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TARGET ARTICLE

Informed Consent: What Must Be Disclosed and What Must Be Understood?

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ABSTRACT

Over the last few decades, multiple studies have examined the understanding of participants in clinical research. They show variable and often poor understanding of key elements of disclosure, such as expected risks and the experimental nature of treatments. Did the participants in these studies give valid consent? According to the standard view of informed consent they did not. The standard view holds that the recipient of consent has a duty to disclose certain information to the profferer of consent because valid consent requires that information to be understood. The contents of the understanding and disclosure requirements are therefore conceptually linked. In this paper, we argue that the standard view is mistaken. The disclosure and understanding requirements have distinct grounds tied to two different ways in which a token of consent can be rendered invalid. Analysis of these grounds allows us to derive the contents of the two requirements. It also implies that it is sometimes permissible to enroll willing participants who have not understood everything that they ought to be told about their clinical trials.

KEYWORDS

Informed consent; disclosure; understanding; clinical research; therapeutic misconception; valid consent

INTRODUCTION

Patients and healthy volunteers who enroll into clinical trials of new drugs, devices, and diagnostic tools are normally asked to give informed consent to the potentially risky procedures they are expected to undergo. They are told about the purpose of the research study, the procedures involved, the potential risks and benefits, and a long list of other facts, which are usually stated in a written consent form that participants sign. Over the last couple of decades, a slew of studies have examined how much research participants really understand about the clinical trials in which they are enrolled. The results are not encouraging: large numbers of even well-educated, competent participants asked simple multiple choice questions cannot correctly identify key facts about their trials (Flory, Wendler, and Emanuel 2008; Mandava et al. 2012). For example, a study of U.S. cancer patients participating in a range of oncology trials, found that 29% mistakenly agreed "[t]hat the treatment being researched in my clinical trial has been proven to be the best treatment for my type of cancer" and a further 40% were unsure. 64% failed to correctly identify that participation in a clinical trial carried additional risks to those of standard cancer treatment (Joffe et al. 2001).

Did all these people give valid consent to the research procedures they underwent? According to what we call the "standard view" of informed consent they did not. The standard view holds that the recipient of consent has a duty to disclose certain information to the profferer of consent because valid consent requires that information to be understood. Thus, on the standard view, the content of the *disclosure requirement* (what the person requesting consent must tell the person who proffers consent in order for it to be valid) is identical with the content of the *understanding requirement* (what the person proffering consent must understand in order for the consent to be valid).[1] If either requirement is not met then the resulting token of consent is invalid.

Despite copious data showing that many participants do not understand key facts about the studies in which they are enrolled, the reaction from researchers

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[1]Note that even the most ardent proponent of the standard view can accept that there is some information that should be made available to participants but that need not actually be understood. For example, the consent form is a useful place to provide the contact information for the research coordinator and the location of the study. But while this information ought to be provided, its provision is not relevant to the validity of consent. It is therefore not a component of the "disclosure requirement" as we use the term here.

and research ethicists has been rather muted.[2] This might seem surprising given that many of them at least purport to believe some version of the standard view of the informational requirements for informed consent. Conducting clinical research on competent adults without their valid informed consent is usually thought to be an egregious wrong. If people really believed that all these research studies were proceeding without the valid consent of participants we should expect an outcry. At the very least, now that we know about the widespread lack of understanding, we should expect further clinical research to be halted until processes were put in place to test for complete understanding and exclude those who lack it.

But not only does clinical research proceed more or less as it did before, some experts appear willing to lower their standards for what ought to be understood in light of what participants actually understand. In a recent study on informed consent to biobank research, Laura Beskow and Kevin Weinfurt (Beskow and Weinfurt 2019) constituted a multidisciplinary expert panel that achieved consensus—meaning ≥70% agreement—on a set of facts that needed to be understood in order to give valid consent (2019). When presented with data showing that a third of potential participants did not understand all of this information (even after review and retesting), a substantial proportion of panel members wavered. On multiple items, over 30% were unwilling to exclude participants who lacked understanding of that item. When interviewed, many could not reconcile their intuition that it would be ethical to enroll these participants with their views on informed consent. Some speculated that their intuition might be explained by a distinction between what ought to be disclosed and what ought to be understood.

In this paper, we argue that the standard view—and variants of it that still derive the disclosure requirement from the understanding requirement—is mistaken. The disclosure and understanding requirements have distinct grounds tied to two different ways in which a token of consent can be rendered invalid.[3] The primary purpose of disclosure is not the achievement of understanding, but the avoidance of a kind of illegitimate control. In order to avoid this control, the person requesting consent must disclose all the information she knows that she both has reason to think is relevant to the consent decision and that the profferer of consent would reasonably expect to receive (Bromwich and Millum 2015). The understanding requirement is grounded in the conditions for the successful performance of the speech act of giving consent. To meet it, the person proffering consent must understand three things: (1) that she is giving consent; (2) how to exercise her right to give or refuse consent; and (3) to what she is being asked to consent (Millum and Bromwich 2018). Our analysis explains why it is sometimes permissible to enroll willing participants who have not understood everything that they ought to be told about their clinical trials. It therefore implies that the muted reaction to poor participant comprehension may be justified, after all.

