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

Study Title:	**The Synapse Project**
Study Sponsor:	**National Institutes of Health**
Principal Investigators:	**Barbara Bendlin, PhD** **Bradley Christian, PhD** **Sterling Johnson, PhD**
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Participant Consent

_____ **SYN**_____
Participant name Study ID

Invitation

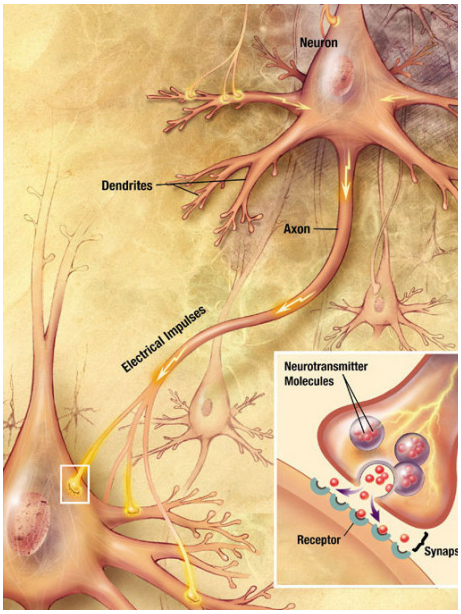
We invite you to take part in a research study about neuronal synapse abundance as shown by PET imaging. We are inviting you to participate in this study because you participate in the Alzheimer's Disease Research Center (ADRC) Clinical Core, the Wisconsin Registry for Alzheimer's Prevention (WRAP) study, or an ADRC-linked study. This study enrolls people with healthy memory function, and those with memory disorders such as mild cognitive impairment or Alzheimer's disease.

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. Data we collect from you will be banked and shared with others for future research and we request your authorization (permission) to use your health information. 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. Once we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent."

IRB Approval Date: 3/28/2023
University of Wisconsin – Madison

Why are researchers doing this study?

The purpose of this research study is to collect brain scans that will provide images of "synapses" and to determine how synapse health is related to Alzheimer's disease progression and pathology. The synapse is located at the end of a neuron (brain cell) and is the point at which an electrical or chemical signal passes between neurons (see photo on the right). Synapses are important for neuronal "communication". As part of this study, researchers will evaluate whether the amount of synapses that can be measured in the brain are related to a person's cognitive function. The ability to image synapses may allow researchers to better understand why some people develop Alzheimer's disease dementia. This study will also examine how synapse health is related to amyloid and tau pathologies (features of Alzheimer's disease). We are doing this research because we have the capability to see the pathology that occurs in Alzheimer's disease, and we want to study synapses in various stages of the disease.



Close-up view of synapses. From: http://www.nia.nih.gov/alzheimers/publication/alzheimers-disease-unraveling-mystery/preface

This study is being done at the University of Wisconsin-Madison (UW-Madison). A total of, about, 120 people will be asked to participate in this study between ADRC, WRAP, ADCP, and clinics. Funding for this study is provided by the National Institutes of Health.

What will happen in this study?

PET SCANS: If you decide to participate in this research study, you will participate in 3-4 Positron Emission Tomography (PET) scans, totaling about 6-8 hours. Approximately two years later, we may invite you to undergo the same scans again under this protocol or a different protocol as funding allows. Two different scanners are used in this study: a PET scanner and a PET/CT (Positron Emission Tomography/Computerized Axial Tomography) scanner. Before participating in the scans, people who can become pregnant will have a pregnancy test. Additionally, your blood pressure will be taken before and after each PET scan you complete, and your blood sugar will be tested (via finger puncture) before an FDG PET scan. PET (and PET/CT) scans use very small amounts of radioactive compounds that allow researchers to image processes in the brain such as synaptic density, amyloid plaques, and tangles. The scans will be performed at the Waisman Center or the Wisconsin Institutes for Medical Research (WIMR). Three scans will be performed: [C-11]UCB-J to detect synapse density, [F-18]MK6240 to detect tangles, and [C-11]PIB to detect amyloid. A possible fourth scan will be performed with [F-18]FDG to detect brain activity. For each scan, an IV (needle) will be placed in a vein in your arm or hand in order to inject the compounds. Before the main scan begins, a

