others can fundamentally reorient our understanding of research. Human subjects research, as an industry, is a multi-billion-dollar enterprise that touches nearly every person on the planet.

Adopting the RPS is hopefully a first step in allowing that process to be disrupted by the radical notion of an empathetic, humanized research system that works better for everyone.

Implementing the RPS will not carry much financial cost in itself and the rewards of doing so will be vast. Applying the standard does not require expensive new equipment or specialized knowledge. However, integrating the standard into everyday practice will have some cost associated. Institutions will need to invest in new training for investigators and IRB members, and there may be additional costs to the research project to instate in increased community engagement activities. However, all of these costs are worthwhile, as they will improve the field of research as a whole, proving that institutions and investigators understand and respect the contributions of volunteer participants in research without whom, the industry would collapse. Additionally, the Common Rule is the de facto standard for research worldwide, thoughtfully implementing the Reasonable Person Standard could have far-reaching effects globally. Considering the Reasonable Person can be especially helpful in promoting ethical research in global health and present an additional value proposition for integrating CE into global health research and practice.

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Appendix 1: *The Reasonable Person Standard: A Critical Examination of a New Requirement for Informed Consent* Project Document

A Critical Examination of a New Requirement for Informed Consent

THE REASONABLE PERSON STANDARD

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The purpose of this thesis is to critically examine The Reasonable Person Standard. This standard, used predominantly in legal contexts for most of its history, will be newly required by the revisions to the Common Rule in January 2017. Part I will introduce the changes to the Common Rule that introduce the Reasonable Person Standard (RPS), before exploring the larger context of informed consent for human subjects research to explain how the inclusion of the RPS in enforceable regulation represents a new procedure for designing consent processes. Part II will follow with an explanation of the challenges investigators, Institutional Review Board (IRB) members, and institutions may experience when implementing the RPS. Part III concludes the thesis with suggestions to aid in realizing the goal of implementing the RPS, which is an increased understanding of the needs of participants.

Part I: Introduction and Background

In 1991, the Department of Health and Human Services (DHHS) and 15 other United States government agencies instituted the Federal Policy for the Protection of Human Subjects, often referred to as the Common Rule. Though each agency codified these protections in separate regulations, all committed to abide by them. DHHS promulgated the Common Rule as Section 45 of the Code of Federal Regulations Part 46 part A, and included additional regulatory provisions for vulnerable groups including women, fetuses, prisoners, and children (Office of Human Research Protection, 2016). Since then, the Common Rule has governed all human subjects research conducted with federal funding and has become the de facto standard for ethical research worldwide.

For the past 25 years, the Common Rule was left largely unaltered while the research environment changed rapidly. Technologies unimaginable when the Common Rule was first written, such as those allowing full genome sequencing and the re-identification of de-identified bio-specimens, are now routinely used in research. Multi-site, collaborative research is both increasingly possible and increasingly complex. These issues awoke new privacy concerns for participants and new administrative headaches for institutions, Institutional Review Board (IRB) members, and investigators. Taking all this into account, the Common Rule implementing agencies began the process of updating the Common Rule to strengthen protections for participants in research and reduce administrative burdens on researchers and institutions, particularly those engaged in low-risk research.

After a five-year period of negotiation between rule makers, researchers, and public interest groups, the 16 Common Rule implementing agencies issued a Final Rule in January 2017. The full text of the Final Rule received mixed reviews. Some researchers argued that the original goals articulated in the text of the Notice of Proposed Rulemaking released in 2011, such as increasing public trust in research generally and "enhancing respect and safeguards for research participants" were not likely to be met by the Final Rule, and encouraged greater attention to the Rule's failings (Goldstein, 2017). The partial elimination of continuing review for low-risk studies was generally favored to decrease the administrative burden on investigators and IRBs (Fernandez Lynch, Cohen, & Bierer, 2017; Menikoff, Kaneshiro, & Pritchard, 2017). However, opponents expressed concern about the decrease in regular oversight (O'Rourke, 2017). Discussions of both the Final Rule's role in protecting participants and questions about how it will be implemented still continue, and will until further guidance is received from DHHS (Sugarman, 2017).

The changes to the requirements for informed consent depart significantly from the original text. The Final Rule reiterates the primacy of informed consent and attempts to institutionalize an informed consent process that better prepares people to participate in research (Field-Fote, 2017; Hodge & Gostin, 2017). One new standard mandates that a researcher must provide an organized, concise presentation of key messages in the consent form, which was included to facilitate comprehension of both the consent form and the purpose of the research. The second change requires a specific device, The Reasonable Person Standard, be used to anticipate what a reasonable person might need to know before making their decision to participate in research. Critically examining this standard is the focus of this paper.

