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

BHC Registry

Assessing interest and eligibility, with subsequent informed consent:

When making first contact with potential participants, study team members will explain the study and assess interest and eligibility based upon the inclusion category the participant best aligns with (e.g. Adult over the age of 40, or Caregiver over the age of 18).

Contact can take place in-person or over the phone, or through a secure online REDCap survey https://redcap.medicine.wisc.edu/surveys/?s=YAD4WYR3L3. All formal capacity to consent assessments and contact with LARs will still be done by phone or in person.

- For caregivers, there will simply be two questions on 1) status as caregiver of someone with a dementia diagnosis, and 2) nature and frequency of contact with the care recipient, in addition to the requirements on age and ability to speak English.
- Throughout all steps of over the phone and in person interviews, lack of decision-making capacity will be determined by members of the study team with training and prior experience in making formal capacity assessments.
    - For the online survey, participants will be asked if they are experiencing memory changes. If they select yes, they will be asked if these changes affect their daily life. If they select yes to both questions, they will be redirected to complete the remainder of the survey over the phone or in person, so that the research team may complete an accurate formal capacity screen.
    - In acute care settings, some participants may be referred on the basis of a dementia diagnosis who already lack decisional capacity as evidenced by documentation and/or the presence of an activated LAR, most often an activated Healthcare Power of Attorney. The study team members will complete all procedures with the appropriate LAR.
    - Consistent with best practice for obtaining informed consent, study team members regularly check for questions and understanding of study details throughout the consent process. If during initial and later contact, a potential participant expresses memory concerns or demonstrates challenges remembering key study details, the study team members will complete a formal capacity assessment.
    - 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 first explain the purpose of a formal 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.
    - A question gauging presence of concerns about memory or cognition that impact daily life is built into the online eligibility, informed consent & intake tool. If the potential participant indicates they are experiencing changes in memory or cognition that impact daily life, the online process will be stopped and a study team member will contact them for a formal capacity assessment.
    - Formal capacity assessment will follow the Evaluation to Consent measure – a widely used reliable/valid procedure designed for this purpose that study team members have applied to previous research. 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:

1. What is the potential risk of your participation?
2. What will happen in this study?
3. What if you don't want to continue the intake interview?
4. 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 member will determine whether a LAR who meets criteria listed below is present, following the order for LARs as outlined. The study team member will enroll the participant by having the LAR provide informed consent on their behalf.
- 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 member 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 member will provide resources for the interested participant on LARs and ensure they have the study team member'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.
- Study team members will make contact with the designated Legally Authorized Representative (LAR) according to the criteria and hierarchy detailed below, in accordance with institutional policy and state law. If the study team members feel it is necessary to deviate from the criteria and hierarchy below they will consult with UW Legal Counsel prior to enrollment.

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."

   - The study team members will again confirm the inclusion category the participant best aligns with (e.g. Adult over the age of 40 not experiencing changes in memory, Adult over the age of 40 experiencing changes in memory, or Caregiver over the age of 18) and conduct informed consent with HIPAA authorization. Signatures have been waived for both the informed consent and HIPAA authorization.
   - Consent procedures will occur before any study procedures, like intake, happen.

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- Consent procedures conducted in person or over the phone will occur in a private location of the person's choice, over the phone or by secure, UW-approved videoconferencing platform (WebEx) in a private location.
- Consent obtained through the online survey is completed within the secure REDCap survey. The informed consent document within the REDCap survey reminds participants of the importance of protecting personal information and encourages participants to complete the survey in a private location if possible. Participants will receive a copy of the informed consent document for their records, sent to their preferred contact method. The study has a waiver of consent with the IRB. After reviewing the informed consent document, participants will be asked to indicate whether or not they agree to participate in the study.
- The study team member will use the informed consent documents as a tool during informed consent, reviewing each component. Potential participants will also have the option to access a copy of the informed consent documents real-time via email with their express permission or by access a live version of the informed consent documents online. Throughout the informed consent process, potential participants will be provided time and opportunity for questions, deliberation, and consultation with family/friends as needed. Once the process is completed the potential participant and/or their legally authorized representative will have the option to give verbal consent to the study procedures and their verbal consent will be documented by the study team member in REDCap. Study participants and/or their legally authorized representative will then be postal mailed or emailed a copy (per their preference and with express permission) of the consent document for their records.
- Participants will also have the option to opt in/out of a mailing provided by the Brain Health Community to stay connected and receive additional information related to the registry and brain health more generally.
- If participant has a visual impairment, the consent form will be provided in large-font and read in its entirety. The study team member will ensure that the potential participant has access to and is using their glasses if applicable. Participants with visual impairment will be offered the large-font consent form and a pre-recorded audio version of the informed consent for their records.
- If a participant has a hearing impairment, they will be provided with a copy of the consent form and will be given ample time to review it before deciding whether to participate. When going through the consent process, the study team member will use a clear, strong voice to speak with the potential participant. The study team member will ensure that the potential participant has access to and is using their hearing aid(s) if applicable.
- If participants are completing online enrollment, they have the option to increase the size of the text on the screen. Participants have the option to enable text to speech on the REDCap online survey, where a voice will read the text on each page.
- We will provide potential participants who decline to participate with the option to speak with the research team about their decision not to participate. Individuals who decide not to participate will be given the study team's phone number as well as email address. If the individual reaches out to the study team, the study team will answer any questions and the information given by the individual will be used to better understand perceptions of the registry, barriers to participation in the registry, and potential improvements. Contact information and any other identifiable information given by the participant will be deleted immediately after the individual makes contact with the study team.