Example - IRB Protocol ID: 2019-1148
Please contact Gilmore-Bykovskyi Lab with questions: brainhealteam@medicine.wisc.edu

Registry Capacity to Consent Assessment

Throughout all steps, lack of decision-making capacity will be determined by the study team.

- Regularly check for questions and understanding of key study details.
    - Formal capacity assessment will be triggered by disclosed concerns about memory or cognition, observed challenges following the consent process, and/or demonstrated lack of recollection or comprehension of key study details. In the formal capacity assessment process, study team members will first explain the purpose of a capacity assessment to interested participants and their family members as a tool to check whether participants can independently and safely weigh benefits and risks of research or whether they may need support from someone they trust:
        - "Our team wants to make sure participants are well-supported in making decisions about research participation. Because you expressed (or demonstrated) challenges with your memory (or remembering key details), I just want to make sure you understand the study procedures well, and the risks and benefits."

- Capacity assessment will follow the Evaluation to Consent measure – a widely used reliable/valid procedure designed for this purpose that our team has applied previously. The study team member will clearly explain the study and will use the teach-back method to confirm understanding of the Registry procedures. This method utilizes a series of open-ended questions throughout the process to confirm that the participant understands the Registry and their involvement. These questions include:
    - "What is the potential risk of your participation?
    - What will happen in this study?
    - What if you don't want to continue the intake interview?
    - What if you experience discomfort during the intake interview?"

- If the participant demonstrates understanding of the Registry and their voluntary rights and risk regarding participation, and is interested in participating, a study team member will perform informed consent procedures as outlined in this protocol.

- If the individual is interested in participating but does not demonstrate capacity to consent, the study team will determine whether a legally authorized representative (LAR) who meets criteria in below is present, following the order for LARs as outlined below, in accordance with institutional policy and state law. If the study team feels it is necessary to deviate from the criteria and hierarchy below they will consult with UW Legal Counsel prior to enrollment. The study team will enroll the participant by having the LAR provide informed consent on their behalf.

  1) A research power of attorney may consent to a potential participant's participation in research, if the agent's decision is not inconsistent with the wishes and preferences of the potential participant expressed in the power of attorney instrument.

  2) A court-appointed guardian of the person may consent to a ward's participation in research if the court order includes the power to consent to research. NOTE: A guardian of the estate or guardian ad litem cannot provide surrogate consent.

  3) A power of attorney for healthcare may consent to a potential participant's participation in research, if the agent's decision is not inconsistent with the wishes

and preferences of the potential participant expressed in the power of attorney for health care instrument.
4) If the potential participant has no research power of attorney, guardian, or healthcare power of attorney, then the potential participant's "next of kin" may consent on behalf of the potential participant.
"Next of kin" can provide surrogate consent in the following order: the spouse or registered domestic partner, adult child, parent, adult sibling, grandparent, adult grandchild, or a close friend of the potential participant.

- If the individual is interested in participating but does not demonstrate capacity to consent and has no LAR, or the LAR cannot be identified, the study team will thank them for their time and interest, end the recruitment process, and destroy any identifiable information about the person. In addition, the study team will provide resources for the interested participant on LARs and ensure they have the study team's contact information for any follow-up questions.

- Persons without decision-making capacity will be as involved in the consent process as possible through evaluation of assent by research team members.

- A participant's preference not to participate in the study will operate as a veto to their participation, even if their representative consents to the research.