The 2018 Common Rule, will, for the first time, *require* investigators and IRB members to consider what a reasonable person would want to know before agreeing to participate in a research study. The concept of the reasonable person is not new to informed consent for research, but its inclusion in enforceable regulation is "unprecedented in U.S. federal human subjects protection regulations" (Odwazny & Berkman, 2017). Because the RPS is now required under the Common Rule, the underlying principles, requirements, and processes of this standard are worthy of greater exploration. In order to determine and enforce the "how" of informed consent, it is necessary to understand "why." The next section will first describe the goals and procedures of informed consent as a concept before further describing the RPS itself.

Informed Consent

Informed consent is the hallmark of ethical research. It exists within the research enterprise to promote protection for research subjects by requiring researchers to explain how participating in research may expose them to various risks of harm. The process is designed to allow prospective participants to decide for themselves whether they are willing to take on these

risks. Obtaining informed consent from participants may in fact be the primary thing that makes research ethical (Capron, 2014). Informed consent works on both conceptual and practical levels to promote self-determination and autonomy, because it assumes that individuals are the best prepared to make the decisions about their own health and welfare (Brock, 2008). The consent process plays an important role for both investigators and participants, encouraging "rational decision-making" for participants and "self-scrutiny" for investigators (Brock, 2008). Practically, informed consent performs several different yet essential roles. It serves participants and institutions "as a means of respecting individual autonomy, protecting subjects' well-being, and achieving intelligent governance of research" (Capron, 2014).

Informed Consent Under the Common Rule

The principles of respect for persons, beneficence, and justice, first codified in the 1979 Belmont Report, provide the "intellectual backdrop" and moral underpinning for federal government protections (Hodge & Gostin, 2017). Each of the procedural requirements of the informed consent process under the Common Rule are built upon these moral principles. Respect for persons gave rise to the informed consent process itself, beneficence translates to requirement for balancing risks and benefits, and justice requires fair subject selection included in both the 1991 and 2018 Common Rules. The Rule lays out the requirements for informed consent clearly, many of which were crafted in response to gross violations of the rights of human participants in research like the U.S. Public Health Service syphilis trials conducted on black share-croppers in Tuskegee, Alabama (Hodge & Gostin, 2017; Levine, 1986). The Common Rule was promulgated with the goal of improving protections for participants in research, minimizing the possibility of further human rights violations, and standardizing the processes of ethical research conducted with federal funding. Additionally, informed consent benefits institutions by

providing protection for researchers against liability for harm (Bierer, Barnes, & Fernandez Lynch, 2017; Hodge & Gostin, 2017).

In practice, informed consent boils down to three parts: the disclosure of materially relevant information to the prospective study participant, comprehension of that information, and a participant's willingness to participate in the research (Capron, 2008). Research ethicists give them slightly different names, information, voluntariness, and competence to make the decision, but they play out the same way (Brock, 2008). Competence is a pre-condition of informed consent, as it is necessary for autonomy in choice about whether participating in research is in a participant's interests (Brock, 2008). When a is person unable to make decisions about what is in their interests based on age or compromised decisional capacity, the ability to give consent can become a thornier issue. The Common Rule allows for a legally authorized representative to make the decision about participation, though this is not allowed in all circumstances.

Disclosure

Disclosure pertains to the type of information that must be given to participants by investigators. Generally, this includes information about the potential risks and benefits of involvement, the purpose of the research and how it will be conducted, as well as other "relevant" information (Brock). What is relevant may depend on the research study, population, and other factors, particularly the things that matter to potential subjects. The Common Rule strictly governs what information must be disclosed to participants during the consent process. The Final Rule lists nine required "basic" elements that must be included in every consent form, and nine additional elements that must be included when appropriate (45 CFR 46.116). This includes information about the purpose and procedures of the study, the risks and benefits the participant may experience, alternatives to participation, the level of confidentiality the

participant can expect from the researchers, whether or not there is the possibility of greater than minimal risk to the participant, that all participation is voluntary, whether or not the research will involve identifiable information or bio-specimens, and contact information for a member of the research team in case of questions (45 CFR 46.116).

