Assessing Capacity to Consent in Adults Flowchart

Potential research subject has condition or circumstances associated with possible diminished decision-making capacity

Does the study have IRB approval for the inclusion of adults with impaired decision-making capacity?

Yes

Perform IRB-approved decisional capacity assessment outlined in protocol

Impairment found?

No

1. Obtain consent from subject
2. Save results of decisional assessment and signed consent in research records

Yes

Is the study IRB approved for surrogate/LAR consent?

Yes

1. Inform subject of your intent to seek surrogate/LAR consent and document this in research record. Exclude subject if they express resistance or dissent
2. Obtain surrogate/LAR consent
3. Save decisional assessment results, signed consent form in research records
4. **Re-consent subject if they regain cognitive ability to consent, if applicable**

No

STOP

Subject is ineligible. Save results of decisional assessment in research records

No

Notify the IRB ***as soon as possible and within 5 business days***
Present a plan for surrogate consent from a LAR and, if appropriate, a plan to periodically evaluate capacity and re-obtain consent