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Attending to the interrelatedness of the functions of consent

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The paper by Dickert and colleagues (2017) is a very significant contribution to addressing the informed consent paradox: Informed consent in research is generally important, but the standard response to the inadequacies of research informed consent of increasing the length and complexity of consent documents has not been successful in improving comprehension and voluntariness (Grady et al. 2017). Dickert and colleagues' overall solution, to first consider the range of potential purposes (or as they label them, functions) of informed consent, is a useful way to reframe how to think about consent. As they point out, focusing on functions can clarify why alternative consent approaches can be justified in settings where using traditional consent forms may be challenging, such as research on medical practices or research in emergency contexts. Further, they note that by identifying the specific functions of consent, this approach can identify when other activities, other than reading and signing a consent form, can achieve the same purpose, and thereby ensure the function is fulfilled even if consent has been modified. Finally, the authors make the very important observation that consent can accomplish some goals related to the relationship between a participant and an investigator, but that there are other purposes related to institutions and the research enterprise.

In fact, because of our enthusiasm for their overall approach, and the hope that their general approach is adopted broadly, we offer the following suggestions for improvement. First, we think that there is an opportunity to pay close attention to the order of the list based on the relatedness between functions and how closely functions fit in with traditional concepts of consent, in order to facilitate others using the list. There is not one clear order, of course, especially because many of the functions are interrelated, but careful sorting can more clearly articulate how some functions may build on or enhance others. Second, we note that *trust* and *integrity* function at both a systems and individual level, which is another aspect of interrelatedness, so we would not explicitly bifurcate the list into two distinct categories, but instead note that a second group of functions can operate at both levels. Third, we think the list requires one addition and one deletion: Respect, a very important purpose of consent, should be included, and the function of "*adhering to regulatory requirements*" should be omitted, as it offers little to clarify a specific approach in a particular context, especially when the regulations are not clear.

Three of Dickert and colleagues' functions most closely track the historical foundation of consent based on respect for autonomy (Faden & Beauchamp 1986), namely, *control and*

authorization, promoting concordance with participant values, and protecting and promoting welfare interests. These three functions operate at an individual level. In fact, the first two are quite interrelated, and even the assessment of welfare interests is often based on values. Grouping these three functions together allows for designing and describing approaches to interacting with prospective participants on an individual level. Operationally, for example, offering specific reasons why some people make different decisions for the same study has the potential to communicate these three functions (Kraft et al. 2017).

A second set of functions includes *transparency, trust, and integrity*, which can function both in the context of the relationship between the participant and investigator, as well as at an institutional and community level. For example, an individual's response to their personal or family participation in research may depend on their perceptions of transparency, trust, and integrity of the particular researchers or the institutions (Platt & Kardia 2015). These perceptions may be influenced by a range of personal, family, and community experiences with healthcare and research (e.g., Boulware et al. 2003). Therefore, we would group these three functions together to support the development of institution-level interventions that appreciate the interrelatedness of participants' and their communities' experiences across healthcare and research. However, we agree with Dickert and colleagues that these three functions are also critically important to public and community perceptions of research.

Furthermore, it was surprising that respect was not included in the list of functions of consent. In fact, Dickert and colleagues discuss respect repeatedly in the second section of the paper when they apply the functions to specific contexts. Nevertheless, we believe it is important to highlight demonstrating respect as a separate function. Actions that demonstrate respect and the perceptions of individuals and communities that they are respected by researchers and research institutions are necessary to foster meaningful research relationships. Respect for persons is not simply about autonomy, or even protecting vulnerable populations, but it should reflect a deep appreciation of the contribution of research participants by expressing gratitude and treating participants as partners. Therefore, one way of assessing the adequacy of a consent process is the extent to which it expresses respect, and well as considering alternative activities that express respect. For example, the concept of respect is central to the rise of community engaged research and patient oriented outcomes research (Ross et al. 2010; Holzer et al. 2014.; Woolf et al. 2016).

Finally, *adherence to regulatory requirements* was included as a function, but the paper does not provide sufficient justification to support its inclusion. First, there is potential tautological aspect of this argument, as depending on regulatory interpretations about consent, consent may or may not be required by regulations. Secondly, Dickert and colleagues only mention this function briefly and do not suggest how it might serve participants beyond simple adherence to regulatory requirements. Thus we do not think that this function will independently guide researchers or IRBs in making decisions that better serve participants.

In summary, we enthusiastically support the underlying approach proposed but we would articulate a slightly different list. There are three functions at the individual level: allowing control and authorization, promoting concordance with patient values, and protecting and

promoting welfare interests. There are four functions at both the individual and community level: expressing respect, providing transparency, promoting trust, and promoting integrity. While some approaches to consent will emphasize some functions and not others, we again note that many of these functions are closely interrelated and interconnected. We also note that these are not simply functions of consent *per se*, but functions of engagement with participants. Consequently, other efforts at both pre-study and post-study engagement can contribute to some of these goals. The conceptual approach offered in the paper provides an ethical rationale for limiting lengthy consent forms for many studies, and offers an opportunity to design and evaluate alternatives to consent forms or even consent, such as individual or community notification, or simple conversations, in some research contexts.

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