short transmission scan will occur. If you are scanned on the PET/CT scanner, this transmission scan is a CT scan. This transmission scan may need to be repeated. The scan will slightly increase your exposure to radiation. After the UCB-J, MK6240, PIB, or FDG is injected through the IV, you will be scanned for up to 120 minutes. In some cases, the scan duration can be shortened, or may include an “uptake” period where you will sit quietly while the compound is absorbed into your body. When you are being scanned, you should relax and keep as still as possible.

UCB-J, PIB or MK6240 have not been approved by the FDA and are considered investigational new drugs. We have obtained permission from the FDA to conduct research with these compounds. UCB-J is a newly developed compound that binds to (or temporarily sticks to) synaptic vesicle glycoprotein 2A (SV2A) which is expressed in synaptic vesicles throughout the brain. This reveals information about synaptic density. The National Institute on Aging has called SV2A PET imaging a “potentially game-changing biomarker in AD and AD-related dementias”.

Most participants enrolling in this PET imaging study will also be enrolled in other PET imaging sub-studies in our Alzheimer’s disease program. If you have recently participated in other PET imaging sub-studies in our program that collect amyloid and tau scans, then you will be asked to participate in only the UCB-J scan of the four Positron Emission Tomography (PET) scans.

If completing all four PET (or PET/CT) scans, multiple day visits will occur (but will not exceed 4 days). The overall time to complete three PET scans at baseline and potentially 2 years later will not exceed eight hours total (six if only three scans are being done).

If any tracer synthesis failure occurs, we will reschedule the visit to a later date.

After the PET (or PET/CT) scans, please drink extra fluids and empty your bladder to help clear the compounds from your system. The compound will clear your system within a few hours after the injection.

Participants who have not undergone an MRI within the last 12 months in our Alzheimer’s disease program will be invited to have an MRI. This MRI scan should last approximately 60 to 90 minutes and may be added to the schedule on days that PET imaging occurs.

MRI SCAN: The MRI scanner will be used to collect detailed pictures of your brain while you are lying still on the scanner table. You are asked not to eat for at least 4 hours prior to this procedure. Two monitors may be comfortably secured to you to measure your pulse and respiration rates during the scan. During the scans it is essential for you to remain as still as possible so as not to blur the images. Your head may be held in place by foam padding to help you keep still during the scan. The procedure takes up to 120 minutes. We will situate you as comfortably as possible and then run several scans that take 2-15 minutes each. In between scans, you will be able to communicate to the scan operator through an intercom. The MRI will be performed at the Waisman Center, WIMR, or the University of Wisconsin Hospital and Clinics (UWHC) at the University of Wisconsin. Some of the MRI data will be acquired using investigational software and hardware installed in addition to the standard software and hardware. The investigational software and hardware enable newly developed features that are not yet FDA approved for clinical use. Before your scan you will be asked a series of medical history questions to make sure it is safe for you to go into the scanner.

BLOOD DRAW: A blood draw will be done to conduct genetic testing for the APOE4 gene (if you have not already done this) as well as to collect plasma and serum for storage and test for fasting glucose & insulin. The blood draw will require a minimum 8-hour fast. **The purpose for an APOE genetic test is to potentially help researchers gain information about the genetics of Alzheimer's disease and if genetics may affect the brain activation.** Because the clinical utility of the APOE test is not established and because it will not be used as part of your clinical care, you will not be told the results of the test. The result of the test is not useful in treatment. The result will not go into your medical record and will remain confidential. If you have already had APOE testing as part of your participation in related studies in our research program, the test will not be repeated. If you have your blood drawn on the same day as a study visit for another study in the Wisconsin Alzheimer's Program, we could draw a total of up to 140 mL (about 9.5 tablespoons).

