Revised UBACC* for Legally Authorized Representatives (LAR) Score Sheet and Instructions

The score sheet will assist you in assessing a LAR's understanding of informed consent information. Read each of the ten questions aloud to the LAR and score them using your best judgement. It is recommended you have the full consent form ready to help you evaluate whether answers are accurate with regard to your trial. We have provided examples of scoring for each item, with examples referring to an imaginary clinical trial of a drug to treat memory disorders.

1. What is the main purpose of the study that was just described to you?	Score
0 = Inaccurate or very incomplete response: For example, "I don't know." or "I can't remember."	
1 = Partially accurate or partially complete response: For example, "you're testing a drug for something."	
2 = Accurate and complete response: For example, "you're testing a drug to treat memory disorders."	
2. What would make someone consider participating in this study?	
0 = Inaccurate or very incomplete response: For example, "I don't know." or "I can't remember."	
1 = Partially accurate or partially complete response: For example, "improve memory"	
2 = Accurate and complete response: For example, "improve memory and attention, help others"	
3. Do you believe this is primarily research or primarily treatment? (Note: If this is a therapeutic trial, the scoring for this question can be adjusted accordingly.)	
0 = Inaccurate or very incomplete response: For example, "primarily treatment"	
2 = Accurate and complete response: For example, "research"	
4. Does someone have to be in this study even if they don't want to participate?	
0 = Inaccurate or very incomplete response: "yes"	
2 = Clearly accurate response: "no"	
5. If someone withdraws from this study, will they still be able to receive regular treatment? (Note: Ordinarily the answer is "yes," however in some cases where no approved treatment is available or all treatment options have been exhausted, consider whether a "no" answer is an appropriate or correct response.)	
0 = Inaccurate or very incomplete response: "no" or "I'm not sure."	
2 = Accurate and complete response: "yes"	
6. If someone participates in this study, what are some of the things that they will be asked to do?	
0 = Inaccurate or very incomplete response: For example, "I don't know." or "I can't remember."	
1 = Partially accurate or partially complete response: For example, at least 1 of the following: answer questions, take 1 pill per day, come to clinic, have a magnetic resonance imaging scan, have blood draws.	
2 = Accurate and complete response: For example, at least 2 of the following: answer questions, bring medications to clinic, magnetic resonance imaging, electrocardiogram, blood draw, urine testing.	

7. Please describe some of the risks or discomforts that people may experience if they participate in this study. (Example: Please describe two serious risks associated with the study.)	
0 = Inaccurate or very incomplete response: For example, "I don't know." or "I can't remember."	
1 = Partially accurate or partially complete response: For example, "A headache."	
2 = Accurate and complete response: For example, "One risk is that they will get placebo and will not benefit. Another is a headache or nausea."	
8. Please describe some of the possible benefits of this study.	
0 = Inaccurate or very incomplete response: For example, "I don't know." or "I can't remember."	
1 = Partially accurate or partially complete response: For example, "I think they said it could improve memory."	
2 = Accurate or complete response: For example, "societal and/or personal benefits, may help memory and attention"	
9. Is it possible that someone who is participating in this study will not benefit from it?	
0 = Inaccurate or very incomplete response: "no"	
2 = Accurate and complete response: "yes"	
10. Who will pay for medical care if someone is injured as a direct result of participating in this study? (Note: Check your consent form for this)	
0 = Inaccurate or very incomplete response: For example, "I don't know." or "I would have to pay."	
2 = Accurate and complete response: For example, "the institution or hospital"	
Total	

Additional scoring instructions:

1. In general, scores of 15 or above indicate that an LAR has understood the study and may have the ability to represent the participant.

2. If an LAR scores lower than 15 points, their current level of understanding should be questioned. If you think they can potentially understand the information, then discussing misunderstood information with them is your best option. Any responses that were not completely accurate should be discussed. Help correct factual errors and improve understanding.

3. If an LAR continues to demonstrate inadequate understanding, then you may need to exclude them from acting as an LAR in this study.

*Adapted from Jeste, D. V., Palmer, B. W., Appelbaum, P. S., Golshan, S., Glorioso, D., Dunn, L. B., . . . Kraemer, H. C. (2007). A New Brief Instrument for Assessing Decisional Capacity for Clinical Research. Archives of General Psychiatry, 64(8). doi:10.1001/archpsyc.64.8.966

See our videos at ConsentTools.org for further guidance.