

**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 Researchers:** 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](mailto:brainhealthresearch@medicine.wisc.edu)

Maria Mora Pinzon, MD, MS University of Wisconsin- Madison School of Medicine and Public Health, Department of Medicine Line: 608-890-2524; Email: [recordando\\_juntos@medicine.wisc.edu](mailto:recordando_juntos@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." If you are a witness, please review this document to attest that all information has been covered during the informed consent process. Please let us know if you have any other questions or concerns.

## **Invitation**

We invite you to take part in the Brain Health Community Registry to build 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 Registry 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. Because the Registry asks you questions about your basic information and experiences, it is also considered a research study. The words Registry and study may be used interchangeably throughout this document.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the Registry. It also explains how health information will be used for this Registry. 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 Registry. This process is called “informed consent.”

## **What is the Brain Health Community Registry about?**

This Registry has 3 main goals:

1. To establish a long-standing community or network of people 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 and education

## **Why is the Brain Health Registry 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

## **Who can participate in the Brain Health Registry?**

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 Registry and obtain informed consent.

- ***An adult 18 years of age or older who is providing/has provided care*** for someone experiencing changes in memory or brain health (may be a family member or friend).

## What will happen in this Registry?

If you decide to join the Registry, there are four parts to participation:

<b><i>Parts to Participation</i></b>	<b><i>What Will Happen?</i></b>	<b><i>What We Ask of You</i></b>
One: Joining the Registry	<input type="checkbox"/> We will ask you questions about your current health, living, and caregiving situations. <input type="checkbox"/> We can schedule an appointment at a time and location that is convenient for you, or you can complete this independently using the online survey.	<input type="checkbox"/> This will take 30-60 minutes; you may skip any question that you do not wish to answer or select prefer not to say. <input type="checkbox"/> During this step, we will complete the informed consent process.
Two: Connecting to Resources	<input type="checkbox"/> If you are interested, we will share information about community services and supports that may interest you. <input type="checkbox"/> Some of these services may require additional steps to get started. We can meet with you to provide guidance and support	<input type="checkbox"/> You have the option to receive a list of resources based on your responses to the questions we ask in the Registry. <input type="checkbox"/> Let us know about potential barriers that might prevent you from getting connected with services.

	<p>on completing these steps.</p> <p><input type="checkbox"/> 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.</p>	<p><input type="checkbox"/> 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 Registry.</p>
<p>Three: Learning about Research Opportunities</p>	<p><input type="checkbox"/> 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.</p> <p><input type="checkbox"/> 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</p>	<p><input type="checkbox"/> You can decide how to receive information (for example, mail vs email vs phone call).</p> <p><input type="checkbox"/> You can decide if you want to participate in each Registry.</p>

	<p>Registry is conducted at another institution..</p>	
<p>Four: Annual Update</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> We will get in touch with you every year for any updates on your contact information, health and living situations.</li> <li><input type="checkbox"/> 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.</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> You can remain a part of the Brain Health Community as long as you meet the eligibility requirements and participate in this annual update.</li> <li><input type="checkbox"/> Being a Brain Health Community member is voluntary and you can contact the brain health team to leave at any time. There will be no penalty to you if you decide to leave.</li> <li><input type="checkbox"/> 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 brain health team at</li> </ul>

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Lead Researcher: Gilmore-Bykovskyi; 608-800-2899  
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		608-800- 2899 or brainhealthresearch@ medicine.wisc.edu or <a href="mailto:recordando_juntos@medicine.wisc.edu">recordando_juntos@ medicine.wisc.edu</a>
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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. We won’t ask about your or your family’s immigration status, social security number, or if you are receiving benefits. We use many ways to protect your information and keep your privacy, and we describe those in later parts of this document.

### **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 Registry participants to determine patterns in research participation and resource use.

### **How is being in the Brain Health Registry 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 Registry is not part of your health care.

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

No, you do not have to be in this Registry. Taking part in research is voluntary. This means that you decide if you want to be in the Registry. If you decide not to take part, you can choose to leave the Registry at any time by letting someone from the research



team know. If you decide to unenroll from the Registry, 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 Registry, the researchers will tell you about new information or changes in the Registry that may affect your willingness to continue in the Registry.

If you decide not to take part in the Registry, or if you choose to leave the Registry, 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 Registry.
- To take back your authorization, you will need to tell the researchers by writing to either Lead Researcher, Andrea Gilmore-Bykovskiy at 800 University Bay Dr., Madison, WI

53715 or [brainhealthresearch@medicine.wisc.edu](mailto:brainhealthresearch@medicine.wisc.edu) OR [Maria Mora Pinzon at 610 Walnut St, Office #946, Madison, WI, 53726 or recordando\\_juntos@medicine.wisc.edu](mailto:RecordandoJuntos@medicine.wisc.edu)

### **How long will I be in this Registry?**

You will be part of the Registry 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.

### **Will being in this Registry help me in any way?**

Being in this Registry 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 Registry. 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 Registry online may minimally increase your risk of your information becoming known to someone not involved in the Registry. 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 Registry information by text may minimally increase your risk of information becoming known to someone not involved in the Registry. 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.

### **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 Registry 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 Registry 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 Registry. We may have to tell appropriate authorities, such as child protective services or adult protective services, if we learn during the Registry 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 Registry 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 Registry team member at 608-800-2899. You do not have to provide your email address to participate in this Registry.

### **Who at UW-Madison can use my information?**

- Members of the brain health 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 Registry go in my medical record?**

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

### **Will being in the Brain Health Registry cost me anything?**

If you choose to receive Registry 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 Registry.

### **Will I be paid or receive anything for being in this Registry?**

When joining the Brain Health Community, you will receive \$10 for completing the initial 30-60 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.

### **Frequently Asked Questions**

- Who is funding the Brain Health community Registry?
  - Funding for this Brain Health community Registry is provided by the National Institutes of Health via the Research Educational Component of the Wisconsin Alzheimer's Disease Research Center
- What happens if I participate in another Registry or research opportunity that I learned about from the Brain Health community?
  - We will share research opportunities with you and if you decide to participate, you might need to complete another intake form and answer similar questions. Be aware that other studies might have other eligibility than the Brain Health community Registry.

- There could be other risks and benefits in other studies that are not related to the Brain Health community Registry.
- If you have questions about other research studies, there will be different people to contact.
- You can say NO to other research opportunities, and it won't affect your participation in the Brain Health community.
- What happens if I don't want to attend educational events or other events?
  - It is okay, all events are voluntary.

### **What if I have questions?**

If you have questions about this research, please contact the brain health team at either 608-800- 2899 for Dr. Gilmore-Bykovskyi or 608-890-2524 for Dr. Mora Pinzon. If you have any questions about your rights as a research participant or have complaints about the Registry or brain health 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.

I will ask you to provide your verbal consent to participate in this Registry. 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 Registry, and the researchers have answered your questions.
- You want to be in this Registry.
- 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 Registry, you are deciding whether the person can be in this research Registry. If you provide verbal consent, it means that:

You believe the person wants, or would want, to be in the Registry; OR, if you cannot find out if the person wants to take part, you believe that participating in the Registry 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

If you are a witness for the person being invited to take part in this Registry, I will ask you to confirm that the written materials reflect what was discussed with the participant. If you confirm, it means that:

- The information in the consent document and any other written information was accurately explained to, and



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apparently understood by the participant

- The participant's questions were answered, and that the consent was freely given by the participant

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