NEUROPSYCHOLOGICAL TESTING and QUESTIONNAIRES (if not previously done with ADRC or WRAP): You will have up to 2 hours of memory and thinking tests and questionnaires. These tests will evaluate your memory and other thinking abilities. We may ask you questions about your age, health history, medications, family history, lifestyle, activities, daily function, mood, quality of life, years of schooling and where you live. These will include psychiatric questions about your mental health. Some of the questions included in the questionnaires can be embarrassing or stigmatizing. These tests may be audio-recorded to make sure we accurately document your responses. You may become bored, tired, or frustrated with the difficulty of certain tasks. We will offer breaks to you as needed.

Consensus Diagnosis (if not previously done with ADRC or WRAP): After each study visit, our expert clinician and research staff will meet to review the information we collect about you and give their opinion about your diagnostic status. In this meeting, we review all data from all participants including those with Alzheimer's disease, mild

cognitive impairment, and healthy older controls. We review your diagnostic status after every study visit because your cognitive function might change as you continue to see our research team year after year. We will protect your identity by not using your name or other identifying information during this meeting. You will be contacted if there are unexpected findings of clinical concern.

(Optional) LUMBAR PUNCTURE: A lumbar puncture is a procedure in which a needle is used to remove spinal fluid from the lower back. An experienced clinician will perform the lumbar puncture if you are eligible and meet all the necessary requirements. You will be screened prior to scheduling and again on the day of the procedure. For this fasting (4 hour fast) lumbar puncture, you will be asked to lie on your side with your knees drawn as close to the chest as possible or to sit with your arms and head resting on a table. Your lower back will then be numbed with a drug called Lidocaine. Lidocaine will help reduce any pain that may be caused by this procedure. A thin needle (typically 1/48 of an inch wide, and 3.5 to 4 inches long) will be placed into the space that contains the spinal fluid, which is below where the spinal cord ends. One and a half tablespoons of spinal fluid will be removed, and the needle withdrawn. If you have your lumbar puncture for this study done at the same time as a lumbar puncture for another study, then we might draw up to 25 ml (about 5 teaspoons of fluid) from your back. During any lumbar puncture procedures, if no spinal fluid is obtained on the first attempt, a second attempt will be made after numbing the area with Lidocaine. If the sample of spinal fluid is not drawn correctly, you will not undergo another lumbar puncture. The lumbar puncture procedure will take approximately 30 minutes. After the lumbar puncture is completed, you will lay on your back for about 20 minutes.

(Optional) ORBITAL X-RAY: If you have a history of metal in your eye(s) as a result of past injuries, hobbies, employment, or other life experiences, an x-ray of your eye(s) may be done as a safety precaution. This x-ray is optional. However, if you have a history of metal in your eye(s) and choose not to participate in the x-ray, you will not be able to undergo an MRI.

Procedures for all participants	**Additional procedures, if not recently completed via another study in our program**	
• Vital signs (blood pressure, pulse, weight) • UCB-J scan • Blood draw	• MK6240 scan • PiB scan • MRI scan • Medical History • Physical/Neurological Exam	• Neuropsychological testing • CDR interviews • Questionnaires • (Optional) Lumbar puncture • (Optional) FDG scan

Completion of study procedures will take 1-4 days depending on procedures due and the schedules of participants, staff, and facilities. If you are enrolled in a partnering ADRC, WRAP, or ADRC-affiliated study, some of your study visits may take place at the same time.

Data use and banking

If you are a participant in either the ADRC, WRAP, ADCP, or another ADRC-linked study, researchers will access your ongoing research records from those linked studies to determine if you are eligible for PET scans and to determine how results from these PET scans relate to diagnosis, other medical conditions that can affect memory and thinking, cognitive testing results, other brain imaging such as MRI and PET scans, results from cerebrospinal fluid tests, questionnaires such as sleep and lifestyle surveys, family history of Alzheimer's disease, and *APOE* genetic test results.

