

## Capacity Assessment Record for Research Informed Consent

Research Candidate (RC) Name: \_\_\_\_\_ MAC 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. \_\_\_\_\_  
(Legally Authorized Representative)

### *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]