# The Strengthen Study

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2/28/25

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

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**Study Title for Participants:** The Strengthen Study Phase 2

**Formal Study Title:** Integrated neuromodulations to refine network plasticity and optimize well-being: mental exercise, and transcranial electrical stimulation with temporal interference

**Lead Researchers:** Richard Davidson, PhD; Center for Healthy Minds and Giulio Tononi, MD,PhD; Wisconsin Institute for Sleep and Consciousness

**Institution:** University of Wisconsin-Madison

**Study Sponsor:** The U.S. Department of Defense is funding this study

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## Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

### Why are researchers doing this study?

This study uses two different types of interventions including electrical brain stimulation delivered during sleep, and brief, daily meditation training. We are trying to figure out whether these techniques, either alone or in combination with each other, can positively impact the brain networks that support our ability to think flexibly and to regulate our emotions. You are being asked to participate in Phase 2 of this study. We will use the information we learn here to design a second study aimed at helping adults who are at-risk for suicide.

### What will I need to do in this study?

If you consent to participate in this study, you will be asked to participate in this research study for up to 5-9 months depending on the schedule of visits. This includes 5-7 consecutive weeks when you must be available for in-person study visits. The first visit will be an overnight baseline in-laboratory sleep study. Then you will come in for a half-day magnetic resonance imaging (MRI) visit where you will do computer tasks and an MRI study. You will complete self-report questionnaires online or in person. In addition, you will also complete different surveys on your phone 6 times each day for one week and wear a wrist watch type physical activity tracker during the day.

After this, you will be asked to undergo four weeks of the study interventions. This will include two non-consecutive overnight studies in a sleep lab each of the 4 weeks. You will receive overnight non-invasive transcranial electrical stimulation during the

overnight visits at the sleep lab. During this 4-week period, you will also be asked to participate in brief, daily training via your mobile phone called the Healthy Minds Program (HMP).

After this intervention period, we will have you come back for another MRI visit, computer tasks, questionnaires and ask you to repeat the daily surveys you did on your phone 6 times a day for one week and wear the physical activity tracker.

Two months after the intervention period, we will ask you to complete one short questionnaire either from your phone or computer, or over the phone.

Four months after the intervention period, we will again ask you to repeat the daily surveys for an additional one-week period and repeat some of the previous questionnaires and tasks from home on a phone or computer.

You can find detailed information about the study procedures in the section below called: **If I take part in the study, what will I do?**

## What are some reasons I might – or might not – want to be in this study?

| **You may want to be in this study if you are:** | **You may NOT want to be in this study if you:** |
|---|---|
| ● Comfortable having researchers ask questions about your personality and well-being<br>● Able and willing to complete an MRI scan<br>● Willing to commit to the high number of study sessions—including 2 in-lab study nights per week for four weeks, several day visits and filling out surveys 6 times each day for 3 non-consecutive weeks<br>● Willing to undergo brain stimulation during sleep<br>● Interested in contributing to scientific knowledge even though you won't benefit directly from the study. | ● Prefer not to answer questions about your personality and well-being<br>● Have any metal in your body, are afraid of tight spaces, or otherwise unable or unwilling to complete an MRI scan<br>● Do not have time for the study visits<br>● Are nervous about undergoing brain stimulation or are concerned about unknown side effects of an investigational device<br>● Do not want to meditate<br>● If you are pregnant or plan to become pregnant in the next 6 months |

## Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

# Detailed Information

The following is more detailed information about this study in addition to the information listed above.

## How is research different from health care?

When you take part in a research study, you are helping to answer a research question. Study tests and procedures are not for your health care.

## Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the study research team. They can be reached by email at strengthen@chm.wisc.edu, by phone at 608-890-2960, or you can write to:

Strengthen Study - Phase 2
Center for Healthy Minds
625 W. Washington Ave.
Madison WI 53703

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.