Brain images from this study will be stored for future use so that they can continue to be used to better understand memory disorders and dementia. Data banking is explained in more detail later in this form.

How long will I be in this study?

You will be a part of the study for approximately 2 years. You will complete the PET (or PET/CT) scans (one UCB-J scan, one PiB scan, and one MK6240 scan), an MRI (if one from the past 12 months is not available), and a blood draw at a baseline visit and may be asked to come back in approximately 2 years to complete the procedures again. An optional lumbar puncture and FDG PET scan may occur at both time points as well.

The researchers may take you out of the study at any point, even if you want to continue, if

- your health changes, and the study is no longer in your best interest
- you no longer meet the requirements to be in the study

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 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.

How we will use your protected health information (PHI)

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results of procedures done as part of this study
- Data described in the "What will happen in this study?" section above that is collected at prior and future study visits as part of your participation in the ADRC Clinical Core study or WRAP study
- Things you tell the researchers about your health

How long will my permission to use my health information last?

Your authorization for researchers to use your protected health information (PHI) does not have an end date. 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, Barbara Bendlin (see contact information on page 1).

Will being in this study help me in any way?

Being in this study will not help you directly. Your participation in the study may benefit other people in the future by helping us learn more about Alzheimer's disease.

What are the risks?

Risks of PET imaging: The types of PET (or PET/CT) scans you will have are a [C-11]UCB-J brain scan (synapse density), [C-11]PIB scan (amyloid scan), an [F-18]MK6240 scan (tau scan), and an optional [F-18]FDG scan (brain activity). PET compounds use small amounts of radiation to generate images of your brain. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation exposure you could receive from this study is about 12 years' worth of background radiation from natural environmental sources. This amount will not be given all at once, but instead spread throughout the course of the study. This amount is well below the annual limit set by the federal government for research subjects and, to minimize risks, this study uses the lowest possible dose of radioactivity needed to obtain a clear image.

PIB and UCB-J have been used in people extensively worldwide in research with no adverse results reported.

MK6240 is a newer compound but is now being investigated at several institutions worldwide (including the UW) with no related serious adverse results reported in over 6000 scans. In 6378 MK6240 scans completed worldwide, the most commonly occurring adverse events possibly related to injection of MK6240 include headache (occurred in 10 out of 6378 participants, or 0.16%) and dizziness (occurred in 2 out of 6378 participants, or 0.03%). The following occurred in only one participant out of 6378, or 0.02%: abdominal distention (bloating or swelling in the belly area), injection site bruising, arthralgia (joint pain), dysgeusia (altered sense of taste), parosmia (altered sense of smell), insomnia (difficulty falling asleep), and dysuria (discomfort when urinating). All reported adverse events were considered mild in intensity, and resolved shortly after the scan. There is a

risk of mild to moderate pain (e.g. a burning or stinging sensation) with the injection of the compound, which typically goes away after a few seconds.

FDG is considered safe and there has not been a report of an adverse event with its use. Despite this information, there is a risk of having an allergic reaction to the FDG. However, this is very rare. Each compound undergoes rigorous safety testing before injection. There are no known side effects besides radiation, and the compounds will clear the body within a few hours. If you believe you are experiencing adverse symptoms as a result of the PET scans, please let the researchers know.

In general, for PET scans, there is a slight risk of discomfort, bruising, fainting, or infection with the placement or removal of the IV needle used for injection. There are no other known side effects, and the compounds will clear the body within a few hours. If you believe you are experiencing adverse symptoms as a result of the PET (or PET/CT) scans, please let the researchers know.

Reproductive risks: The radiation in this study may be harmful to a fetus or breastfeeding baby. For this reason, if you are pregnant or breastfeeding, you cannot take part in this study. If you can become pregnant, you must have a negative urine pregnancy test on the day of the PET scans. This test will be performed at no cost to you.

