Published in final edited form as:

Am J Bioeth. 2019 May ; 19(5): 34–36. doi:10.1080/15265161.2019.1587035.

Understanding as an ethical aspiration in an era of digital technology-based communication: An analysis of informed consent functions

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In their target article, Beskow and Weinfurt (2019) propose that achieving prospective research participants' understanding of the information presented during the informed consent process is an ethical aspiration, rather than a requirement, and that this view may be more reflective of the range of values and considerations expressed by experts involved with research conduct and oversight. We agree that it is more appropriate to view understanding of information as an ethical aspiration than to set a minimum threshold of understanding below which an individual may not be permitted to enroll in a study. This framing of understanding as aspirational is especially important as self-directed, digital technology-based informed consent becomes an increasingly common way for prospective participants to consider study enrollment.

Digital technology-based communication

As digital technology-based communication becomes better integrated into research, text recruitment, e-consent, and other forms of self-directed learning will be compelling methods for researchers to efficiently reach large numbers of individuals across widespread physical locations and assess the efficacy of the informed consent process. Additionally, various types of multimedia and web design features will allow prospective participants to review high-quality information in their preferred format. These improvements in efficiency and quality, however, come at the cost of not having a research team member present to respond to questions in real time and ensure the quality of the informed consent process. Thus, technological tools must be designed in advance to assess outcomes that the research team deems important for an individual to enroll in the study. Understanding is perhaps the key outcome that research teams must decide whether and how to assess, given its historic framing as inherently critical to the informed consent process. Beskow and Weinfurt's work challenges that historic framing and questions whether understanding should be viewed as an ethical requirement, and if not, how it should be integrated into ethical analysis of informed consent.

Against requiring thresholds of understanding

We agree with the assessment that an individual's ability to demonstrate a minimum level of understanding should not be an ethical requirement for study participation. Setting a

threshold for understanding creates a researcher-imposed barrier to participation that may exclude individuals for whom participation would have otherwise been an appropriate choice, given that person's values and priorities. For example, an individual may lack thorough understanding of a study's specific purpose, but may nevertheless view participation in the general type of research as being aligned with their values. Another person may skim over the section of the consent form that describes how data about them will be shared, reasoning that those details are not important to them and would not change their decision to enroll. Or perhaps a patient is not sure how to evaluate the risks of a study, so they seek advice from their doctor about whether participation would protect their interests given what the doctor knows about their clinical history.

These examples emphasize that the informed consent process can achieve a number of goals – including aligning with one's values, allowing decision-making control, and protecting one's interests – outside of simply helping a prospective participant understand the details of the study (Dickert et al. 2017). In what follows, we will examine how understanding particular information relates to different goals, or *functions*, that consent can serve and when it is more or less important.

Three categories of functions

Dickert and colleagues (2017) argue that informed consent serves a range of different functions, some of which may be more or less salient depending on the individual and the research context. When considering how to view an individual's understanding of specific study information, it is helpful to categorize the functions into three groups: (1) those that can be achieved even when all individuals cannot demonstrate understanding of specific information; (2) those that can be fulfilled by activities other than informed consent, even in the absence of understanding of specific information; and (3) those for which understanding of key information is most important and may justify leveraging digital technology to improve communication.

Functions that do not require understanding

Some functions of consent do not require thorough understanding of specific pieces of information. For example, to *demonstrate transparency*, it is not necessary that an individual understands the details of the information presented, but rather that the information is disclosed in an open and honest way that promotes understanding. This is reflected in some interviewee comments regarding specific elements of biobank participation described by Beskow and Weinfurt. For example, in considering whether it is necessary for participants to understand "the blood draw," some interviewees perceived a participant's knowledge that the blood draw would occur as critical, while others perceived understanding the detailed procedures and risks of the blood draw as non-critical (Beskow & Weinfurt 2019, p. X). Rather than framing these responses as divergent views about whether understanding is necessary, it might be more appropriate to describe the former as highlighting the critical nature of *transparency* about study procedures and the latter the non-critical nature of *understanding* of the process.