Our argument proceeds in two stages. First, we argue that the disclosure and understanding requirements have different contents. Then we provide explanations of how disclosure and understanding can go wrong that allow us to derive the content of each requirement. We offer an analysis of these informational requirements understood as necessary requirements for valid consent. We focus on validity because it is foundational: *only* valid consent succeeds in waiving rights, thereby permitting acts that would otherwise be rights violations. There is, of course, more to the ethics of consent than whether rights are waived and duties altered. Like others, we think that the informed consent *process* serves functions unconnected to validity—as we note in the section entitled "Other obligations"—but those functions are not our primary focus here. Further, although we restrict our analysis to consent to clinical research participation in this paper, our conclusions apply *mutatis mutandis* to consent to non-clinical research participation and consent to treatment in the context of clinical care.

THE STANDARD VIEW

According to the standard view, the content of the disclosure requirement is identical to the content of the understanding requirement. This view is articulated in all the major statements of research ethics. According to Article 1 of the Nuremberg Code, voluntary consent requires that the person giving consent:

> should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made

[2]Some exceptions include: Manson and O'Neill (2007); Miller and Wertheimer (2011); O'Neill (2002); Sreenivasan (2003); and Wendler (2004).

[3]Cf. Sreenivasan (2003). Sreenivasan also rejects the standard view, but suggests a different account of what the informational requirements for informed consent are. We reject Sreenivasan's analysis of those requirements in Section 5 (see footnote 12).

> known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment (Nuremberg Military Tribunal 1947).

The Declaration of Helsinki (World Medical Association 2013) states:

> In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. … After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent … (2013, Article 26).

The Council for International Organizations of Medical Sciences (CIOMS) lists 26 items of information that must be provided as part of the consent process, as well as another nine context-specific requirements (Council for International Organizations of Medical Sciences 2016). The 26 cover the purposes of the research, procedures, risks and benefits, alternatives to participation, research-related injuries and various other topics. Regarding all this information, the CIOMS Guidelines say:

> The person obtaining consent must ensure that the potential participant has adequately understood the information provided. Researchers should use evidence-based methods for imparting information to ensure comprehension (CIOMS Guideline 9).

Finally, following a discussion of what information should be provided to research subjects, the Belmont Report addresses comprehension, stating: "Investigators are responsible for ascertaining that the subject has comprehended the information" (National Commission 1978).

Note that, charitably construed, none of these documents requires comprehensive understanding of the elements that they list. It would, for example, constitute an impossible bar to valid consent if participants had to be able to explain the exact magnitude and probability of every possible harm that might occur during a study. Instead, it seems reasonable to assume that there is some level of understanding of each required element that counts as "adequate" (as CIOMS puts it). In the case of risk, for example, that bar might be a grasp of the approximate magnitude and probability of the most common and the most serious harms that the research procedures might cause.

The standard view of the relationship between disclosure and understanding is not only enshrined in these guidelines; some variant of it is defended by most scholars who have analyzed the concept of informed consent.[4] We now consider their arguments and show that they cannot establish that the content of the disclosure requirement is given by the understanding requirement or vice versa.

SEPARATING THE DISCLOSURE AND UNDERSTANDING REQUIREMENTS

As a first step, note that the disclosure requirement and the understanding requirement are conceptually distinct. The fact that valid consent requires that the person giving consent needs to understand *something* and the person receiving consent needs to disclose *something* does not *entail* that the content of the two overlaps at all. It would be rather odd if they had nothing to do with one another; but that is a substantive matter. We make this point in order to call attention to the fact that some argument must be given for the relationship between the two requirements, whatever it is.

Furthermore, reflection on some cases in which we are confident in our judgments about the validity of consent suggests that the two requirements in fact have different contents.

Consider, for example, a case in which a researcher requests the consent of an individual for participation in a clinical trial designed to test an investigational drug. Assume that all non-informational aspects of the consent process are carried out impeccably. Moreover, the researcher accurately describes to the potential participant everything that regulations and guidance documents say she should—risks and benefits, the purpose of the study, conflicts of interest, and so forth. He understands everything she says and she gives him the consent form. The researcher's disclosure requirement is surely met. But this does not

[4]Two notable exceptions are Gert et al. (1997) who identify the purpose of disclosure as the avoidance of deception and Sreenivasan (2003) who argues that the disclosure and understanding requirements should be separated.

exhaust everything that the potential participant must understand. For instance, he must also understand that *by signing the consent form he thereby tokens consent*.

This simple case shows that there is information that must be understood that does not have to be disclosed: in this case the researcher does not have to inform the participant that by signing the form he gives consent because it is very reasonable to assume that he already knows this. In a culture where signing a form is not a well-known way to signify consent, the researcher would not be able to assume this background knowledge and would presumably be obliged to explicitly disclose it.

Of course, one might still think that the reverse relationship holds: that is, that everything that ought to be disclosed must be understood. The proponent of this variant of the standard view might argue as follows. The function of disclosure is to provide information so that the person giving consent can make a decision about whether to consent. If she does not adequately understand that information, then it does not help her make a decision, and disclosure has not fulfilled its function. Alexander M. Capron seems to take this view. He writes: "[p]lainly, comprehension is essential for truly informed consent, for the act of disclosure would otherwise be pointless" (Capron 2008, 625). Likewise, Ruth Faden and Tom Beauchamp note that there could be cases in which the person giving consent already understands everything he needs to know and could therefore give consent without any further information being disclosed (1986, 276). They then assess possible standards for ascertaining what needs to be disclosed. The adequacy of those standards are judged by whether they result in patients or research participants understanding all the facts needed for autonomous authorization (Faden, Beauchamp, and King 1986, 305–330).

