Taylor & Francis
Taylor & Francis Group

The American Journal of Bioethics

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/uajb20

Response to Open Peer Commentaries on "Informed Consent: What Must Be Disclosed and What Must Be Understood?"

Danielle Bromwich & Joseph Millum

To cite this article: Danielle Bromwich & Joseph Millum (2021) Response to Open Peer Commentaries on "Informed Consent: What Must Be Disclosed and What Must Be Understood?", The American Journal of Bioethics, 21:7, W1-W5, DOI: 10.1080/15265161.2021.1926581

To link to this article: https://doi.org/10.1080/15265161.2021.1926581

Published online: 21 Jun 2021.

THE AMERICAN JOURNAL OF BIOETHICS
2021, VOL. 21, NO. 7, W1–W5
https://doi.org/10.1080/15265161.2021.1926581

Taylor & Francis
Taylor & Francis Group

CORRESPONDENCE

Response to Open Peer Commentaries on "Informed Consent: What Must Be Disclosed and What Must Be Understood?"

Danielle Bromwich[a] and Joseph Millum[b]

[a]University of Massachusetts Boston; [b]National Institutes of Health

In "Informed Consent: What Must be Disclosed and What Must be Understood?", we reject a dogma at the heart of research ethics (Millum and Bromwich 2021). We demonstrate that the constitutive claim of this dogma—that the content of the disclosure requirement can be derived from the content of the understanding requirement—is false. Despite being enshrined in research ethics regulation, disseminated in every major guidance document, assumed by most bioethicists, and held by many of those sponsoring, overseeing, and conducting human subjects research, it is a view without a coherent justification. As we read the excellent commentaries on our paper, we were heartened to see so many agree with us.

Among those who agree with us that the standard view of the informational requirements for valid consent is false there remain important disagreements about what alternative view is correct. Tom Dougherty and Gopal Sreenivasan propose their own accounts, while other commentators raise challenging cases for us to address. In what follows, we provide three reasons to prefer our view to the alternatives. In doing so, we engage with several important points raised by the commentators. We thank them all for reading and engaging with our work.

FIRST REASON: THEORETICAL FOUNDATIONS

Consider why we need a *theory* of informed consent in the first place. There is something we are trying to explain: valid consent. Valid consent involves someone successfully waiving their rights. At minimum, then, any view that claims that some condition is *necessary* in order for a person to waive their rights, thereby giving valid consent, must be able to explain why. We derive the contents of the disclosure and understanding requirements from an analysis of validity, so we are able to meet this theoretical constraint. However, this is a challenge for Dougherty (2021) and Sreenivasan (2021) because it's unclear how their alternative requirements are connected to validity.

Take Sreenivasan's understanding requirement. When a research study is properly and independently assessed and when it has a favorable risk-*direct* benefit ratio, Sreenivasan holds that prospective participants need only "… comprehend both what it means to consent and a basic description of what they will undergo—injections, for example." (Sreenivasan 2003, 2018) Sreenivasan observes that our understanding requirement looks remarkably similar to his, and he thinks that "… the differences seem decidedly less important than the similarities." (Sreenivasan 2021, 66)

We disagree. First, the similarities are only evident in a very specific set of clinical research studies—those in which participants are better off in the study than receiving clinical care. As one of us argues elsewhere, this is a very small subset of clinical research and not one that has provoked much alarm about participant understanding (Bromwich 2015). So, while our understanding requirement applies to all clinical research, Sreenivasan's applies to very little. Second, even if that were not the case, any similarity would be a feature of the example selected, not something deeper or more generalizable. To see this, return to the theoretical question: what explains *why* consent is valid when participants only understand a minimal amount of information? We have an answer because our requirement is derived from a lengthy analysis of what needs to be understood in order to successfully waive one's rights (Millum and Bromwich 2018). What is Sreenivasan's answer? It is unclear. However, there is some indication that his understanding requirement is grounded in an *interests view*—a view we argued is

CONTACT Danielle Bromwich Danielle.Bromwich@umb.edu Philosophy Department, University of Massachusetts Boston, 100, Morrissey Blvd., Boston, MA 02125-3393, USA

false. When discussing why a participant's consent is valid when they are ignorant of the true risk-benefit ratio of their net benefit trial, Sreenivasan correctly points out that the trial is in their clinical interests anyway, and so their ignorance does "not actually change the trial's risk-direct-benefit ratio." (Sreenivasan 2003, 2017). This implies that the reason why their consent is valid is because they understand enough to protect their interests. Any *interests view* would imply the same. However, this does not mean that our view is essentially indistinguishable from an *interests view*. The difference is evident in any study in which a participant's interests are not protected—that is, in almost every *genuine* case of clinical research. It simply means that our view generates the same verdict as an *interests view* in this case. Of course, Sreenivasan might not hold an *interests view*, but this brings us to the final reason to prefer our view over his: our understanding requirement is grounded in an analysis of validity; his is either grounded in an *interests view* (then it's false) or its ungrounded (then it's ad hoc).