## If I take part in the study, what will I do?

You will be assigned to one of four groups. The intervention will differ for each group, but we would still like to collect the same data no matter which group you are assigned.

Study visits will occur in three places:

1. Center for Healthy Minds (CHM), located at 625 West Washington Avenue, Madison, WI 53703
2. The Wisconsin Institutes and Psychiatric Clinics (WISPIC), located at 6001 Research Park Boulevard, Madison, WI 53719
3. The Waisman Center, located at 1500 Highland Ave, Madison, WI 53705

**Initial visit with surveys (CHM; ~3 hours):** The research team will first ask you to come for a consent visit in which you complete some surveys about your medical

history. The medical history may include some sensitive questions about your mental health and whether you use prescription drugs that impact brain activity. At the visit, you will also be shown a cap of electroencephalography (EEG) electrodes and watch a video about MRI.

**Baseline sleep visit (WISPIC; ~10 hours):** You will then come to spend one night in the WISPIC sleep lab. This will involve wearing a cap of EEG electrodes on your head so we can record your brain activity. You will also wear some other sensors to record physiological activity such as muscle activity (EMG) on your chin, two electrodes to monitor your eye movements (EOG). These recordings are similar to EEG in that they are simply recording your electrical activity but from different parts of your body. This visit will last about 10 hours (~8 hours of sleep). The next morning, we will ask you to fill out a brief survey to tell us how well you slept.

**MRI, behavioral tasks and surveys (Waisman; half day; before and after intervention):**

Before each of these visits, you may be asked to fill out additional online surveys about your emotional health and thinking style. We may remind you to complete the questionnaires. If you are not able to finish them online, you will be able to do so in person.

At these visits, you will perform computer tasks that measure emotion and thinking styles and undergo a magnetic resonance imaging (MRI) scan. You will be in the scanner for about two hours. During the first MRI visit, you will do an initial practice MRI scan in a fake MRI scanner prior to the two-hour scan to ensure you are comfortable with the process.

- The MRI scans take pictures of how the brain is built (structural scans) and the wiring of the brain while you are at rest and performing tasks (functional scans). These scans help us understand how the brain performs these functions in real-time.
- During the functional scans you will complete 2 tasks while we use functional imaging to monitor your brain activity in real time:
  - In one task, you will view pictures that are meant to inspire feelings like sadness, happiness, etc. In some sessions, the pictures might require you to press a button to respond to a question.
  - The second task will assess your brain's responses when you identify a target letter, are presented with feedback that may or may not be accurate, and are given an opportunity to change your mind.

**Daily Surveys for 1 week each at 3 times: week before, week after and 4 months after the intervention:** The week before the study intervention, we will ask you to respond to brief surveys on your phone about how you are feeling in the moment six times each day. You will do this again the week following the intervention and for a third one-week period four months after completing the intervention. This will help us understand how your normal emotionality may have changed after the intervention and

whether any of these changes last. During this time we will also ask you to wear a wrist watch type device that will record your physical activity (body movement) during the day.

**Interventions (4-week duration):** All groups will receive either electrical brain stimulation during sleep, or fake stimulation during sleep. However we will not tell you which you are receiving.

The sleep intervention will take place at WISPIC and the Healthy Minds program will be performed remotely using your phone or a computer.

**1. Healthy Minds Intervention: All groups (5-30 minutes a day; 4 weeks):** You will be asked to install the Healthy Minds Program (HMP) on your phone or visit a website. We will help you set up the study version of the HMP on your phone at your in-person visit. You will spend four weeks using the program to do mental exercises for a few minutes every day and may ask you to use the program specifically before sleep in the sleep lab. This may involve meditation practices or not. You will not be able to choose which group you are in. You will also have to answer a few questions each day about how you are feeling. We may remind you to do the practices. After the study, you can keep using the program if you want by downloading the free mobile app version. We will track when and how much you use the program during the study .