Risks of MRI: Some people should not participate in MRI studies. These include persons with shrapnel or certain metallic implants, such as prostheses, or aneurysm clips, or persons with electronic implants, such as cardiac pacemakers or implanted hearing devices. The magnetic field generated by the MR machine can cause a displacement or malfunctioning of these devices. There are no other known risks to body tissues associated with the magnetic field strength used in this study. Some people report anxiety or claustrophobia in the MR scanner since the head must be placed fully inside the scanner tube. If anxiety or claustrophobia occurs, please let us know and we will stop the scan right away. Fatigue and physical discomfort are also possible. The MRI scanner makes a great deal of noise when taking images. You will be fitted with disposable earplugs to reduce the noise volume. These will not eliminate all sound, so that communication with you is still possible.

X-ray exam: If you might have any metal in your body as a result of past injuries, hobbies, employment, or other life experiences, an x-ray of the affected part of your body may be done as a safety precaution before your MRI.

Fasting before MRI, PET, blood draw, or LP: You may be asked to fast before your MRI, LP, and blood draw. Fasting means that you cannot eat or drink anything except water for 4 hours before an MRI, PET, or LP, and for 8 hours before a blood draw. If you are a smoker, nicotine should be avoided for 1 – 2 hours prior to your MRI scan.

You may take your usual medications with water only during the fast.

Risks of the (optional) Lumbar Puncture (LP): Approximately 22-25 milliliters of spinal fluid may be taken during each LP and your body will make up for the loss. During the procedure, you may have temporary pain and discomfort in your back. The most common complication of spinal fluid collection is a headache. When done in most clinical settings, headache occurs in about 10 out of every 100 people who have the procedure. On the other hand, the number of people who get headaches is less than 2 out of every 100 people when a special needle is used. This special needle is used for spinal fluid collection in every lumbar puncture in this study. Drinking a lot of fluids before the spinal fluid collection may also help prevent headaches, and drinks with caffeine may help treat headaches from spinal fluid collections. We will call you the day after your spinal fluid collection to see if you have any side effects. During the spinal fluid collection, about 13 out of every 100 people feel brief electric shocks if the needle touches a nerve. Damage to the nerves that come off the spinal cord can rarely occur. In 1 out of every 150,000 people, bleeding from a broken blood vessel can cause a pocket of blood. If the procedure is performed at the improper level, the needle may injure the spinal cord. A doctor does a physical exam before the spinal fluid collection to make sure you have no neurological conditions that would make spinal fluid collection unsafe.

Lidocaine: Lidocaine is the drug used to numb the lower back before the collection of spinal fluid. There are rare cases of allergic reactions to lidocaine, such as redness and swelling of the skin. If you have had a previous reaction to lidocaine, please inform study personnel right away.

Risks of Blood Pressure Check: The risk of the blood pressure test is minimal. You may experience a few seconds of discomfort as your arm is squeezed by the blood pressure device.

Risks of blood draw and blood sugar finger test: There may be some discomfort, minor bruising, or fainting associated with having blood sampled by venipuncture. There is also a very small chance of infection (less than 1%) at the needle puncture site.

Risks of genetic tests: If you take part in the genetic test, the results may create risks for you. These risks may include emotional upset, insurance or job discrimination, and/or family conflicts from learning unknown information about your parents or blood relatives. To protect you from this, results will be deemed for research only and will not be entered into the medical record or given to you or family members.

In some cases, a new federal law call the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurers and employers to discriminate against you based on your genetic information. But you should know that there are limitations to this law; for example, it does not apply to businesses that employ fewer than 15 people or life insurance, disability insurance or long−term care insurance. An abnormal genetic test could result in denial or much higher rates for life insurance, disability insurance, or long term care insurance if your genetic test results were to become known.

Risks of neuropsychological testing: These tests may be recorded to make sure we accurately document your responses. Recordings will be kept until your tests are scored and will be destroyed following scoring. You may become bored, tired, or frustrated with the difficulty of certain tasks. We will offer breaks to you as needed.