Suppose this view of the relationship between the disclosure and understanding requirements were correct. What would need to be disclosed? The research ethics literature suggests two views of the understanding requirement that would give plausible implications for what must be disclosed. According to the *interests view*, a necessary condition of valid consent is that the person giving consent understands all the true propositions about the research that are relevant to his or her interests. For example, a prospective participant must understand the serious potential side effects of a drug because those side effects are relevant to his interests. David Wendler and Christine Grady appear to hold this view (Wendler and Grady 2008; Wendler 2009).[5] According to the *inducements view*, a necessary condition of valid consent is that the person giving consent understands all the true propositions about the research that he would consider relevant to his consent decision. For example, a prospective participant must understand the serious potential side effects of a drug because what the side effects are is likely to be relevant to his decision about whether to take it. Faden and Beauchamp (1986) defend a version of this view.

On the interests and inducement views, what must be understood for valid consent is derived from what is relevant to a potential participant's interests or his decision-making. What must be disclosed for valid consent is derived from what must be understood. Everything that must be disclosed must also be understood because that allows participants to protect their interests or make decisions on the basis of what matters to them.

To see why this argument fails, consider now a pair of stylized cases in which a researcher requests the consent of an individual for participation in a clinical trial designed to test a drug that has risks A, B, C, and D (Bromwich and Millum 2015). Assume that everything else about the consent process—including the disclosure and understanding of information not related to risks—is carried out impeccably.

> Case 1. The researcher only knows that the drug has risks A and B. She does not know about risk C or D. At this time, no one knows about these risks, so the researcher is not negligently ignorant. During the informed consent process, she discloses that the drug has risks A and B and that there may be unknown risks. The prospective participant fully understands the information that is disclosed and agrees to ingest the drug.

> Case 2. The researcher knows that the drug has risks A, B, *and* C but she does not know about D. Again, she is not negligently ignorant. During the informed consent process, she discloses that the drug has risks A and B and that there may be unknown risks; but she does not disclose risk C. The prospective participant fully understands the information that is disclosed and agrees to ingest the drug.

In *Case 1* the participant's consent clearly seems valid. Given the nature of medical research, participants are frequently asked to give consent to procedures for which risks are unknown to all parties to the consent transaction. In *Case 2* it seems equally clear that the participant's consent is invalid.

[5]Sreenivasan also suggests that what must be understood is related to what is in participant interests, though he does not explicitly endorse an interests view (Sreenivasan 2003, 2019).

However, in both cases the participant understands exactly the same information—that the drug has risks A and B and there may be unknown risks. In fact, in both cases the participant understands everything that is disclosed to him. However, the standard view's explanation of the disclosure requirement cannot explain why his consent is valid in the first case but not the second since the participant is no better equipped to protect his interests or make decisions consistent with his values in *Case 1* than *Case 2*.

The proponent of the standard view might think that she can explain the discrepancy. While the participant understands everything that *is* disclosed to him in both cases, he does not understand everything that *ought* to be disclosed to him. In *Case 1*, he understands everything the researcher knows and has reason to think might be relevant to the consent decision, but not in *Case 2*. In that case, the researcher withholds a risk that she knows and has reason to believe is relevant to his consent decision, and it is this failure to understand a fact that ought to be disclosed that explains why his consent is invalid. This explanation implies that the disclosure requirement should be modified as follows: The recipient must disclose everything that she knows and has reason to think might be relevant to the consenter's decision. And, in order for consent to be valid, the consenter must understand everything that ought to be disclosed.

Of course, proponents of the *interests* and *inducements* views might have an *intuition* that this premise about the understanding requirement is true. Faced with such a proposal, though, we can legitimately ask them *why* they think this. How do their views explain why valid consent requires the consenter to understand everything that the recipient knows and has reason to think might be relevant to the consenter's decision?

Here, the proponent of the standard view faces a problem. On their view, the content of the disclosure requirement must be derived from what is relevant to a potential participant's interests or his decision-making. Their original (very natural) explanation does just that: understanding facts that are relevant to a decision allows the consenter to—for example—protect his interests. He has to understand these facts in order to give valid consent and they must be disclosed in order for him to understand them. However, as *Case 1* illustrates, this explanation cannot be correct. Someone can give valid consent to an act that has unknown risks *provided that they are not being withheld from him by the recipient of consent*. And, if that's possible when risks are unknown to both the consenter and the recipient, then the consenter does not need to understand everything that would be necessary to protect his interests or would be material to his consent decision in order to give valid consent.

