Consenting Decisionally Impaired Adults in Research
Only allowed when inclusion is necessary to answer the study question
Consent is obtained from a Legally-Authorized Representative (LAR), assent is obtained from the subject

Is the subject DECISIONALLY IMPAILED?

No, but may become impaired during the study

A. Obtain informed consent from subject
B. Have subject identify a research specific proxy as future LAR

Did the subject previously identify a research proxy?

No

Is the study greater than minimal risk?

Yes

Is there prospect of direct benefit to individual subjects?

Yes

Are risks not substantially greater than alternatives AND is study likely to improve understanding of subject population’s condition?

Yes

Meets requirements for consent by LAR 1, 2, or 3

No

Meets requirements for consent by LAR 1 or 3

Enrollment of decisionally impaired NOT ALLOWED

LAR 1: research proxy/court-appointed guardian
LAR 2: general healthcare proxy
LAR 3: next of kin

5/31/2016