COMMENTARY

Dimensions of Research-Participant Interaction: Engagement is Not a Replacement for Consent

Emily Shearer, Nicole Martinez, and David Magnus

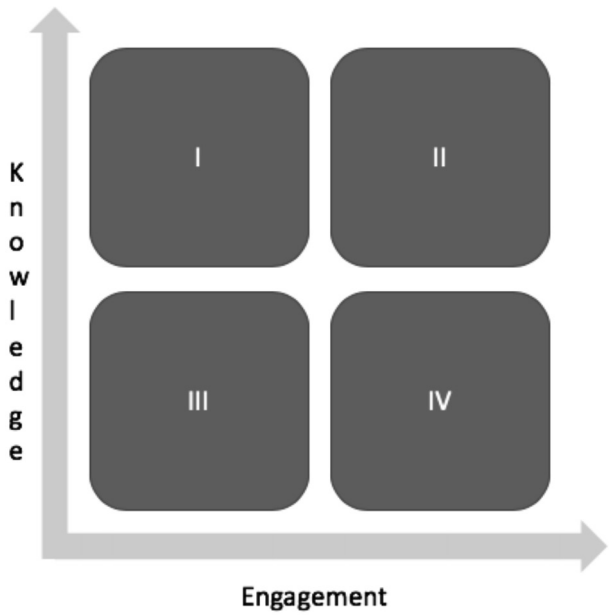
In their article, "From 'Informed' to 'Engaged' Consent: Risks and Obligations in Consent for Participation in a Health Data Repository," Bromley et al. focus on the challenges of traditional informed consent in the setting of participation in health data repositories, in which individuals agree to have their data stored for future research purposes. Because these future purposes are almost always unknown or unspecified at the time of consent, informed consent in the traditional sense, in which participants are fully informed of the purpose, risks, and benefits of the research at the outset of participation, is improbable at best. Drawing on insights from stakeholders within the research field, they propose a new form of consent — *engaged* consent — in which researchers engage participants in an "ongoing relationship" with the repository that can "serve as a substitute or adjunct" to traditional information exchange at enrollment.

Their conclusion hinges on two major assumptions: 1) that such a substitution is acceptable to research participants, whom they acknowledge were absent from their study, and 2) that, even if all parties could agree on the form of said substitution, participant engagement is feasible in practice.

Setting aside assumption 1) for now, attempts to sustain ongoing engagement with participants involved in health data repositories can be difficult. One problem is that strategies for engagement over the long-term may be highly prone to bias, as strategies that work for one population may be disastrous for others. For example, some strategies may be more successful for those who interact with a healthcare system on a regular basis with physicians in whom they trust, compared to patients who lack regular health care. In this case, engagement would be biased towards groups already likely to be advantaged. Retention in long-term research efforts, therefore, may be as difficult as recruitment for research has been historically, with the same ethical issues of preservation of diversity.

Figure 1

Dimensions of research/participant interaction.



The smaller number of studies that have tended to actively engage participants in an ongoing fashion, such as Project Baseline or the National Institutes of Health All of Us Research Program, have tended to do so because the researchers are interested in

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ongoing collection of data in a longitudinal fashion. Thus, engagement is not a replacement for consent, but requires ongoing agreement for participation to continue.

At the same time, most previous studies investigating participants' knowledge of the research they are engaged in suggest it is exceedingly low, even in the best of circumstances.[1] If all research repositories do to maintain engagement is "disclose" information, understanding will be no less an issue for engaged consent than informed consent, but with the added difficulty of needing to achieve this understanding over and over again with each point of contact.

This seems to leave us in a dilemma: What are we left with if participants have neither high engagement, nor high knowledge? If we focus on achieving one, which do we prioritize: high rates of engagement, but low rates of knowledge? Or, conversely, high rates of understanding, but low rates of engagement, as does the traditional model of consent?

We propose that these alternatives can be visualized in a two-by-two schematic (Figure 1), in which one axis represents patient knowledge and the other patient engagement. Using this figure as a guide, it is easy to see that quadrant II (high engagement, high knowledge) is the optimum. Conversely, we can easily see that quadrant III (low engagement, low knowledge), represents the worst possible outcome. What about quadrants I (low engagement, high knowledge, as in traditional consent) and IV (low engagement, high knowledge)?

Interestingly, experience with the All of Us Research Program, in which participants are given "pop quizzes" as a means to assess understanding, indicates participant understanding is high by historical standards. This is done because the All of Us Research Project hopes to collect longitudinal data over time. But do we really want to criticize research repositories that do not have scientific reasons to seek longitudinal engagement, such as egg donation repositories in which a one-time collection is all that is needed? We argue researchers may be ethically justified in following a more traditional view of informed consent, in which understanding, but not engagement, is sufficient (quadrant I) for at least some research.

It is also possible to imagine scenarios in quadrant IV that are ethically problematic. Indeed, though we recognize this to be an extreme example, high engagement with virtually no understanding describes exactly what happened in the Tuskegee studies, in which participants continued to come back year after year but lacked fundamental knowledge of what they were "consenting" to, because they were misled.

In conclusion, it seems unclear whether moving to an "engaged" model of consent leaves us with any fewer problems than traditional informed consent. Indeed, just as traditional informed consent has been difficult to achieve in practice both in terms of understanding and recruitment, so too, may longitudinal engagement, with retention of diverse groups being additionally problematic.

In conclusion, it seems unclear whether moving to an "engaged" model of consent leaves us with any fewer problems than traditional informed consent. Indeed, just as traditional informed consent has been difficult to achieve in practice both in terms of understanding and recruitment, so too, may longitudinal engagement, with retention of diverse groups being additionally problematic. If neither knowledge nor engagement can be achieved in practice, too often we will end up in the least desirable quadrant. Henry K. Beecher acknowledged this difficulty, stating though obtaining true informed consent is demanding, it is nonetheless "essential to *strive* for it for moral, sociologic and legal reasons."[2] Similar to Beecher, we acknowledge that true informed and engaged consent may never be achievable; however, we similarly argue that in general, it is a laudable goal to pursue.

Note

The authors have no conflicts to declare.

References

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