

University of Wisconsin-Madison Consent to Participate in Research and Authorization to Use Protected Health Information for Research

Study Title: Building a Brain Health Community

Formal Study Title: Building a Brain Health Community and Network of Persons Interested in Research Opportunities on Aging, Brain Health and Caregiving

Lead Researcher: Andrea Gilmore-Bykovskyi, PhD, RN, School of Medicine & Public Health. Reach our team at the Brain Health Community Line: 608-800-2899; Email: brainhealthresearch@medicine.wisc.edu

If you are a Legally Authorized Representative (LAR) providing informed consent on someone else's behalf, please read "you" as "your loved one."

Invitation

We invite you to take part in a research study about building an improved network of people who are interested in participating in research about brain health, aging, and caregiving. We are inviting you because you may be interested in participating in this study due to your own experiences with or interest in aging or brain health changes, or because you care for someone who is experiencing changes in memory or brain health.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent."

What is the Brain Health Community study about?

This study has 3 main goals:

1. To establish a long-standing community or network of people in the Greater Madison Area and beyond who are interested in brain health
2. To share information about research opportunities related to aging, brain health, and caregiving
3. To make participating in research easier by connecting people to helpful resources

Why is this study important?

It is very important that people from all backgrounds have opportunities to participate in research. This will help more people benefit from what researchers learn

- Providing people with information about research opportunities and providing resources to support participation can make it easier for more people to take part in research studies
- Funding for this study is provided by the National Institutes of Health

Who can participate in this study?

- You are eligible to participate if you are either:
 - **An adult 40 years of age or older** who is not experiencing changes in memory and is interested in brain health resources and research opportunities.
 - **An Adult 40 years of age or older** who is experiencing changes in memory and is interested in brain health resources and research opportunities.
 - If you are experiencing changes in memory that have led to difficulty making decisions, we will work with your legally authorized representative, for example a power of attorney, to explain the study and obtain informed consent.
 - **An adult 18 years of age or older who is providing care** for someone experiencing changes in memory or brain health (may be a family member or friend).

What will happen in this study?

If you decide to join in this research study, there are four parts to participation:

<i>Parts to Participation</i>	<i>How We Will Help</i>	<i>What We Ask of You</i>
One: Joining the Research Study	<ul style="list-style-type: none"> ▪ We will ask you questions about your current health, living, and caregiving situations. ▪ We can schedule an appointment at a time and location that is convenient for 	<ul style="list-style-type: none"> ▪ This will take 45-90 minutes; you may skip any question that you do not wish to answer or select prefer not to say. ▪ During this step, we will complete the informed consent process.

	<p>you, or you can complete this independently using the online survey.</p>	
<p>Two: Connecting to Resources</p>	<ul style="list-style-type: none"> ▪ If you are interested, we will share information about community services and supports that may interest you. ▪ Some of these services may require additional steps to get started. We can meet with you to provide guidance and support on completing these steps. ▪ We will follow up one month after sending you information about resources to check if you were able to get connected and see if further assistance is needed. 	<ul style="list-style-type: none"> ▪ You have the option to receive a list of resources based on your responses to the questions we ask in the study. ▪ Let us know about potential barriers that might prevent you from getting connected with services. ▪ <i>If you feel you do not want to learn about services, you may opt out of this step and still be a participant in the study.</i>
<p>Three: Learning about Research Opportunities</p>	<ul style="list-style-type: none"> ▪ We will partner with researchers within and outside of the University of Wisconsin-Madison to send you information about research opportunities that may interest you. Information will be sent by our team as well as the researchers we partner with. ▪ These research opportunities are reviewed by an ethics board, such as the University of Wisconsin-Madison Institutional Review Board (IRB) or the equivalent if the study is conducted at another institution.. 	<ul style="list-style-type: none"> ▪ You can decide how to receive information (for example, mail vs email vs phone call). ▪ You can decide if you want to participate in each study.

<p>Four: Annual Update</p>	<ul style="list-style-type: none">▪ We will get in touch with you every year for any updates on your contact information, health and living situations.▪ We will send a semi-annual newsletter to stay connected. The newsletter will include information about ongoing studies, classes or events of interest, or other information related to brain health. You can always opt out of receiving the newsletter with no impact to your participation.	<ul style="list-style-type: none">▪ You can remain a part of the Brain Health Community as long as you meet the eligibility requirements and participate in this annual update.▪ Being a Brain Health Community member is voluntary and you can contact the study team to leave at any time. There will be no penalty to you if you decide to leave.▪ At any point, you may choose to update your preferred mode of communication (email, mail, phone call, or text message) or stop receiving email or text messages by reaching out to the study team at 608-800-2899 or brainhealthresearch@medicine.wisc.edu
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What kinds of health information will you collect from me?