As we suggested, the proponent of the standard view can modify the disclosure requirement so that just those facts that the recipient of consent knows and believes are relevant ought to be disclosed. However, while the proponent of the standard view now gets the right result, she can no longer avail herself of the natural explanation. There is no good reason to think that the consenter sufficiently protects his interests or his inducements when he understands *precisely* that set of facts that the requestor of consent happens to know and believe is relevant to his interests or material to his consent decision. In fact, the *interests* and *inducements* views suggest that the content of the understanding requirement will often differ from the set of facts that a researcher happens to know and believe is relevant.[6]

An alternative way to try to capture the difference between *Case 1* and *Case 2* while preserving the standard view might be to say that the content of the understanding requirement is limited by the principle that "ought implies can."[7] On this variant, a prospective participant must understand everything that is relevant to his interests or inducements within the limits of what he *can* understand. In *Case 2* but not *Case 1* the participant could know about risk C (since the researcher could tell him about it) and so only in *Case 2* is understanding of risk C required for valid consent. The challenge for this variant is that it risks holding the recipient of consent hostage to what the person giving consent could know, even when she lacks access to the information herself. Suppose, to vary *Case 1*, an acquaintance of the prospective participant just read an unpublished study involving the experimental drug and now knows about risk C. The acquaintance could inform the prospective participant,

[6]Especially, that is, in clinical research where so much information that is likely to be relevant to a potential participant's interests or would be material to his decision is unknown. To illustrate, consider *Case 1* again. If the set of facts that the prospective participant needs to understand in order to protect his interests or would be material to his enrollment decision is identical to the set of facts that the researcher happens to know and believe is relevant at the time consent is requested—i.e. risks A, B, and that there may be further unknown risks—then the researcher would not need to disclose risk C were she to learn of it before the trial starts. After all, risk C is not in the set of facts that would be material to his decision or necessary to protect his interests *on this modified version* of the standard view because *that* set of facts is precisely the same as the set of facts the requestor of consent happened to know and believe was relevant at the time consent was requested. This is clearly implausible. But, more importantly, it is not implied by the *interests* or *inducements* views; it is only implied by a version of those views retrofitted to deal with the original objection.

[7]Our thanks to an anonymous reviewer for this suggestion.

and so it is now true that he *could* know about a fact that is relevant to his interests or inducements. It is implausible that not understanding this fact renders his consent invalid. It is equally implausible that the researcher ought to have disclosed risk C—it might be a knowable fact, but not by her.[8]

The foregoing arguments illustrate why the standard view of informed consent is mistaken. The view's constitutive claim—that the contents of the disclosure and understanding requirements are identical—is false: it is neither true that everything that ought to be understood in order for consent to be valid must also be disclosed nor is it true that everything that ought to be disclosed in order for consent to be valid must be understood. Plausible modifications of the standard view that seek to retain the idea that the disclosure requirement can be somehow derived from the understanding requirement lack a coherent justification.

We now offer an alternative explanation of each requirement. These explanations imply that the disclosure and understanding requirements will differ in their content just as the examples we have given imply that they do. The explanations are also independently plausible. Thus, we provide a principled ground for our view of each requirement and the content that we derive entails intuitively plausible judgments about consent in uncontested cases.

THE CONTENT OF THE DISCLOSURE REQUIREMENT

We approach the question of the content of the disclosure requirement by looking at the function of disclosure. We assess the function of disclosure by looking at how it can go wrong in ways that invalidate consent.

Persons have various rights that protect their bodies and property against others. Competent adults can waive those rights in specific ways in order to permit actions that would otherwise be wrongful. For example, by giving valid consent, a patient can transform wrongful battery into permissible surgery. An individual's autonomy right to give or withhold consent in this way can be violated if another person exercises illegitimate control over the consent decision. This is most obvious in cases of coercion, where an illegitimate and credible threat of harm controls someone's decision. Consent issued under such a threat is invalid. However, there are other forms of illegitimate control, such as manipulation and deception. These can also invalidate consent under certain conditions (Mandava and Millum 2013). In general, if one agent illegitimately controls another agent's decision about something over which he has an autonomy right, then she undermines the voluntariness of his decision.

One way to control someone's decision is by providing or withholding information that is relevant to that decision. In *Case 2* above the researcher knows about risk C and she has good reason to think that that information would be relevant to her prospective participant's decision. Further, given the context, he has good reason to think that she would tell him about any important risks she knows about. Suppose that the information is in fact relevant to his decision. By withholding it, she controls her prospective participant's decision by illegitimately controlling the information he gets to consider in giving or refusing consent. This usurps his agency and thereby undermines the voluntariness of his consent.

We call the kind of disclosure that undermines consent by withholding or misrepresenting information *fraudulent disclosure*. A diagnosis of fraudulent disclosure explains why problems with the disclosure process can lead to invalid consent.[9] It also helps us derive the content of the disclosure requirement by analyzing the conditions under which someone can illegitimately control another person's decision by controlling the information she discloses.

First, and most obviously, it is only possible to control someone's decision by providing or withholding information when one has access to that information oneself.[10] This explains the connection between what the recipient of consent knows and what she ought to disclose.

[8]The standard view implies that she ought to disclose risk C because the content of the understanding requirement determines the content of the disclosure requirement. Since risk C is a fact that he could understand, she ought to disclose it. But this is not a duty she can discharge. Any attempt to avoid this consequence by limiting her duty by the "ought implies can" principle would only push the problem back to that of the original modification. If she were only required to disclose those facts that she knows, we could once again ask: why think that the participant's interests or inducements are protected when he understands everything the researcher knows rather than everything he could understand? There is no satisfactory answer here. After all, in the case under discussion, she does not know about risk C, and yet that is a fact that he could understand and which is relevant to his interests and inducements.