Now, take Sreenivasan's disclosure requirement. While he takes an "explicitly pluralist view" (Sreenivasan 2021, 67) about the function of disclosure, he worries about our monism. He argues that disclosure serves myriad purposes: it "fosters trust," "satisfies individuals' preferences for information," and allows prospective participants to "protect themselves" and "make good decisions" (Sreenivasan 2021, 67). And yet, he says, we think that its only function is the avoidance of illegitimate control.

We agree that disclosure can serve all these functions and more (as we discuss in section 6.1). But only one of these functions is connected to validity. The challenge for those who think that there are additional functions *connected to validity* is, again, to explain why. We explain why avoiding illegitimate control is connected to validity by deriving our disclosure requirement from an analysis of how illegitimate control invalidates consent. We do not see what would explain why consent is vitiated when a researcher fails to meet one of those other duties of disclosure, such as achieving trust or good decision-making.

Dougherty also claims to have an alternative view to ours. He argues that the recipient of consent has facilitative duties "to put the consent-giver in a suitably good position for giving consent," and "if the consent-giver consents because the consent-receiver has breached one of these facilitative duties, then the consent-receiver cannot appeal to the consent to justify how they treat the consent-giver." (Dougherty 2021, 69) These duties include disclosing certain facts.

But there's a problem: Dougherty either cannot explain why breaching these facilitative duties of disclosure invalidates consent or he can but only by relying on facts about control and illegitimacy (i.e., by adopting our view of disclosure). Consider a case in which the recipient of consent fails to facilitate consent but does not exercise control over the profferer's consent decision. For example, suppose that Dougherty's negligent nurse has failed to disclose an important treatment alternative to a patient, but unbeknown to them, their colleague already carried out a thorough disclosure. In this case, a third party has already put the patient in a suitably good position to consent, and so, intuitively, the nurse's failure to recall an important component of the required disclosure does not invalidate the consent. What explains the fact that consent is invalid when the facilitative duty is breached in one case but not the other? We think the natural explanation is that in the redescribed case the withholding didn't succeed in controlling the consent decision. But, if that's the explanation, then Dougherty's purported alternative view seems to collapse into ours: a failure to disclose certain information invalidates consent when it predictably causes someone to give consent (i.e., is controlling) and breaches a duty (i.e., is illegitimate).

SECOND REASON: PRINCIPLED GUIDANCE ON HARD CASES

We want a theory of consent to explain validity, but also guide our thinking about hard cases. If an ethical theory does not give guidance for cases in which we are uncertain about what to do, then the theory is not useful. The second reason to favor our view, then, is that it issues principled guidance. It can do so precisely because it is derived from an analysis of validity.

Dougherty provides the first hard case: "Suppose that in seeking consent to treatment T1, a nurse is obligated to disclose to a patient that T2 is an alternative treatment. However, because the nurse is approaching the end of back-to-back shifts, they are so fatigued that they forget to disclose that T2 is an alternative. This omission causes the patient to consent to treatment T1." (Dougherty 2021, 69). Dougherty thinks that it is intuitive that the patient's consent is invalid. He prefers his view to ours because his implies that result. As an aside, it is not clear that his view does imply this—or not without violating

"ought implies can." After all, the nurse's tiredness causes them to temporally forget T2. How can they be obliged to disclose a fact that they don't have epistemic access to at the time of disclosure?

Our main objection, however, is a methodological one: this is the wrong way to use hard cases in theorizing. What makes this such an interesting case is that it is *genuinely unclear* whether the nurse's failure to disclose T2 invalidates the patient's consent. As Dougherty makes plain, the nurse's actions do not bear the hallmarks of malicious intent or manipulative, deceptive, or controlling behavior, and yet the patient has not been told a piece of relevant information that the nurse—in some sense—knows. It's precisely in cases like this that we need theory, not intuition, to guide us.