We may ask you questions about your physical and mental health. We may also complete simple screening to determine your capacity to consent to research. All of this information falls under the umbrella of “protected health information,” also called PHI, as it is health information that includes your name or other information that can identify you, like your date of birth.

How is being in this study different from my regular health care?

Though we may ask you questions about your health to match you with research opportunities and resources, we will not provide you with any direct health care services. Given this, this study is not part of your health care.

Do I have to be in the study? What if I say “yes” now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time by letting someone from the research team know. If you decide to unenroll from the study, you will also be asked to share a reason for your decision but are not required to do so.

If you decide to take part of the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health, or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) is indefinite. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect new information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Andrea Gilmore-Bykovskyi at 800 University Bay Dr., Madison, WI 53715 or brainhealthresearch@medicine.wisc.edu

How long will I be in this study?

You will be part of the study for as long as you wish and as long as you continue to meet eligibility requirements. We will get in touch with you every year about updates on your contact information, health, and living situation. Each update will take about 20-30 minutes, and can be performed in-person at a comfortable location of your choice or over the phone.

How will my information be used?

Your information will be used to match you with research opportunities and resources. We will also use information of all study participants to determine patterns in research participation and resource use.

Will being in this study help me in any way?

Being in this study could help you find out information about existing resources that you did not know about previously. However, we cannot promise this will happen.

- Educational information
 - You will receive information about aging and brain health, and about community events hosted by the Brain Health Community.
- Help identifying resources
 - We can connect you to resources such as respite care, childcare, and transportation assistance.
 - We may be able to provide additional assistance to connect to these services.
- Information about research
 - You will get information about research projects that may interest you.
- Helping others
 - Your participation in the Brain Health Community can help improve the future lives of people who experience changes in memory, as well as their families and caregivers.

What are the risks?

There is the possibility of becoming upset in discussing the challenges of aging or brain health changes. If this happens, you may skip questions or end the interview entirely. We will also have a list of resources on hand for you.

There is a risk that your information could become known to someone not involved in this study. If this happens, it could affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job. We have procedures in place to lessen the possibility of this happening (see “How will my confidentiality be protected?” section below).

Completing this study online may minimally increase your risk of your information becoming known to someone not involved in the study. Completing this survey online in a public location may increase the risk of someone seeing your personal information. If possible, when completing the online survey, use a personal computer or mobile device in a private location.

Choosing the option to receive study information by text may minimally increase your risk of information becoming known to someone not involved in the study. If your phone is lost or stolen, someone may be able to see confidential information that was sent over text. To protect your information, please avoid sending any personal, sensitive information over text message. The research team will not send any personal or sensitive identifying information to you over text message.

Will being in this study cost me anything?

If you choose to receive study information by text message and dependent on your telephone plan, there may be costs related to receiving and sending text messages and/or using cellular data. There will be no other cost to you for the interviews and annual updates that are part of this research study.

Will I be paid or receive anything for being in this study?

- When joining the Brain Health Community, you will receive \$10 for completing the initial 45-90 minute conversation.
- Each year when you update your information with us, you will receive \$5.
- Payments will be your choice of either cash or gift card.

How will my confidentiality be protected?

We have strict rules to protect your personal information. We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information that might identify you in a legal proceeding or in response to a legal request, without your consent. If there are publications that result from our work on the Brain Health Community, we will only use group characteristics and not your personal information or name.

All study information will be stored on a secure Department of Medicine server. However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring the safety of this study. We may have to tell appropriate authorities, such as child protective services or adult protective services, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

We are requesting your email address so we can send you information about research studies that might interest you. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact a study team member at 608-800-2899. You do not have to provide your email address to participate in this study.

Who at UW-Madison can use my information?

- Members of the research team
- Collaborating researchers who are a part of UW-Madison
- Offices and committees responsible for the oversight of research

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- Collaborating researchers outside UW-Madison

Will information from this study go in my medical record?

None of the information we collect for this study will go in your medical record.

What if I have questions?

If you have questions about this research, please contact the study team at 608-800-2899. If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

HS IRBs #: 2019-1148

Lead Researcher: Gilmore-Bykovskyj; 608-800-2899

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I will ask you to provide your verbal consent to participate in this study. If you provide your verbal consent, it means that:

- You have read this consent form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

If you are a Legally Authorized Representative (LAR) for the person being invited to take part in this study, you are deciding whether the person can be in this research study. If you provide verbal consent, it means that:

- You believe the person wants, or would want, to be in the study; OR, if you cannot find out if the person wants to take part, you believe that participating in the study is in the person's best interest
- You give authorization for the person's protected health information to be used and shared as described in this form

****You will receive a copy of this form****