[9]We say "can lead to invalid consent" because control is a matter of degree and it is plausible that some degree of illegitimate control, while still disrespectful of a person's autonomy, is nonetheless compatible with his giving valid informed consent. As Faden and Beauchamp put it, valid consent tokens must be "substantially noncontrolled," but this is not the same as entirely uncontrolled (1986, 256–262).

[10]This has an interesting implication for cases in which the recipient of consent *ought* to know certain facts. For example, a professionally negligent researcher may be ignorant of well-known risks of an experimental procedure, and so fail to disclose them. Her disclosure is problematic, as we argue later. However, she's not guilty of *fraudulent disclosure* because she is not in a position to invalidate her prospective participant's enrollment decision by way of illegitimate control with respect to the risks of the procedure. She is in no better epistemic position with regards to the information than he is even if she ought to be.

Second, providing or withholding information gives someone *control* over another's decision only when the information is relevant to the decision being made. In the case of consent to research participation the decision is about being in research. Hence, a researcher can control a prospective participant's decision only if she withholds information that could be dispositive of his decision to enroll.

Third, there are several ways in which providing or withholding information can be *illegitimate*. The most important for ascertaining the content of the disclosure requirement is through deception. This can occur when information is misrepresented. For example, a consent form describing the potential side effects of a lumbar puncture might say, "In rare cases, you might experience a transient headache, which you can treat with over-the-counter medications." Such a description would falsely imply that a spinal headache is trivial and will almost certainly not occur. Deception can also occur through omission. For example, not to mention the possibility of a spinal headache—which affects up to a third of people who undergo a lumbar puncture (Ahmed, Jayawarna, and Jude 2006)—would imply to most people that this was not a risk of the procedure. It is natural to expect that a clinician would disclose common, non-trivial risks of a procedure and so natural to infer that the risks disclosed comprise at least all the ones that are common and non-trivial.

Fourth, the ethical concept of fraudulent disclosure is distinct from, though obviously related to, the legal notion of fraud. In particular, it is possible to commit fraudulent disclosure without intending to defraud the victim of anything. For example, a researcher might withhold information she has reason to think is relevant because she benevolently wishes to avoid worrying a potential participant. Despite her benign intention, if what she withholds is dispositive of his enrollment decision, she exercises the kind of illegitimate control that invalidates consent.

Together, these conditions tell us the content of the disclosure requirement. In order to avoid illegitimate control, the person requesting consent must disclose a piece of information if and only if: (1) she knows the information; (2) she has reason to think it is relevant to the potential participant's consent decision; and (3) she judges he would reasonably expect to be told it. Of course, she might be unsure what is relevant to her participant's enrollment decision. In that instance, she ought to start by disclosing all those facts that it would be reasonable to expect would be relevant. Then she should ask whether he would like additional information. In this way, she ensures that the information disclosed comes as close to a participant-specific standard as possible.

Note that it is possible to disclose all the information that one ought but to do so in a way that still exercises illegitimate control. For example, if a researcher explains the risks of a study in English to a potential participant whom she knows only speaks Spanish, this controls the information he receives just as surely as if she did not tell him at all. Similarly, disclosure in scientific jargon may predictably make it impossible for most potential participants to understand what is going on. A researcher ought, therefore, to provide the information in a manner that she has reason to think potential participants are able to understand.

The regulations and guidelines are therefore correct that a lot of information ought to be disclosed to participants. There are a lot of facts about research studies that researchers have reason to think may be relevant to potential participants' decisions and that potential participants would expect to be told.

Our analysis also suggests some directions for improving the content of disclosure. To help researchers avoid inadvertently exercising illegitimate control, we should learn more about participant expectations and so what the disclosure process *actually* communicates to them. Furthermore, since the only cases in which inappropriate disclosure will control participants involve misleading them about facts that would affect their decision, we should learn more about what potential participants *actually* want to know about research studies (Dranseika, Piasecki, and Waligora 2017; Karbwang et al. 2018). Along with those facts that are typically disclosed, we might find that those that are not—such as, the likelihood of study non-completion or the clinical experience and performance rates of those responsible for invasive procedures—are highly relevant to participants' enrollment decisions and so ought to be disclosed (Burger, Schill, and Goodman 2007; Clarke and Oakley 2004; Wertheimer 2014).

Concern about the consent *process* is also warranted. In order to ensure that participants are able to use the information disclosed to them in their decision-making (should they so choose), it should be disclosed clearly, in a familiar language, at an appropriate level of complexity, and so forth. However, these measures alone are insufficient. The data on poor participant comprehension underscores an established psychological finding: humans are predictably irrational (Ariely 2010). Our preferences are

shaped by myriad cognitive biases and misconceptions (Saposnik et al. 2016; Tversky and Kahneman 1974, 1981) and we have difficulty processing unfamiliar or complex information, such as risks and randomization (Flory et al. 2008; Mandava et al. 2012). Potential participants are no more given the opportunity to use relevant information in their decision-making when their deliberative frailties are ignored than they are when a consent form is written at too high a reading level. While we are still learning how to communicate risks, uncertainty, and other complex facts effectively, RECs ought to ensure that evidence-based communication strategies are used in the disclosure portion of the informed consent process (Fischhoff 2005; Morgan et al. 2002). Finally, our analysis implies that the social and cultural context in which consent is obtained can impact what must be disclosed. Take, for example, a blood draw. This is a medically low-risk procedure, and in many cultural settings it is appropriate to treat it as such. But in others, for example where blood has symbolic power, and is believed to be used in harmful practices, like sorcery, it may be important to spell out exactly how participants' blood will and will not be used (Marshall 2007).