So, what does our view say about this case? We agree that the nurse has failed in an ethical duty of care, since they ought to ensure that they take the time and care to disclose relevant information to the patient, such as by using a consent form as a guide to discussion. (Of course, the hospital management also failed in their duties by requiring the nurse to work back-to-back shifts and thereby putting patients at risk from exhausted overworked staff.) However, we do not think that the patient's consent to the treatment they receive is invalid. The nurse did not have access to the information that should have been disclosed at the time of disclosure, their non-disclosure is therefore not voluntary, and it therefore does not constitute control.

A second set of hard cases come from Soled, Dickert, and Blumenthal-Barby (2021). They are interested in whether nudges—"small changes in the architecture of choices that alter people's decisions in predictable ways without forbidding any options" (Soled, Dickert, and Blumenthal-Barby 2021, 63)—invalidate consent. After all, they point out, nudges do not always involve withholding or misrepresenting information.

In brief, we accept that where a nudge does not involve withholding or misrepresenting information it will not violate the disclosure requirement. Non-deceptive nudges are therefore consistent with fulfilling the informational requirements for valid consent. Two cautionary notes are in order here. First, a nudge may not invalidate consent but may be wrongful for other reasons, such as that it constitutes manipulation (Mandava and Millum 2013). Second, what is communicated during a consent process is not reducible to what is literally said or written. For example, consent forms that look like "terms and conditions" may communicate that their content is benign or can be ignored. The mode of presentation may be deceptive due to the norms of communication that are being utilized, even if all relevant propositions are provided.

On the other hand, nudges that are designed to achieve other goals of the informed consent process, such as facilitating good decision-making, might well be desirable because they are autonomy respecting. We therefore agree with the authors that nudges vary in nature, not all invalidate consent, and the manner of disclosure matters as much as its content. We take it that a virtue of our analysis is that it allows us to carefully delineate between those nudges that invalidate consent and those that do not.

We do disagree with Soled et al. on a couple of important points. One concerns intent. We work with an ethical, not a legal conception of fraud (Bromwich and Millum 2015). Whereas the latter typically requires fraudulent *intent*, the former only requires that certain facts be *voluntarily* withheld. Hence, we do not think that "the intent of the nudger … poses a relevant consideration behind what may count as fraudulent and/or consent-undermining disclosure." (Soled, Dickert, and Blumenthal-Barby 2021, 64). We also do not agree with what the authors say about the "stakes of the decision" (Soled, Dickert, and Blumenthal-Barby 2021, 65). We worry that they conflate whether fraudulent disclosure invalidates consent with how bad it is to proceed on an invalid token of consent. Suppose that their Front Door Authorization would entail a minor breach of privacy if consent were invalid (we confess to being uncertain what right is supposed to be waived in this example). Enrolling someone in a Phase 1 oncology trial without consent would involve multiple violations of their bodily integrity. The latter is far worse, even if both result from fraudulent disclosure.

A final hard case comes from Resnik: a case of consent without trust. "Consider buying a new home. You sit down with a realtor and attorney and skim through hundreds of pages of documents full of complex legal jargon that you are asked to initial and sign. It would [be] unreasonable for you to consent to this transaction if all you understood was that you are buying a particular home and you know how to exercise your right to buy or refuse to buy this home, unless—and this is the key point—unless you have [a] great deal of trust in the realtor, the attorney, their employers, and their respective professions to help you make a decision that protects your interests and reflects your values" (Resnik 2021, 62).

We agree that trust may be vitally important in this case. One reason is that warranted trust involves the more knowledgeable parties looking out for the interests and values of the buyer, as Resnik notes. But another is that in this context it is mutually understood that the documents full of legalese do not contain information that is expected to be relevant to the buyer's decision. As we argue in the paper, it is possible to invalidate consent by disclosing all the relevant facts, but in a way that exercises illegitimate control over the consent decision. Just as the realtor would not discharge their duties of disclosure if they were to disclose relevant facts in a foreign language that the buyer could not understand, so they would not discharge them if they disclosed these facts by burying them in the middle of a long and complex document that the buyer is not expected to read. Warranted trust is often a reason for someone to believe that they can safely token consent. When you are justified in trusting your researcher or research facility, you're also justified in believing that no-one is acting in ways that are likely to undermine the validity of your consent, for example, by deceiving you.