**2. Transcranial Electrical Stimulation with Temporal Interference (TES-TI) intervention during sleep:** TES has been used in research and clinical settings for many years in places around the world. TES-TI is a newer, investigational tool that operates at a much higher frequency than TES. This kind of stimulation can be steered to selective brain regions with more precision than TES, leading to a lower chance of skin discomfort from the electrical current, but less is known about its potential impact on deep brain structures.

**2/wk Groups (~10 hours; twice weekly; 4 weeks):** will come to the WISPIC sleep lab for two nights per week for a total of 4 weeks. These nights will be separated by at least one night.

All groups will have electrical stimulation and EEG during sleep. After each night of sleep, you will complete a few questions about how you felt you slept through the night.

**Two months after the intervention period**: We will ask you to complete one short questionnaire either from your smartphone, computer, or over the phone.

**Final surveys and tasks 4 months after Intervention**: You will be asked to complete online surveys about your emotional health and thinking style. This may include computer tasks that measure emotion and thinking styles.

**Protected health information (PHI) used in this study**

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 tests or procedures done as part of the study (including MRI)
- Things you tell the researchers about your health

## What happens if I say yes, but I change my mind later?

You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. 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.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

If you stop being in the research, already collected data may not be removed from the study database. 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, Richard J. Davidson, Ph.D.

## Will being in this study help me in any way?

Being in this study is unlikely to benefit you directly. The stimulation might not affect you at all, or it might have unknown side effects. However, your participation in this study may help other people in the future by helping us learn more about brain stimulation with meditation and how that affects your emotion and thinking styles.

## What are the study risks?

The main risk of taking part in this study is that your study information could become known to someone who is not involved in performing or monitoring this study. A breach of confidentiality could result in damage to you or your reputation, but the chances that this will happen are very small. Although we will most likely share data with other researchers at other universities and with the study sponsor, when we do this, we remove any information that identifies you (name, date of birth, etc.). All your data is stored with a code, and only study staff will be able to link the code to you.

Risks associated with procedures include:

Interview and Questionnaires: You may feel uncomfortable answering some of the questions, particularly about sensitive health topics. You may skip over these if you want to.

Emotion and Thinking Tasks**:** You may find some of the pictures you view to be mildly upsetting, or you may have difficulty in accomplishing some of the tasks. You may find the tasks boring or frustrating. You are always free to stop the experiment at any point.

Activity Tracker: Wearing an actigraph device, while generally safe, carries minimal risks like potential skin irritation from the band and possible social embarrassment

EEG recordings: EEG is considered a safe and non-invasive way of measuring brain electrical activity. The only risks are some discomfort from preparing the scalp for the recording electrodes, and an extremely low risk of a minor scratch where the scalp is prepared.

MRI Procedure: During the MRI some individuals may experience feelings of claustrophobia, or fatigue and/or physical discomfort from lying still on their back during the scanning session. Some people have also reported tingling or tapping sensations, or muscle twitches in different parts of their body during the imaging procedure. These sensations are not hazardous and should not cause you any discomfort. Occasionally, people who have clasped their hands tightly together during the study have reported a feeling of electrical shock in their hands and arms. This is also not hazardous; however, to avoid any possible discomfort, you should not clasp your hands together during the study. Due to the electromagnetic forces, scans cannot be obtained on people who have pacemakers or metallic surgical implants. You will be screened for such metals before your scans. In the rare case that an item with metal is introduced to the scanner environment it can become a projectile and possibly hit an individual hard enough to cause a significant injury or even death. All staff are trained in MRI scanner safety and in the importance of maintaining a safe environment in the scanner through the prohibition of ferrous magnetic items from the scanner suite. You are free to stop your participation in the MRI at any time if you feel uncomfortable, or for any other reason.

Some of the MRI data will be acquired using investigational software and hardware in addition to the standard MRI technology. The investigational software and hardware enable newly developed features that are not yet FDA approved for clinical use. Although not approved by the FDA, the system is being operated under the FDA safety specifications.