Risks of the (optional) Orbital X-ray: Orbital x-rays involve exposure to radiation, equivalent to 12 days of background radiation (living on Earth for 12 days).

Risk of Breach of Confidentiality: Because your personal information will be retained, there is a small possibility that your information could become available to unauthorized persons. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job. As part of this study, researchers are analyzing data collected during your WRAP or ADRC participation, which includes sensitive information such as memory diagnosis, other medical conditions that can affect memory, cognitive testing results, family history of Alzheimer's disease, and *APOE* genetic test results.

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

You will be paid as follows:

$100 for a UCB-J scan
$100 for an FDG scan (if being collected as part of this research study)
$100 for a PiB scan (if being collected as part of this research study)
$100 for an MK6240 scan (if being collected as part of this research study)
$75 for an MRI scan (if being collected as part of this research study)
$100 for a lumbar puncture (if being collected as part of this research study)
$25 total for blood draw, physical exam, and cognitive testing (if being collected as part of this research study)

You could be paid up to $600 for your baseline participation in this study, and up to $600 for the potential 2-year follow-up. You will be paid even if you decide to discontinue study participation during that visit. Your study partner will be paid $25 for each study visit.

As appreciation for your participation, you may receive a souvenir picture of your brain.

What happens if I am injured or get sick because of this study?

Being injured during this research is very unlikely. However, accidents can happen. If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems contact your regular health care provider.
- Call the Lead Researcher, Barbara Bendlin, at (608) 265-2483 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

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

The PET and MR scans that you will receive in this study are NOT the same as those used to diagnose medical problems. These images, test results and any reports are not entered into your medical record. If you are having symptoms that you believe may be related to an illness or disease, you should see your primary physician, who will then order the types of studies that are required for your medical care.

Possible Discovery of Unanticipated Findings

When brain scans are performed for research, there is a chance of finding something unexpected, given your health history. Unexpected findings can be medically important, or medically unimportant. Findings that are medically important have clear clinical significance and are those for which treatment might be available, and for which we generally know the risks of non-treatment.

You will only be informed of findings with clear clinical significance, which may be revealed during the MR imaging procedure or neuropsychological testing/questionnaires. You will not be informed of findings judged as medically unimportant by our clinicians.

To assist us in interpreting the results of your tests and brain scans, we are also seeking permission to review your medical records if you are or have been a patient at UW Hospital and related clinics. Clinical research staff will have access to your entire UW Hospital and Clinics Medical Record.

There may be benefits to learning such results (early detection and treatment of a medical condition), but there are risks as well (problems with getting insurance or a job or feeling worried about a finding for which no treatment is required or appropriate). Please note that any further clinical care or tests you receive from your doctor might lead to costs incurred by you or your insurance company. The research team and University of Wisconsin will not reimburse you for those additional tests.

You may also choose to have your physician informed of any findings of clear clinical

significance that we report to you by checking the box below. Please note, however, that if you choose to have your physician informed of findings of clinical significance, that report may be placed in your medical records by your physician. We will discuss this with you at the time you are informed.

Please indicate your preference by signing your initials on the appropriate line:

_____ Please inform me and my doctor of findings of clinical significance.

_____ Please only inform me. Do not inform my doctor of findings of clinical significance.

Name of Physician to contact:

_____

City or Clinic:

_____

Additional Contact by Mail, Telephone or Email

Being part of this study means that you will be contacted by study staff before and after each visit. We will contact you to make sure that things are going well for you, and that we have all the necessary details in place for your next visit.

