

# Study sheds light on importance of comprehension when obtaining biobanking consent

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A study from Vanderbilt's Center for Biomedical Ethics and Society is bringing renewed focus on the concept of comprehension of informed

consent for research purposes.

The study, published recently in the *American Journal of Bioethics*, sought to test the effectiveness of a simplified biobanking consent form. To do so, a multi-institutional study team, led by Laura Beskow, Ph.D., MPH, Ann Geddes Stahlman Professor of Medical Ethics, first developed a measure to assess comprehension. Over the course of the research, they realized that implementing such a measure raised important questions about what should happen when prospective research participants failed to grasp essential information.

The team interviewed a multidisciplinary panel involved in the research to explore in depth their thoughts on [informed consent](#) comprehension, including whether there should be a threshold for "adequate" understanding in biobanking consent and a consequence for not meeting it, and whether the level of risk involved in a study would affect any such threshold.

According to Beskow, the questions highlighted by the results are worthy of urgent debate, both as an ethical matter and as a practical policy matter that researchers will increasingly confront—particularly those using electronic consent and other self-directed approaches that involve less [human interaction](#) and thus require ways to gauge comprehension other than studying staff judgment. At the heart of the debate is whether comprehension should be viewed as an ethical requirement or an ethical aspiration.

The findings have at least three important implications for the research community. First, researchers have an obligation to promote consent comprehension, and significant effort is needed up front to design the best possible consent materials and processes, Beskow said.

"Second, study teams that wish to consider a threshold for what would

constitute adequate understanding may want to collect data on how many potential participants would meet that threshold," she said. "We found that judgments about what is essential for participants to understand may be strongly influenced by such data."

Finally, although [consent comprehension](#) may be viewed by some as an ethical requirement—with the only remaining question being what must be understood—the reflections and realizations of the expert panelists suggest that the combined notion of thresholds with consequences is difficult to put into practice.

"If thoughtful colleagues struggle with how to act upon the notion of understanding as an ethical requirement, perhaps viewing [understanding](#) as an ethical aspiration is more consistent with the range of values and considerations involved in making real-life decisions about research participation," Beskow said.

**More information:** Laura M. Beskow et al. Exploring Understanding of "Understanding": The Paradigm Case of Biobank Consent Comprehension, *The American Journal of Bioethics* (2019). [DOI: 10.1080/15265161.2019.1587031](#)

Provided by Vanderbilt University

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