TES-TI procedure: TES-TI is a newer procedure, and less is known about its safety profile. The established risks are the same as those of TES (itching, tingling, burning sensation / discomfort or headache), but we will ask you about any discomfort or changes you notice during the stimulation. There is a small chance that you might see flashing lights for a few seconds, but this is unusual. If we find any reason to suspect

the stimulation may be harming you, we will discontinue your participation in the study. You are also free to withdraw any time.

Healthy Minds Program: The HMP is designed to promote and protect psychological well-being through skills training, which is taught through high-quality guided practices. You will listen to lessons and/or practices and occasionally answer pre and post questions about your feelings using your smartphone or computer. Although these questions are not particularly sensitive, this program is developed and delivered through a third party vendor who collects your responses as well as usage data like date, time, duration, device type, lesson or practice, week, lesson or practice type (awareness, connection, insight, or purpose), and name of lesson or practice. This means you are releasing your information to a third party outside of the research team.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. You should not be or become pregnant or participate in sex that could result in pregnancy while participating in this research study.

## What happens to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We will limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program, and the U.S. Food and Drug Administration. Representatives of the U.S. Department of Defense will have access to research records as part of their responsibilities for human subjects protection oversight of the study.

We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

It is important to note that the Healthy Minds Program is owned by an outside company, Healthy Minds Innovations. When you set up an account for this program, any data associated with this account—including your registration data, such as your name, age, and any other information you share with the program, as well as data on how frequently and how long you use the program and answers you provide to any survey questions—will be accessible to Healthy Minds Innovations. However, they have

entered into a Business Associates Agreement with us that governs their use of the information they collect from you. They are permitted to use your data for any of their efforts related to experience design, software analysis, quality assurance testing, micro-intervention content creation, and product development for the Department of Defense/DARPA grant-related research. They have agreed to otherwise abide by the same rules and laws that we have for protecting your personal information and protected health information (PHI) when it comes to the use or disclosure of your PHI. **We will not provide Healthy Minds Innovations with any information about you beyond the data you provide them with through the Healthy Minds Program. The rest of the data collected during the process of this study will not be shared with Healthy Minds Innovations.** We encourage you to review the Healthy Minds Innovations privacy policy if you have any additional questions or concerns.

Authorizing the research team to use your PHI means that we can release it to the people or groups listed in this form 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 confidentiality protections, we might use information that we collect during this study for other research, or share it with other researchers without additional consent from you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

This study involves sharing of data via open access.

Open access data sharing includes the following:
- Removal of any personal information from the study data that could identify you (like name, birthdate, age, gender, address including zip code, medical record number, etc.). This is called de-identified data.
- Each participant's data will be assigned a code number to distinguish one study participant from another.
- De-identified data from this study are made publicly available (e.g. on a website).
- Anyone can use the data for any purpose in the future.

Participation in this study requires that you agree to this open access data sharing.

**What risks and benefits are associated with open access data sharing?**
Any research data collected from you, excluding your personally identifiable information, could be included in the open access data sharing. However, even with your identifiable information removed, there may be a risk of you being identified. Anybody in the world can have access to information in an open access database. If you tell

other people that you participated in this study, you may increase the chance that someone will be able to link your data to you.

We do not know how likely it is that your identity could become re-connected with information shared through open access. As of today, we believe there is a low risk that most de-identified study data could be used to re-identify you. However, data that cannot be used to identify you today could be used to identify you in the future.

If you decide to withdraw from the study after consenting to open data sharing, we will not have any way to know who has already used your data before you withdrew and will not be able to prevent continued use of your data.

There is no direct benefit to you from placing your data in an open access database. If you agree to open access data sharing, this will help a wider range of researchers make discoveries that may help others in the future.

**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. The researchers are not required to release health information to you if it is not part of your medical record.