Beyond the required and additional disclosure elements, investigators must decide on a study by study basis the level of detail that must be included. In the 2018 Common Rule, this level of detail is now governed for the first time by two new standards. The first, the "key messages" standard, requires investigators to disclose a concise, focused presentation of key messages about the study that will facilitate understanding and aid in the decision whether or not to participate. The second new standard is the RPS, which will be further discussed in Part II.

Comprehension and Voluntariness

The next requirement for informed consent is comprehension. Giving a participant information means nothing if that person is unable to understand it. Research consistently finds that comprehension is low among participants in research, even after they have signed meticulously crafted consent forms (Falagas, Korbila, Giannopoulou, Kondilis, & Peppas, 2009; Lo & Barnes, 2016; Lorell, Mikita, Anderson, Hallinan, & Forrest, 2015). Promoting comprehension is consistently lauded as the primary way to increase protection. Proposed solutions to this problem include ever more complex methods of ensuring understanding, like comprehension quizzes and multimedia consent processes.

Opponents argue that complete comprehension, at least in the sense of a participant being able to regurgitate the list of disclosures, is not necessary to achieve an ethical level of protection for participants as long as other forms of protection and oversight are present (Gopal

Sreenivasan, 2003). This includes a review by the IRB and a participant's free decision not to participate. However, gaps in comprehension about the purpose of research like the therapeutic misconception, where a participant is unable to "appreciate the difference between research and treatment" (Henderson et al., 2007), are not only possible but also well-documented in clinical research. Research ethicist Gopal Sreenivasan argues that if perfect comprehension is required for an ethical consent process, any participant with the therapeutic misconception is unfit to participate. He argues that a modern obsession with comprehension has disadvantaged the research enterprise because enforcing the exclusion of any participant on this basis "would bring enrollment in many valuable and otherwise ethical clinical trials near to a halt" (G. Sreenivasan, 2005). He proposes that researchers should take "reasonable steps" like writing in "clear, non-technical language, at an appropriate reading level, in the prospective participant's mother tongue; providing opportunities to ask questions throughout the trial; and using short consent forms" to achieve a sufficient baseline of comprehension (Gopal Sreenivasan, 2003). Beyond that, voluntariness should be the primary consideration.

Voluntariness is at the core of the logic of legal doctrine of informed consent, and should not be distorted or displaced to by the modern obsession with comprehension. As mentioned above, participants must know and agree to the procedures of the study, but full and complete comprehension of the study may not be necessary to freely, ethically agree to join the project (Sreenivasan, 2003). A participant may not fully understand the minutiae, but can still give valid consent. Researchers are responsible for ensuring that consent to join the study is freely given, not obtained through coercion or undue influence. Outright coercion, such as an implicit or explicit threat that they will be made worse off if they don't participate is "no doubt rare" (Brock, 2008). More commonly, voluntariness is undermined by undue influence, such as

offering outsized incentives or conducting research among populations where the researcher has near total control.

The Reasonable Person Standard

Now that we have laid the groundwork of informed consent as it fits within the Common Rule, I will explore the Reasonable Person Standard in more depth. This section will trace the history of the reasonable person from its origins and mutations in the legal profession and describe how the Reasonable Person may be used in practice as implemented under the 2018 Common Rule.

The Final Rule introduces the reasonable person in the Common Rule using the following language: investigators must provide "the information that a reasonable person would want to have in order to make an informed decision about whether to participate" and the opportunity to discuss that information (45 CFR 46 .116(a)(4)). This is the first time such language exists in the U.S. Federal Regulatory scheme. It is important to note that while the 2018 Common Rule enshrines the RPS in federal regulation for the first time, the concept of the reasonable person has a long history in the legal profession, where it is used as a comparative standard to determine the appropriateness of an individual's action or to determine liability for harm.

The Reasonable Person in Law, Medicine, and Research

The legal standard of the reasonable person can be traced back to 1837. From its inception, the reasonable man of "ordinary prudence" has served as a "personification of a community ideal of reasonable behavior, determined by the jury's social judgment" (Peterson, 1999). Consideration of the reasonable person has been used in tort, criminal, discrimination, and sexual harassment lawsuits. It is applied primarily to render judgement over an individual's

actions, based on what an imagined reasonable person would do in the given circumstances. It is important to remember that the reasonable person does not refer to a specific individual. Instead, s/he is a depersonalized figure that seeks to strike a balance between objectivity— "some fixed dimension"—and subjectivity— an individual's "particular qualities and attributes"—to judge what is appropriate in a given situation (Moran, 2010). While its wide application may lead the uninitiated to believe that the reasonable person standard is well-defined and universal, the truth is that, as a test, the reasonable person "is characterized by a lack of clarity about the exact nature of the subjective and objective characteristics" (Moran, 2010). Thus, the standard is highly contextually dependent.