The relationship between fraudulent disclosure and illegitimate control explains the normative relevance of what the researcher knows. It also explains an underappreciated normative implication of the data on poor participant comprehension. As just noted, we now know quite a lot about what people do not understand, and so quite a lot about *unsuccessful* communication strategies. Given the purpose of disclosure, these data imply that we risk exercising consent-invalidating control when we continue to use communication strategies that we know do not convey information in an understandable way and when alternatives are available to us.

WHAT IS THE CONTENT OF THE UNDERSTANDING REQUIREMENT?

Our derivation of the disclosure requirement did not require any reference to actual understanding—only about information being understandable. Consequently, one might be tempted to infer that potential participants do not need to actually understand anything in order to give valid informed consent. Perhaps, one might suppose, once we have ensured that the person giving consent is competent, acting freely, and has been presented with all the relevant information, there is nothing else to valid consent.

But such a view cannot be correct: if someone could give valid consent to an act without understanding anything at all about it, then we would not be able to distinguish between him giving consent and him doing something else entirely. If a physician asks for permission to draw her patient's blood and he mishears and thinks that she is asking whether there was bad traffic on the highway, then an affirmative response is not even a token of consent, let alone valid consent to the needle stick. Likewise, if he thinks that she is asking his permission to bill his credit card, then at most he has given her permission to do that, not to stick him with a needle.[11] Even Gopal Sreenivasan, who flirts with the idea that participant understanding of what is disclosed is unnecessary if a clinical trial's risk-direct benefit ratio is favorable, acknowledges that: "Strictly speaking, consent cannot be entirely ignorant. The very act of consent arguably entails a bare minimum of comprehension" (2003).

The minimum content that must be understood is therefore given by what a participant must understand in order for us to make sense of him consenting to the act being proposed, rather than some other act. But this information does not include many of the components of the disclosure requirement, such as—in the research context—the act's risks or the actor's purpose. To see this, suppose you decide to enroll in a trial studying the safety of a novel chemical compound for the treatment of tuberculosis. The researcher proposes that she do X, where X may be drawing blood, administering the experimental drug, or some other act. You could query her: "What are the risks of X?" "Why do you want to X?" We can make sense of the notion that you can agree to X without knowing these facts, since the act of doing X is conceptually distinct from its risks, purposes and so forth. However, it is not possible to make sense of you agreeing to her doing X if you do not know what X is. With regard to X itself, you can only query: "What is X?" That is, "What is it that you are proposing to do?" Without knowing this, you cannot agree to her doing X, you can only agree to something else.

Our analysis of the minimum requirements for understanding also suggests that they constitute upper bounds on what must be understood. Just as we can make sense of someone tokening consent to an act

[11]Note that the question of whether consent is valid in these cases is distinct from the question of whether it is permissible for the recipient of the consent token to proceed. If the physician has no reason to think that she has been misunderstood, then she may have good reason to think that she has been given valid consent, in which case she may be ethically permitted to insert the needle. In this case she would be innocently mistaken about the validity of her patient's consent.

without understanding—for example—its risks or purpose, there are cases in which consent is clearly *valid* and yet the person proffering consent does not understand the risks or purpose. If a researcher has an honest null hypothesis she may not know herself about the risks of an experimental intervention, but we commonly think that people can still agree to receive it. In contexts where it is not the norm to disclose one's purpose (and so it is plausible that the disclosure requirement may be met) valid consent may be given without knowing why the recipient of consent wants it. For example, I can consent to you using my car for an hour without knowing why you need to borrow it. Understanding of risks, purpose, and the like, cannot, therefore, be necessary components of the understanding requirement.

This discussion suggests that the content of the understanding requirement can be broken up into three components. The person giving consent must understand: (1) that he is being asked for consent; (2) how to exercise his right in order to give or refuse consent; and (3) to what he is being asked to consent (Millum and Bromwich 2018).[12] The first component is necessary in order for him to be giving consent, rather than engaging in some other speech act. The second is a necessary condition for someone to be competent to give consent at all (though, of course, not *sufficient* for competence). These two components therefore seem straightforward. The third component is more complex and so needs further analysis.

The profferer of consent needs to understand the act to which he is giving consent, but that act can be accurately described in many different ways. Some of these are very general; for example, "I would like to do something to your body." Others are so complex that neither the recipient nor the profferer of consent might be able to understand them; for example, a description of what is happening to the component sub-atomic particles. What is the right way to describe an act for the purposes of the understanding requirement?

To work this out, we turn to the function of consent. Why does it matter whether someone has given valid consent? It matters because valid consent transforms an act that would otherwise be a rights violation into one which is permissible. It does this by redrawing the duties and permissions of the parties receiving and proffering consent. What the person giving consent needs to understand, then, is exactly how these normative boundaries are being redrawn by the speech act of consenting. This is what it means to understand *what* one is consenting to.