Sometimes study participants prefer to be contacted via email to arrange scheduling or other participation-related details. If that is preferable to you, we will collect your email address. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to get access to email. Please 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 due to a medical emergency, call 911. For non-emergency calls, you may also contact our on-call clinician: call 608-263-6400 to reach the UW page operator and provide the name of the clinician from your last visit. Clinicians involved on this study include Dr. Nathaniel Chin and Dr. Cynthia Carlsson. You do not have to provide your email address to participate in this study. If you agree to share your email address, please provide it here:

Continued Participation

Some persons may progress to the point where they are no longer able to competently make their own decisions regarding medical research. If we suspect you have lost this capacity, we will evaluate this. You can choose now if you want to continue in this study should you lose mental capacity to make this decision later. Please initial one of these options:

_____ Yes, I wish to continue participating even if my decisional capacity becomes impaired.

_____ No, If I become impaired, I wish to stop participating in this study.

If you would like to continue your participation in the study, please write the name of the surrogate you would like to make decisions on your behalf.

_____

Name of Surrogate

How will the researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). 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. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

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 this study.

Others at the UW-Madison and its affiliates, who may need to use your health information in the course of this research:

- UW-Madison regulatory and research oversight boards and offices
- Accounting and billing personnel at the UW-Madison
- Research support services staff at the UW-Madison and its affiliates

Others outside of UW-Madison and its affiliates who may receive your health information in the course of this research:

- U.S. Office for Human Research Protections
- The sponsor of the study, National Institute of Health
- National Alzheimer's Coordinating Center (via Laboratory of Neuroimaging (LONI))

- Cerveau Technologies, provider of the MK6240 compound
- Authorized representatives of the U.S. Food and Drug Administration (FDA)
- Researchers conducting work relevant to dementia or aging who apply to use your coded data
- Other NIH-specified repositories

Will information from this study go in my medical record?
Authorizing the research team to use your PHI means that we can release it only to the people or groups listed above, and only for the purposes described in this form. However, 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, if ALL information that can identify you is removed from the health information collected in this study, then it is no longer PHI, and this authorization will no longer limit how the remaining information can be used. This means the information could be used or shared for reasons other than the ones described in this form such as a research study about another kind of disease. It also means that the information could be shared with researchers working at institutions that are not listed above.

The PET images, MRI images, and spinal fluid samples collected in this study will be coded with unique participant numbers. This coding means no one except study personnel will know your identity and test results. If you participate in a partnering ADRC or WRAP study, researchers from that study will have access to the code and images. Any data that leaves the UW will be coded.

Because some of the study procedures you will undergo will be on the Clinical Research Unit (CRU) unit, your visit to the CRU will be recorded in an electronic medical record. If you receive care through UW Health, this information will be included in your existing medical record. If you do not already receive health care through UW Health, a record will be created for you.

This means that if you receive health care from UW Health, your UW Health providers will see that you took part in a research study. If you are participating in a study as a “normal healthy volunteer” (for example if you might be at risk for Alzheimer’s disease but you don’t have it), the title and purpose of the research study you are taking part in will not appear in the electronic medical record and you will be identified as a healthy volunteer to help protect your privacy.

Some of the results of the procedures or tests performed for the study will be recorded in your electronic medical record and others will not. Results that would not link you to Alzheimer’s disease or results that are not considered sensitive information will be placed in your electronic medical record, such as nursing documentation, results of blood work, and the results of cell counts performed after the Lumbar Puncture.

Study results that would link you to Alzheimer's disease or are considered sensitive information will not be placed in your electronic medical record without your consent. This means that if you have UW Health care providers, they may be able to discover the results of those study tests that are put in your electronic medical record. Because the procedures being done for this study are being done for research purposes only, the study team does not plan on reporting the results back to you unless they suggest a clinical concern. However, because the results of your tests are resulted in your UW Health record, your usual health care providers may follow up with you regarding the tests. If your health care providers discover your results and want to perform additional follow up tests, that is up to them. If your UW Health care provider asks you why you visited a UW Health facility, such as the CRU, and had procedures or tests done, you can simply state that you participated in a research study and do not need to share the details of the study. If you have any questions about what information will go into the electronic medical record created for you, ask the study team for more information.