Clinical medicine also brings insight into the application of the reasonable person. Unlike its legal test, the reasonable person is used in medicine as a prospective step in the informed consent process rather than a retrospective judgement about behavior. A clinician may consider a "reasonable patient" when deciding what information is materially relevant to present about a procedure that would help a patient make the right decision for their own care. Because some clinical research feels familiar, like a doctor visit, clinicians may be more likely to have a sense of what kinds of information are likely to be pertinent to the decision to participate in research. This is not a perfect analogue, especially in light of the therapeutic misconception. Most patients do not understand what they want or even need from a clinical encounter, much like most research participants understand little about what want or need out of participating in a research study. Considering physician- patient counseling, then, gives some insight into what might be considered reasonable when building a consent form, but still carries risks of harm from a basic misunderstanding between experts and non-expert.

In research, the ultimate goal of using the RPS is to guide decision-making about which

information investigators need to disclose in the consent form. Imagining what a reasonable participant would want to know before joining a study should lead investigators to an appropriate level of disclosure about the procedures, risks, and benefits of the study. In practice, using the RPS should follow this procedure. When designing the consent processes, a research team will have to make assumptions about what a prospective participant in their project would want or need to know to make an informed decision about joining the study. These assumptions could be informed by anything—the investigators' previous work, primary or secondary information the researcher has on the population, etc. These assumptions may have nothing to do with the participants' circumstances or interests, but may fundamentally form the language of the consent document. After the protocol is submitted, it will come before the IRB. The reviewers, then, may take one of two paths. First, they may trust the writer's assumptions and approve the proposal, or, second, they may interrogate the consent form more deeply, questioning why the investigators believe a reasonable person would need that information specifically. At that point, the research team may amend the content of the form with or without any meaningful contribution from the prospective participants themselves. Thus, the success of the entire process hinges on several levels trust in how well the researchers understands the needs of their subject population.

Using the reasonable person standard, then, can theoretically provide increased protection for participants by improving the understanding between researchers and subjects. Research ethicist Robert Levine, one of the writers of the Belmont Report, was advocating for the reasonable person standard as the determinant of the minimum amount of information that a researcher should provide to a research participant as early as the writing of the Belmont Report. After meeting the reasonable person standard as a baseline, investigators would engage in a

"consent negotiation" to determine what more a participant would want to know before deciding to join the study (Levine, 1986). Robert Veatch, another famous research ethicist, advocated for disclosing more than a reasonable person might require if an individual participant requires more information in order to exercise their own self- determination (Veatch qtd. in Odwazny & Berkman, 2017). In each case, the reasonableness of a participant is highly relied upon to determine whether information should be disclosed. Determining what is reasonable, however, requires discernment and a thorough knowledge of the prospective participant. Scholars affirm the value of reasonableness, but questions remain about how the baseline should be met.

Tracing its history shows that the reasonable person standard has been used in research before. However, it has never been used on the scale the Common Rule will require, or with the strong arm of federal enforceability. Thus, it is important to dive deeply into the what instituting the RPS will mean for institutions, investigators, and IRBs who play a vital role in protecting participants and reducing the potential harms of misusing this standard.

Part II: Challenges Implementing the Reasonable Person Standard

The previous section examined the history of the reasonable person, from its inception in the legal tradition to its applications in clinical and research contexts. I highlighted some of the difficulties in applying and utilizing reasonableness as decision-making tool. In this section, I will examine some of the hazards that are likely to arise in applying the reasonableness test to topics and behaviors studied in public health research. In this second part of the thesis, I will explore the potential challenges institutions may have implementing the RPS. Specifically, I will explore the practical assumptions underlying claims of reasonableness, acknowledge the harms that may exist for those who are deemed "unreasonable", and explore the difficulties of standardizing a highly contextual test.