Promoting trust also falls into this category, as a well-developed consent process has potential to build or maintain an individual's trust in the research team regardless of the extent to which that individual understands the study's details. While trust-building is not the primary goal of the federal regulations governing informed consent, it nevertheless has an important role to play from both a participant and researcher perspective. Similar to the example of transparency, Beskow and Weinfurt interpret their interview data about the element of "study contact information" as reflecting a difference of opinion about whether individuals need to understand this information, but interviewee comments about the importance of knowing "who owns this process" (p. X) could instead emphasize how disclosure of contact information can contribute to trust in the research team.

Functions that can be fulfilled by activities other than informed consent

Other functions, including *protecting participants' welfare interests* and *promoting the professional integrity of researchers*, need not necessarily be addressed within the informed consent process but can be encompassed in other aspects of study design or oversight. Regulations about risk in pediatric research are a paradigmatic example of an oversight mechanism that prevents exposing participants to unnecessarily high levels of risk but is separate from the informed consent process. Similarly, oversight or advisory boards can help protect participants' interests while also requiring accountability from research professionals. In fact, some of Beskow and Weinfurt's interviewees identified the role of these types of protections outside of the consent process in their justifications for not requiring a minimum threshold of understanding in the biobank context (p. X), suggesting that these functions can be appropriately viewed as distinct from informed consent.

Functions for which understanding is most important

One function of informed consent that requires some level of understanding is enabling individuals to make decisions that are *aligned with their values*. However, the aspects of the study that the research team deems important may not align with what an individual participant deems relevant to their decision, as at least one of Beskow and Weinfurt's interviewees noted when raising autonomy concerns in response to the idea of testing understanding: "if they truly have received all the information they needed to make the decision and they have decided, then it isn't my place to step in" (p. X). Therefore, it is important that any measures of understanding are responsive to the values of those who are invited to enroll. To help prospective participants clarify the extent to which their values align with study participation, researchers could propose an empirically derived list of reasons why somebody might or might not want to enroll in such a study (Kraft et al. 2018).

Understanding may also be relevant to other functions, but to a lesser degree. For example, to exercise *control and authorization*, an individual must understand that they have the right to make a decision, free from undue influence. Yet while Beskow and Weinfurt's interviewees seemed to agree about the importance of knowing the existence of the right to withdraw from research, as noted in Table 1 (p. X), they did not require detailed understanding in order to exercise that right.

Conclusion: Leveraging technology to achieve broader goals of consent

As the research community moves toward e-consent and other self-directed tools, this technology offers an opportunity to improve understanding where it is most important and emphasize other goals where it is less so. For example, developing smartphone-optimized tools that utilize principles of user-centered design can improve accessibility and ease of reading for a wide range of individuals. Integrating multimedia, such as audio, still images, and video, into web tools may further support understanding among those who are auditory or visual learners, while also achieving other goals including demonstrating dedication to transparency and building trust among those who may otherwise feel excluded from research. Digital technology also offers opportunities to provide immediate, responsive feedback during the consent process, as has been done in the *All of Us* research program (Kraft & Doerr 2018). As these tools become increasingly common, they can be used to achieve a broader range of outcomes beyond understanding that reflect the spectrum of informed consent's goals, such as decisional satisfaction or values concordance. By considering how technology can help achieve a broader range of goals, researchers can provide a better consent process for their prospective participants that aspires for, but does not require, understanding.

Acknowledgments

This work was supported by the following grants: UL1TR002319 (NCATS, PI Disis; supporting Kraft and Wilfond); Clinical Research Scholars Program (Seattle Children's Hospital and Research Institute, PI Kraft); K01HG010361 (NHGRI, PI Kraft); and K01HG008818 (NHGRI, PI Garrison).

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