Certificate of Confidentiality
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed to meet the requirements of the Federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

If you indicate your intent to harm yourself or others, the Certificate of Confidentiality cannot be used to prevent disclosure of that intent to state or local authorities.

Data Banking for Future Unspecified Research
In the future, there may be additional research studies conducted on the data we collect to better understand memory disorders and dementia. By storing your brain images and test results for future study, researchers may be able to develop or test future biological markers. Your brain images will be stored indefinitely in the UW Hospital, Wisconsin Institutes for Medical Research, or VA Hospital in Madison, WI. The data and images may be shared with other researchers at the University of Wisconsin-Madison and outside the University. If you want to have your data removed from the study, you may contact Dr.

Bendlin at the address or phone number listed on page 1 of this form. The brain images will be marked with a code and not your identifiable information.

Sharing Results
As a participant of the Alzheimer's Disease Research Center Clinical Core (ADRC) or the Wisconsin Registry for Alzheimer's Prevention (WRAP), you agree that prior and future results from the main ADRC or WRAP study be made available to this linked study so we can relate the findings to your ADRC or WRAP tests. These prior results include neuropsychological testing (i.e., memory testing), laboratory and genetic tests, surveys, medical history (including family history of AD), MRI brain images, PET brain images, and cerebrospinal fluid results. By signing this consent, you also give permission for us to share the information gathered in this study with the main ADRC or WRAP study, depending on which study you are a participant in.

Data sharing
As the sponsor of this study, the NIH requires that we share the data collected from you with other researchers to increase the scientific value of the data. The Lead Researcher, Dr. Bendlin, will be responsible for deciding how and with whom your data will be shared. Information about you will only be shared in a coded manner so that you will not be directly identifiable. Data sharing may include sending your coded data to a "bank," or repository of brain images, including ones maintained by the NIH. Those repositories will keep your data and may send your coded data to other investigators who apply to use it. Data sharing may also include sharing your coded data with private, for-profit institutions or companies who apply to use it.

By signing this consent form, you agree to the sharing of your brain images and data with qualified UW and non-UW researchers. Other researchers must apply to use the data and may only use it for the approved purposes.

What if I have questions?
If you have questions about this research, please contact the Lead Researcher, Barbara Bendlin, PhD at (608) 265-2483. If you have any questions about your rights as a research subject 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.

Pregnancy Screening

The radiation in PET (and PET/CT) scans may be harmful to a fetus. For these reasons, this study is not approved for the enrollment of pregnant women. You should only take part in this study only if you are certain you are not pregnant. If applicable, a pregnancy test will be conducted prior to each PET visit.

I confirm that I am not pregnant and am not planning on becoming pregnant during this study.

_____ _____

Signature of Participant Date

☐ N/A (Participant is male)

Souvenir Picture

As appreciation for your participation, you may receive a souvenir picture of your brain. If you have questions about your health, contact your primary care provider. You (or your insurance company) will be responsible for costs related to any follow-up care.

_____ Yes, I wish to receive a souvenir picture.

_____ No, I do not want a souvenir picture.

☐ N/A (MRI is completed under a different protocol.)

IRB Approval Date: 3/28/2023
University of Wisconsin – Madison

Consent Form Questions

Do you have to participate in this study?

_____
_____

What would you do if you decided that you no longer wanted to participate?

_____
_____

Do you understand that there is a small risk of harm?

_____
_____

Do you want to participate in the procedures that have just been described to you?

_____
_____

Agreement to participate in the research study
AND
Permission to use and/or disclose my health information

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization 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.

_____
Printed Name of Research Participant

_____
Signature of Research Participant Date

_____
Signature of Person Obtaining Consent and Authorization Date

****

Please provide the research team with your study partner's contact information, so we can contact her/him to schedule an interview about you.

_____
Name (study partner) Phone number

_____
Mailing address

_____
Relationship to Participant

☐ N/A (Participant is a part of the ADRC or WRAP studies.)

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

IRB Approval Date: 3/28/2023
University of Wisconsin – Madison