Challenge 1: Defining Reasonableness in the Reasonable Person Standard

In order to understand what is reasonable, one must understand the practical assumptions that underlie reasonableness. I will identify two here: the first, that reasonable behavior is "normal" and the second that behavior is reasonable when it is justifiable. Both of these assumptions have serious implications for research, and, if left unexamined, may cause serious harm to participants. Reasonableness is generally understood to be what is "normal" or "ordinary" (Moran, 2010). This is a traditional shorthand for the decision-making standard. It can be prompted by asking, *is this expected or acceptable behavior from a member of this community?* If the answer is yes, there is no need for deliberation. It is reasonable. Then, if research poses a high risk associated with that "normal" behavior, like washing your hands, driving a car, or crossing the street, a reasonable person will consider it material to making a decision about participating in a study. The risks should then be disclosed in the consent form. Using "normal" as a metric can also aid in decision-making when the potential risk of the study is considered to be unacceptable to the general population. For example, because people generally fear (or at least wish to avoid) death, should the possibility of death be included on every single consent form even if the possibility is miniscule? What would a reasonable threshold for risk of death be before the investigators consider disclosing to assuage reasonable fear? This is an inherent problem with the RPS. In its focus on discerning contextually appropriate information for an individual, it can be difficult to balance against creating a more general set of disclosures applicable to the entire subject population.

The "normal" test can be helpful but it comes with a dark side. Accepting that reasonable equals normal exposes the ugly opposite— that anything abnormal is unreasonable. This perspective quickly stigmatizes fringe behaviors or beliefs, creating several problems for the

research system. First, many people engage in health-sabotaging behaviors that may need and merit study. Smoking is an excellent example. While overall smoking rates have decreased, not everyone quits, and smoking is no longer considered normative behavior. In creating a consent form for a study of smokers, investigators may assume that engaging in this abnormal behavior makes one unreasonable, incautious, or less concerned with potential risks of participation. Deciding what disclosures are material using these assumptions is dismissive. Intravenous drug users, adolescents trying to get pregnant, and people who trust healing crystals all act outside the range considered normal. This does not necessarily make them any less concerned by the possible harms of participating in research. The potential harm in making the judgement that those with fringe beliefs or behaviors are unreasonable is that it may lead researchers to inappropriately exclude some disclosures from the consent form. Ultimately, relying on assumptions about what someone may find reasonable, even if those assumptions are based on another, known behavior, may undermine the protections informed consent offers research participants. Doing so would illuminate a lack of respect for a prospective participant's concerns and undercuts his ability to consent to joining the study based information materially relevant to him. The investigator may not have made extra effort to determine what that would be, abiding by assumptions rather than specific knowledge about the prospective participants' circumstances. Technically, the standard was met because the investigator considered what a reasonable person might want to know before giving consent. However, the researcher just did not deem his prospective participants reasonable enough to need certain information. Investigators and IRB members should remain focused on making disclosures based on a participant's belief about what is reasonable, not the research team's.

A second concern with the equation of normal and reasonable is focused on the person of the standard. Considering that the reasonable person standard originated in the 19th century, the person was a working-class, heterosexual, white man. This perspective has been codified as reasonable and objective. This obviously creates some egalitarian concerns. By this metric, anyone not meeting that specific profile is non-normative, and therefore unreasonable. To combat this, the Reasonable Woman Standard has at times been employed in legal proceedings, particularly in sexual harassment cases (Peterson, 1999). However, the reasonable woman is generally afforded much less objectivity than the reasonable man. She represents a more specific worldview. Defaulting to a perspective that considers the concerns of white men to be more valuable than others could severely undermine understanding and protection of participants that do not meet that profile. I do not mean to suggest that the research enterprise is tailored specifically to meet the needs of participating men, but it is worth considering the dangers of defaulting to a norm that does not reflect the population being studied.

A second assumption about reasonableness is that one's ability to explain why they are engaged in a behavior, belief, or fear is what makes it reasonable (Gardner, 2001). On its face, defining reasonableness as the ability justify beliefs of behavior carries promise for deciding disclosures. This is potentially less stigmatizing than defining reasonableness as normal, but I will show that it too can be harmful to participants. Justification is a major part of the legal understanding of reasonableness. Rationale alone, however, is not sufficient, because some reasons are better than others. Simply having a reason for not vaccinating your children, e.g. "I heard on the radio it causes autism" does not mean that it is inherently a good one. This brings up questions that are central to why we do research—because through research we aim to find some inherent, objective truth. It is not hard to imagine an investigator probing, *where do my*

prospective participants get their health information? From an expert or a provocateur? Where are the data that lead them to this behavior?