THIRD REASON: THE VALUE OF EVIDENCE-BASED HEALTH COMMUNICATION

The final reason to favor our view is it provides a normative foundation for much of the excellent work in evidence-based health communication detailed by Day et al. (2021), McKinney (2021), Porter, Weiss, and Kraft (2021), and Rogers and Johnson (2021). It also helps us prioritize empirical research questions on informed consent.

We distinguish two key functions of the informed consent process. The first is to obtain valid consent—a requirement for most research. The second is to facilitate good decision-making—an ethical aspiration. It is *because* obtaining valid consent is a requirement, not merely an aspiration, that we ought to prioritize the research and implementation of interventions that improve the probability of a successful rights waiver. We therefore agree with Porter *et al* that we ought to learn more about how to make accessible and understandable those facts that need to be understood for valid consent. This will involve engaging with "key stakeholders" (Porter, Weiss, and Kraft 2021, 72), examining practices from other domains in which consent operates successfully (Rogers and Johnson 2021), and learning from a "participant and community" centered approach (Day et al. 2021, 74). We also agree with McKinney that there's a lot to learn about what prospective participants want to know about the research, what they expect to be told, and how to communicate this information in an understandable way. We've outlined a theory of what needs to be disclosed and what needs to be understood in order to obtain valid consent to medical research participation; the value of this empirical work in bioethics is that it shows us how we can achieve this in practice.

DISCLOSURE STATEMENT

The views expressed are the authors' own. They do not represent the position or policy of the National Institutes of Health, the U.S. Public Health Service, or the Department of Health and Human Services.

ORCID

Joseph Millum http://orcid.org/0000-0003-0716-9880

REFERENCES

Bromwich, D. 2015. Understanding, interests and informed consent: A reply to Sreenivasan. *Journal of Medical Ethics* 41 (4):327–31. doi: 10.1136/medethics-2013-101499.

Bromwich, D., and J. Millum. 2015. Disclosure and consent to medical research participation. *Journal of Moral Philosophy* 12 (2):195–219. doi:10.1163/17455243-4681027.

Day, P., D. Satin, R. P. Lennon, and M. Tunzi. 2021. Utilizing community research committees to improve the informed consent process. *The American Journal of Bioethics* 21 (5):73–5. doi:10.1080/15265161.2021.1906997.

Dougherty, T. 2021. The grounds of the disclosure requirement for informed consent. *The American Journal of Bioethics*. 21 (5):68–70. doi:10.1080/15265161.2021.1907000.

Mandava, A., and J. Millum. 2013. Manipulation in the enrollment of research participants. *Hastings Center Report* 43 (2):38–47. doi:10.1002/hast.144.

McKinney, R. 2021. Why have uniform informed consent documents when the research volunteers are so diverse? *The American Journal of Bioethics* 21 (5):59–60. doi:10.1080/15265161.2021.1907001.

Millum, J., and D. Bromwich. 2018. Understanding, communication, and consent. *Ergo, an Open Access Journal of Philosophy* 5 (20201214):45–68. doi:10.3998/ergo.12405314.0005.002.

Millum, J., and D. Bromwich. 2021. Informed consent: What must be disclosed and what must be understood? *The American Journal of Bioethics* 21 (5):46–58. doi:10.1080/15265161.2020.1863511.

Porter, K., E. Weiss, and A. Kraft. 2021. Promoting disclosure and understanding in informed consent: Optimizing the impact of the common rule "key information" requirement. *The American Journal of Bioethics* 21 (5):70–2. doi:10.1080/15265161.2021.1906996.

Resnik, D. 2021. Informed consent, understanding, and trust. *The American Journal of Bioethics* 21 (5):61–3. doi:10.1080/15265161.2021.1906987.

Rogers, B., and L.-M. Johnson. 2021. Informed consent conversations: Neither the beginning nor the end. *The*

American Journal of Bioethics 21 (5):76–8. doi:10.1080/15265161.2021.1907481.

Soled, D., N. Dickert, and J. Blumenthal-Barby. 2021. When does nudging represent fraudulent disclosure? *The American Journal of Bioethics* 21 (5):63–6. doi:10.1080/15265161.2021.1906995.

Sreenivasan, G. 2003. Does informed consent to research require comprehension? *The Lancet* 362 (9400):2016–8. doi:10.1016/S0140-6736(03)15025-8.

Sreenivasan, G. 2021. Varieties of minimalism about informed consent. *The American Journal of Bioethics* 21 (5):66–8. doi:10.1080/15265161.2021.1906999.