Take a simple example from outside the medical context. Suppose Shannon asks Yusef if she may kiss him. Yusef has a right to bodily integrity that includes a claim against every other individual that they not trespass on his body. As a competent adult, he also has the power to waive this right by giving consent. When he does so, we can redescribe Yusef's claim. Suppose he successfully consents to Shannon's proposal that they kiss. This entails that one specific person (Shannon) no longer has a duty not to kiss Yusef. It does not affect anyone else's duties with respect to Yusef's body and it does not give Shannon permission to do anything other than kissing him (she still may not cut his hair, for example). In brief, then, when Shannon says, "May I kiss you?" and Yusef says, "Yes," Yusef needs to understand that Shannon will now be permitted to press her lips against him.

Notice that Yusef's understanding relies on a great deal that is not explicitly stated by either party. For example, given the context that most of us are probably imagining, Yusef has consented to being kissed on the mouth, cheeks, and neck. But there are definitely places that he has not consented to be kissed. He has also consented to being kissed now, or very soon, but not tomorrow—she would have to get consent again for that. What has been understood here is a matter of what has been communicated. And successful communication involves much more than grasping the literal meaning of the words that are said; it is a matter of what is implied—or *implicated*—given the context and the background norms of communication (Grice 1989).

Thinking about the conditions for successful communication can be helpful in thinking about consent in clinical contexts. When a clinician asks her patient, "Can I draw your blood?" and he agrees, this is effective only because of their mutual understanding of what her request entails. Obviously, he recognizes that by "draw" she means to take some of his blood, not sketch it. But more, in a context of a patient looking for a diagnosis, "drawing blood" is understood to

[12]Cf. Sreenivasan's characterization of the "ultra-minimal" understanding requirement (Sreenivasan 2019). Note that there will be cases in which what must be understood on our view and what must be understood on the interests or inducements view will coincide. For example, when a trial is properly and independently assessed and when it has a favorable risk-direct benefit ratio, Sreenivasan argues that the trial is in the participant's clinical interests anyway, and so the participant need only understand "what it means to consent and a basic description of what they will undergo—injections, for example" (Sreenivasan 2003, 2018). While our view implies that the same information ought to be understood in this unusual case in which participants' interests are assumed to already be protected by other means, the similarity is a feature of the example, not the underlying theory. The implications of the views will diverge in any case where research poses net risks.

involve inserting some sort of thin needle into one or the other arm and the removal of a small quantity of blood. It does not involve the removal of a pint of blood, or the insertion of a needle into his foot. These would require explicit communication to that effect, since—in the treatment context—they are not covered by what is communicated in a request to simply "draw blood." The nurse who said, "But you agreed I could draw blood!" after removing two full pints would be deliberately misconstruing the norms of communication that applied.

OTHER OBLIGATIONS

We have argued that the disclosure and understanding requirements for valid consent are distinct, that the understanding requirement is relatively minimal, and the content of the disclosure requirement—though usually more extensive—depends on what the researcher knows and has reason to think the potential participant would want to know and expect to be told. Our conclusions might seem to permit a very thinly informed consent and thereby give rise to two concerns. One is that they seem to imply that it is permissible to enroll participants into highly risky research even when they do not understand important facts about the research. The other is that they seem to imply that ill-informed researchers do not have the same disclosure responsibilities as their more responsible colleagues. Here, we address these concerns in turn. In each case we show that the concern is legitimate, but that it reveals an additional duty that researchers possess, over and above the duty to obtain valid consent from participants.

Duties of Care

Suppose that Billy is giving consent to participation in a phase 1 clinical trial that implants a neurostimulation device into the brains of people with drug resistant epilepsy. The consent form contains all the relevant information, and the doctor obtaining consent has talked through the procedures, but Billy does not seem to have been engaged—he stared out the window, barely skimmed the consent form, and asked no questions. Billy might have had all the necessary information disclosed to him and he might understand enough that he realizes that he will be giving permission for the surgeons to open up his skull and implant something into his brain. On our account, then, it may look like both the disclosure and understanding requirements for valid consent are met. Still, it may seem wrong to enroll Billy in this study, given that he probably does not understand the serious risks that would be involved. We agree. There are two possible explanations for why.

First, in the case as described, although the right propositional content has been disclosed, it is still possible that the disclosure requirement has not been met. As we noted above, someone can exercise illegitimate control even when she has disclosed everything she should. For example, if the consent form was written in language too complex to expect Billy to understand and the doctor talked in jargon, she would not have fulfilled the disclosure requirement.

However, the consent process could be sufficient to meet the disclosure requirement and still predictably leave participants like Billy not understanding everything that is relevant to their participation decision. The data on participant understanding with which we began suggests that this may be relatively common. In fact, in Beskow and Weinfurt's study, a third of people willing to participate in that biobank research had not understood everything disclosed to them *even after the information was reviewed and they were retested*. Should we allow such people to ignorantly consent to research studies?