Reasons for belief can be difficult for individuals to articulate to themselves and even harder to understand by outsiders. It is also possible for people to rely on bad reasons to engage in a behavior. A researcher dismissing a father's hesitation to vaccinate his child because he found a website linking it to autism is entirely possible because it does not line up with her own beliefs about reasons to vaccinate. She may then neglect to communicate that vaccines do not cause autism in the consent form because she believes the reasoning linking the two is so faulty, it is unreasonable and should not need to be disclosed to a prospective participant. Poor justification, then, can have the same possibility of dismissing participant concerns. At this point, the investigator could argue she considered what was reasonable and met the RPS, but the result is the same as not using it—a weakening of the relationship of trust between researcher and participant and respect mandated by the Common Rule. There we see that justification does not entirely solve the problem of determining disclosures, so we need another way to conceive of it.

Reasonableness "requires a high degree of co-ordination among one's various aims" and balancing of competing priorities, commitments, and deadlines (Church, 1987). Considering this, it becomes vital for researchers hoping to apply the standard to take a broader view of reasonableness beyond equating it with what is normal or even the ability to explain it. This will require a commitment to a deeper acknowledgment of participants' interests when designing the consent process. Thoughtfully using the RPS to promote participant protections hinges on understanding participants' interests, as they determine what is reasonable at that particular time and place in a given population.

This leads to an absolutely vital assumption about reasonableness. It cannot be static and it cannot be universal. This is a fundamental correction to the assumption of objectivity that some believe the RPS requires. The goal of the standard is to engineer a generic way of making decisions that does not require researchers to have deep understanding of individuals. There is no one reasonable person, there is no one list of disclosures that will apply in all circumstances to all people. The paradox is that individual interests, and the situations in which they develop, have a fundamental role in shaping what a person would want to know before agreeing to join a study. Thus, it is important to recognize that determining what a reasonable person would want to know before making a truly voluntary decision can only be decided on a case by case, or, more accurately, a study-by-study basis. Because what a reasonable person may want to know changes from context to context, so will the information investigators must disclose to participants. Contextual variations must play a role in determining the subjective and objective elements of the reasonable person test (Moran, 2010). Refusing to participate in research may look self-defeating, i.e., unreasonable, to outsiders, but it may in fact be a reflection of other, unexplored factors. Declining to join a study that may help an individual or their community may be reasonably justified by research fatigue, competing priorities, general disinterest, or a history of harm by other researchers. These things are perfectly reasonable to prospective participants. The research enterprise is not, and never will be a-historic. It is only by entering the context of the prospective research participants and truly knowing their interests that a researcher will be able to abide by the intention behind using the RPS. Even then, there is no guarantee of success.

Challenge 2: Applying the Reasonable Person Standard

The second part of the challenge of implementing the RPS will be in its actual application. Here we move beyond the conceptual underpinnings of the standard into the

practical steps that must be taken to adopt the RPS as standard procedure. There are multiple parties with specific regulatory obligations and responsibilities for implementing the RPS. Institutions will govern compliance, investigators will create informed consent processes, and IRB members will evaluate if the RPS has been met. Each of these parties will experience different challenges implementing the RPS. However, there are two over-arching challenges: the first, with the tension of standardizing a highly contextual entity and the second, the challenge of applicability to different types of research. Figuring out what is germane to the reasonable person is more clear-cut for individual, clinical research, but will bring additional considerations to community-focused and public health research.

The largest challenge by far in implementing the RPS will be ensuring it is used consistently within similar contexts of application. While investigators, institutions, and IRBs have the same goal, they each have slightly different responsibilities in determining how and when the RPS is met. Investigators will primarily be responsible for applying the RPS during the creation of each consent form. Institutions, in charge of ensuring compliance with the Final Rule, may write policies describing what IRBs should be looking for in protocols and consent forms to ensure that the RPS is met. Generally, this has taken the form of checklists or templates for what disclosures are required under the Common Rule. There is inherent tension within the Final Rule's new consent procedures, as the paradox of using the reasonable person standard is that it is neither "standard" nor objective. A standard generally outlines what falls within an appropriate range of acceptability in a given context, it is a shortcut. In contrast, if used thoughtfully, the RPS will involve an iterative process, prompting questions and answers about the context in which it is being applied. It will no doubt take more work to craft a consent form than before. Institutions and IRB members may be able to make suggestions as to what information will meet

the standard, but creating a checklist of disclosures misses the point. The result will be easier to judge, but may disadvantage prospective participants because of its lack of specificity. There is no single definition for reasonable. An appropriate definition of what is reasonable to a given population will require a thorough understanding of that subject population. Ideally, implementing the RPS *should* shift the processes of research toward power sharing, empathy, and deep respect; ultimately humanizing the research enterprise. How that will be reflected in a protocol remains to be seen.

