

Capacity Assessment Checklist for Research Informed Consent

Research Candidate (RC) Name: _____ ADC Protocol ID #: _____
Research Protocol Name: _____
Date of Consent Meeting/Assessment: _____ Time of Day: _____
Protocol Staff Members Present: 1. _____ 2. _____
Participant LAR or Family Present: 1. _____ 2. _____ 3. _____

Capacity Assessment Record

CONSENT DIALOGUE

1-Was protocol presented to/discussed with RC? Yes () No () Other: _____

2-Was protocol presented to/discussed with RC's LAR/family? Yes () No () Other: _____

CONSENT ABILITIES

3-Did RC *make a choice* to participate/not participate in research protocol? Yes () No () Marginal ()
Choice: Participate () Not Participate () Defer Decision () Decision Unclear () Other ()

Briefly explain: _____

4-Did RC show *understanding* of the research protocol and its elements, including risks/benefits of participation?
Yes () No () Marginal ()

Briefly explain: _____

5-Did RC *show reasoning/provide rational reasons* for participation/non-participation in the research protocol?
Yes () No () Marginal ()

Briefly explain: _____

6-Did RC show an *appreciation of the personal risks/benefits* of participation/non-participation in the protocol?
Yes () No () Marginal ()

Briefly explain: _____

CAPACITY /INFORMED CONSENT/ASSENT

7-Was RC competent to consent to participation/non-participation in research protocol?

Yes () No () Other: _____

Briefly explain: _____

8-Was informed consent for research participation obtained from the RC?

Yes () No () Other: _____

Briefly explain: _____

9-If RC unable to consent, was informed consent for research participation obtained from RC's LAR or family?

Yes () No () N/A () Other: _____

Briefly explain: _____

10-If RC unable to consent and LAR/family approved participation, did RC show *assent* to participation?

Yes () No () Unclear () N/A () Other: _____

Briefly explain: _____

Completed by: _____ **Date:** _____

[Signature]