Here it is helpful to distinguish two separate functions that the informed consent process can play. The primary function of the informed consent process is to ensure that consent is valid. This function has been the focus of this paper. An important secondary function is to promote good decision-making (Bromwich and Millum 2017; Dickert et al. 2017). Individuals have an interest in making decisions that align with their values. They are more likely to do so when they understand the information that is relevant to their decision. It is therefore possible for someone to understand enough to give valid consent while lacking understanding of facts that would improve her decision-making.

These two functions bear in different ways on the obligations of researchers and clinicians who obtain consent. Because consent involves waiving a right, proceeding on an invalid token of consent violates the person's right. Where consent is needed, obtaining valid consent is therefore a stringent ethical obligation.

The obligation to promote good decision-making is not so stringent. It is good for participants to make better decisions and it is plausible that researchers and clinicians have professional duties of beneficence toward prospective participants (Burt 1979; Emanuel and Emanuel 1992; Katz 2002). It is therefore

plausible that there is a limited professional obligation to promote good decision-making. Insofar as researchers have such an obligation, it will have greater force the more that participants have at stake in a decision about research participation. It will be rare that someone makes a really bad decision by their own lights if they choose to enroll in a study that is very low-risk or that does not deviate significantly from standard clinical care. We should not be surprised, then, that many of the experts surveyed in Beskow and Weinfurt's study had the intuition that it would be permissible to enroll willing participants who had less than perfect understanding of the study. After a thorough disclosure process, these potential participants understood enough to give valid consent to the research procedures. Their failure to understand everything disclosed to them was unlikely to lead to them making very bad decisions given the low risks of the research. By contrast, prospective participants may have a lot at stake if they are deciding whether to enroll in a first-in-human study of a new drug or to undergo deep brain stimulation for a novel indication rather than try an approved therapy for their disease. In such cases, the obligation to ensure good decision-making and therefore to ensure understanding of relevant facts will be much more stringent.

A case like Billy's suggests we should sometimes test participants' understanding. This is useful not only to determine whether they understand enough to waive their rights, but whether they understand enough to make a good enrollment decision. In fact, the more we learn about what *actual* participants struggle to understand, the better equipped we will be to design consent processes for future participants.

Professional Duties to Have Expertise

Turn now to a different type of case that might also seem troubling. Consider again our researcher who is herself ignorant about a serious risk of an experimental drug. Suppose, though, that other experts in the field do know about the risk, since it has been recently reported in several high profile journal articles. She tells the prospective participant about the other risks of which she is aware and he agrees to be part of the study.

Again, there seems to be something ethically problematic about the case. Again, though, we think that it is not a problem with the validity of the consent. The researcher has failed in another professional duty—the duty to acquire and maintain expertise related to her area of specialization. Just as a physician should work to stay abreast of medical developments of relevance to her patients, a researcher should strive to learn about the latest developments in her research area. This is for the sake of both research participants and the quality of her scientific output. Though it is rarely mentioned as such, we think this is well-recognized as one characteristic of virtuous researchers (Grady and Fauci 2016).

IMPLICATIONS FOR CONSENT TO CLINICAL RESEARCH

We have argued that the content of the disclosure requirement and the content of the understanding requirement are distinct. Researchers have a duty to *disclose* all the information that they know, have reason to think is relevant to a potential participant's consent decision, and that they judge such a participant would reasonably expect to receive. In addition, in order for consent to be valid, prospective participants must *understand* that they are giving consent, how to give consent, and what they are giving the researchers permission to do. What does this new account of the informational requirements for informed consent tell us about the challenge with which we began?

Our account of the informational requirements for informed consent suggests that the relatively muted reaction to the data showing poor participant understanding may be justified. Provided that the participants understood that they were being asked for consent, how to give it, and what they were permitting the researchers to do, their understanding was sufficient for valid consent. Provided that the researchers gave the participants a fair opportunity to understand the other considerations that could reasonably be expected to be relevant to their decisions, disclosure may have been appropriate, too. Thus, the number of participants whose consent to research participation was actually invalid may be quite small.

Nevertheless, our analysis does not imply that current practices for obtaining consent to clinical research are unproblematic. To illustrate, consider written consent forms. Studies show that these forms are typically *very* long, exceed the recommended eighth grade reading level, and are formatted as legal or institutional documents (Kass et al. 2011; Paasche-Orlow, Taylor, and Brancati 2003). The problem is not merely that they do not facilitate understanding. It is that their very format communicates something false about the consent process: that it is *not* about understanding or informed decision-making. These

consent forms often look very similar to another set of forms we frequently engage with outside the medical context: terms and conditions. These too are replete with complex legal boilerplate and institutional protections, and are often composed of several pages of dense language in small font. When confronted with these forms, most people sign them or click "Agree" without a second glance (Bakos et al. 2014). Given our well-documented deliberative frailties, is it reasonable to expect potential participants to engage with consent forms for medical research any differently from ones they encounter outside this context? Norms of communications suggest that researchers and RECs are guilty of expecting a different kind of engagement without flagging the difference.

We therefore applaud the recent revisions to the Common Rule that requires that the disclosure process start with "a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research" (HHS, NIH, and OHRP (Department of Health and Human Services National Institutes of Health and Office for Human Research Protections) 2018). Our analysis in this paper implies that this presentation ought to interpret the "key information" as (1) the information that must be understood in order to give valid consent, plus (2) the information that actual prospective participants would consider relevant and expect to be told.

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