Public health research brings its own unique challenges to implementing the RPS. Participation in public health research involves risks and benefits not only within a body, but within a community. While physical harm is not beyond consideration, risks like social consequences, stigmatization, and isolation are more likely in public health research. As a result, risks can be misunderstood, mischaracterized, or poorly defined. Additionally, these risks are not spread evenly throughout the population. Vulnerable groups may be more likely to experience poor social outcomes than higher-status members of the community, and if they do it may be more psychologically harmful. Global health research will require an even more careful consideration of the reasonable person standard because of the many opportunities in cross-cultural settings to rely on assumption, biases, and ethnocentrism to judge if behavior is reasonable. Multi-site, multi-national research is growing only more common. Unfamiliarity with the culture of prospective participants may leave investigators with blind spots about what risks are important to communicate. For example, consenting to an interview about experiences with menstrual hygiene may lead to a broader discussion about gender roles. This may in turn create pressure to disclose traumatic experiences, such as sexual violence. This is not the purpose of the questioning, but it is a possibility, and it could be profoundly difficult for the women to re-

live. It would therefore be reasonable to disclose that information to a participant to help her make a decision about whether she wants to open herself up to that experience in a research setting. This is the power of thoughtfully applying the RPS. Carefully considering the perspectives of participants will build trust, convey respect, and increase protection against harm.

Part III: Illuminating and Mitigating Harms

In this final part of the thesis, I will attempt to further explore how potential harms of using the standard inappropriately, such as the possibility to rely on assumptions, can be reduced. I propose three options: First, I will discuss how accounting for a reasonable person in the standard may highlight the power imbalance between participants and investigators in traditional research paradigm. Second, I will suggest tools that IRBs and investigators can use during the creation of the consent process that will help avoid harming participants. Though the implementation date of the Final Rule, and hence the new RPS, was pushed back to mid-2018, and possibly further, I urge institutions to take a few practical steps now to begin to shift the culture around informed consent back to a participant focus.

Carefully attending to the RPS' conceptual and philosophical underpinnings can help us understand its potential shortcomings. However, understanding the underlying problems with assessing reasonableness cannot help us ameliorate all the ills associated with the research enterprise. Significant power imbalances exist within individual research studies and the larger field— between investigator and participant, funding organizations and research teams, and researchers and IRB members, and even investigators from different research methods and paradigms (Edwards, 2013; Giampapa, 2011; Lunde, Heggen, & Strand, 2013). A major force behind the revision of the Common Rule was to better protect participants in research. Changing

informed consent requirements, including the addition of the RPS, is an important step. Relying on these changes alone, however, will ultimately fail because they pay no explicit attention to remedying those power dynamics. In fact, over-reliance on a single standard may even exacerbate these problems.

In their role as experts, investigators must wield their power appropriately and respectfully in order to reduce the possibility of harm to participants. This cannot be an empty ethical goal. The distinct challenge in applying the RPS is the seduction of the standard. In short, this would be defaulting to what investigators find reasonable and then believing that because *a* reasonable person standard has been met that the requirement was fulfilled. If an investigator bases the consent form disclosures on what they themselves would reasonably expect to be told, they may be committing to a far lower bar of disclosure, or to one that pays insufficient attention to the interests and circumstances of the prospective participants. IRB members may compound the problem by making the same error. Both parties can affirmatively answer the question, *is this reasonable?* However, this is neither the point nor purpose of the RPS. Allowing a generic standard to prevail reaffirms a deeply ingrained hierarchy where participants are afforded the least authority to determine the reasonableness of informed consent disclosures. All the while, researchers and IRB members believe they have increased protections for participants because they asked themselves about reasonableness. This changes nothing and undermines all the work that went into changing the Common Rule. To avoid falling for the seduction, investigators can use many tools. There is an increased focus on qualitative and community-based participatory action research (CBPAR), particularly in the field of public health. These methods are being used to better understand and protect the needs of participants and communities during the research process. Instituting a few principles from community engagement during the implementation of

the RPS will help improve the researcher/ participant relationship and decrease the likelihood of unintended harms.

