Sample text that can be used to justify assessing consent understanding

What is the purpose of this document?
Below we provide sample text that you can use in IRB applications or with Sponsors to provide the rationale for, and help justify, administering a validated assessment of consent understanding. Specifically, the Revised UBACC is a 10-item assessment of consent understanding that is administered verbally with a participant or Legally Authorized Representative (LAR), and scored to determine how much information the participant understands about the consent process. We have included key references from the literature supporting this practice.

How can I use the text you provide?
You can use the text to support IRB applications or to justify to Sponsors the rationale for administering the Revised UBACC. For instance, you could use the text below in the "Background", "Rationale", or "Protocol" sections of the IRB application to justify the use of an assessment in your consent process. IRB applications may ask for relevant references, which we have also provided. This information can also be used for Sponsors to justify the rationale for administering an assessment, or other individuals or bodies who require further information on this practice.

You will need to select how you will respond to participants that score below the assessment cutoff point. There are four potential responses highlighted in yellow; we recommend selecting one or more of these responses to include in your informed consent procedures.

In the revised UBACC, the suggested cutoff point is 15 points (out of 20 possible points). You might set a lower or higher cutoff depending on the risk level of your particular study. A simple minimal risk study may not require the same level of understanding as a complex intervention trial. Consider discussing the appropriate cutoff for your study with your research team and IRB.

**You have permission to use the text below verbatim,
or to adapt it as needed for your purposes.**

Suggested text and references to support administering a validated assessment of consent understanding

Researchers tend to overestimate how well participants understand and appreciate informed consent information.[1] To address this problem, we will administer a validated instrument to participants to assess their understanding and appreciation of the informed consent information. The instrument, an adapted version of the University of California Brief Assessment of Capacity to Consent (UBACC), is a validated assessment that is easy to administer and score, and produces trustworthy ratings of consent understanding.[2] The instrument contains 10 items, which will yield scores ranging from 0-20 points.[2] Sample items include "What is the main purpose of the study that was just described to you?" and "If you participate in this study, what are some of the things that you will be asked to do?" As a general rule, scores of 15 points or more demonstrate adequate understanding of consent information. For participants who score below 15 points, we will first try to educate potential participants on the information they have misunderstood. Any responses that are not completely accurate will be discussed, and we will help correct factual errors and improve

understanding.

If, however, the potential participant continues to demonstrate inadequate understanding, we will [select one or more of the following:

a) try to obtain informed consent on another day (if we think their cognitive abilities fluctuate)
b) ask them to appoint a surrogate decision maker or identify a legally authorized representative to consent on their behalf
c) exclude them from the study].

References

1. Montalvo W, Larson E. Participant comprehension of research for which they volunteer: a systematic review. *J Nurs Scholarsh.* 2014;46(6):423-431. doi: 10.1111/jnu.12097
2. Jeste DV, Palmer BW, Appelbaum PS, et al. A new brief instrument for assessing decisional capacity for clinical research. *Archives of General Psychiatry.* 2007;64(8):966-974. doi: 10.1001/archpsyc.64.8.966