Suggestion 1: Integrating Community Engagement Strategies

Communities are an essential part of public health systems and research (South & Phillips, 2014). Community engagement (CE) is a blanket term used to refer to a range of practices researchers employ to build, maintain, and strengthen relationships with participants in research and public health interventions. CE focuses on eliciting what is important to stakeholders in research projects, with a specific aim of understanding the complex relationships among competing priorities, potentially mutually incompatible goals, and non-obvious desires that make up a person's interests. Utilizing the tools of CE like community advisory boards, public meetings, and informant interviews can strengthen the individual consent process by virtue of its broader understanding of individuals as parts of communities. Having at least a baseline knowledge of the scope of participants' interests is vital to appropriately understanding what is reasonable to a person or population. There is no better way to determine what a reasonable member of a community would do in given situation than to ask. An investigator can fulfil the requirements of the RPS by translating a community's actual beliefs into those of the standard's reasonable person. The only way to do this is in some form of relationship with members of the community (King, Kolopack, Merritt, & Lavery, 2014).

How will this work? Before writing a consent form, a research team should form relationships with the potential participant community and set up some system for soliciting their interests. This should continue at least until non-obvious interests have been identified among the participants. Prospective participants may refuse to join an experimental drug trial out of fear that the packaging of the medication they bring home may link them to having a stigmatized

disease. Researchers can then ensure that the method of dispensing treatment will not expose the participant's condition to household members. Solving this problem benefits both the study and the participants. More generally, involving CE strategies will allow investigators will see trends that will help understand what a reasonable person in that community would want to know about a study. Once interests are known, it is nearly impossible to default to a generic standard. Further along in the process, IRBs will read the consent form and protocol and recognize that investigators are not defaulting to the standard disclosures because they have specific knowledge of the participant community.

This is far from the first time that integrating CE into consent processes has been proposed. There is a long history of discussion about who is best qualified to write ethical consent forms and the correct parties to make judgements about the quality of the consent process. Robert Levine, co-writer of the original Common Rule, believed that the individuals who generally serve on IRBs were not the best people to make the decision. He favored a system of surrogacy, whereby a member of the research population unable to participate in the study would review the consent form and examine whether or not the disclosures were reasonable. Finding this surrogate may be difficult, but it is important not to let challenges get in the way of accomplishing the ethical goals set forth in the Final Rule.

Suggestion 2: Increased Training for IRBs

A second suggestion is for institutions to create additional training opportunities for their staff focused solely on the reasonable person. This could be added to the informed consent training required for investigators and IRB members before they are allowed to engage in research. Intermittent training is already required for investigators and researchers, but this is an especially good time to reacquaint investigators, researchers, and others with the basics of

informed consent while introducing the new standards. This is an excellent opportunity for institutions to communicate what will be expected from investigators and IRB members in regards to the Reasonable Person. Because no further guidance on using the standard has been released by the Common Rule agencies, institutions are grappling with how to use RPS more or less by themselves. For example, CDC, in its trainings on informed consent under the Final Rule, is advising its researchers to show consideration of the RPS by conducting primary or secondary research on their subject population to determine what are reasonable disclosures. IRB members are being taught to ask specifically what investigators knew about subject population that led them to the consent form disclosures. Understanding and practice are necessary for the RPS to take root in institutions. Beginning now with training can only help change the research environment for the better.

Conclusion

Thoughtfully applying the Reasonable Person Standard carries promise and great power. In the right hands, it can guide researchers to a better understanding of the interests and needs of participants, to fulfill the ethical goals of the Final Rule, and reduce unintended harms to participants from the research enterprise. In order for its potential to be realized, however, the RPS must be understood and used consistently by all implementing parties. There will be challenges ahead, but approaching these challenges with sincerity, openness, and a determination to better understand those willing to accept personal risk for benefit of others can fundamentally reorient our understanding of research. Human subjects research, as an industry, is a multi-billion-dollar enterprise that touches nearly every person on the planet. Adopting the RPS is hopefully a first step in allowing that process to be disrupted by the radical notion of an empathetic, humanized research system that works better for everyone.

Implementing the standard will not carry much financial cost in itself. Applying the standard does not require expensive new equipment or specialized knowledge. However, integrating the standard into normal use will have some cost associated. Institutions will need to invest in new training for investigators and IRB members. There may be additional costs to the research project to instate in increased community engagement activities. However, all of these costs are worthwhile, as they will improve the field of research as a whole, proving that institutions and investigators understand and respect the contributions of volunteer participants in research, without whom, the industry would collapse. Because the Common Rule is the de facto standard for research worldwide, thoughtfully implementing the Reasonable Person Standard could have far-reaching effects worldwide. Considering the Reasonable Person can be especially helpful in promoting ethical research in global health, and present an additional value proposition for integrating CE into global health research and practice.

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