**Will I receive the results of research tests?**
The questionnaires you will complete in this study may show that you are experiencing symptoms of emotional distress such as depression/suicidal thoughts/anxiety. We are using the questionnaires only for research, not to diagnose mental health issues. We will not tell you the results. If you are experiencing emotional distress, you should contact your physician or other health care provider, such as a mental health professional. No treatment, therapy, or medical care is offered in this study. However, if the questionnaires show that you are experiencing suicidal thoughts, we may ask you to speak with a clinician in order to assess risk. If we think you are at high risk, we will call 988, 911 or the local authorities where you are located.

When an MRI or sleep studies are done for research, there is a chance of finding something unexpected. In this study, we will tell you about any findings of clear clinical significance that may be discovered during the imaging procedure or sleep study, but you will not be informed if there are findings of uncertain clinical significance. In the case of a detected finding of potential clinical significance, we will contact you.

## Can I be removed from the research without my agreement?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- signs of any adverse reaction or significant discomfort from the stimulation

- you do not follow the study rules or no longer meet the requirements to be in the study
- the study is stopped by the sponsor or the researchers

## What else do I need to know?

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.

**Will I receive anything for participating?**

If you agree to take part in this research study, we will pay you up to $2,440 for your time and effort. Due to UW-Madison limitations on payments, we are only able to provide payment for this study to individuals who are United States citizens or permanent residents (green card holders). Payment will be provided either via a reloadable debit card . If paid via a debit card, you will receive the debit card during your first in-person visit. Additional funds will be loaded onto the debit card at various points, depending on the parts of the study you complete.

Below is the compensation amount by timepoint and task for this study:

| Activities | Compensation amount per activity | Total compensation amount | |
|---|---|---|---|
| | | | 2/wk Group |
| **Screening** | | | |
| Web screen and phone screen | $0 | | $0 |
| **Baseline activities (up to $480)** | | | |
| In person consent, cap intro and MRI simulation | $50 | | $50 |
| Baseline sleep study | $150 | | $150 |
| Baseline MRI with tasks | $150 | | $150 |
| Baseline assessments | $50 | | $50 |
| Baseline 7-day EMA and activity tracker | $80 | | $80 |

| | | | |
|---|---|---|---|
| **On Study ( 2/wk Group: up to $1,480)** | | | |
| Smartphone activities: mental exercises and in-app questions | $70 per week | | $280 ($70 x 4 weeks) |
| Sleep Study | $150 per visit | | $1,200 ($150 x 8 visits) |
| **Post-intervention (Up to $280)** | | | |
| Post-intervention MRI with tasks | $150 | | $150 |
| Post-intervention assessments | $50 | | $50 |
| Post-intervention 7-day EMA | $80 | | $80 |
| **Follow-up visits (up to $200)** | | | |
| 2-month follow-up assessment | $20 | | $20 |
| 4-month follow-up assessments | $50 | | $50 |
| 4-month follow-up 7-day EMA | $80 | | $80 |
| Bonus for completing all activities | $50 | | $50 |
| **Total** | | | **$2,440** |

If you leave the study early, you will receive payment for the portions of the study you completed.

If you are determined to be ineligible for the study during the baseline sleep lab visit, you will receive $50 for your time and effort in addition to being paid for the visits completed.

Researchers may develop products from the information you provide for this study. Some of these products may have commercial value. If the research team or others use your information to develop products of commercial value, you will not receive any profits from products created from your information.

**Permission to communicate about the study by email**
We requested your email address so we can communicate with you about the study, such as scheduling in-person study visits, payment, or to share findings from the research. 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 **608-890-2960.**

We also requested your cell number so we can text you if we need to communicate any urgent scheduling issues. You do not have to agree to receive texts to participate in this study. Please indicate your choice below.

- **Yes**, you may use text messaging to contact me for this study.
- **No**, **I do not** want to be contacted by text message.

**How many people will be in this study?**
We expect about 70 people will be in this research study.

**Who is funding this study?**
This research is funded by the U.S. Department of Defense (DoD)

**Financial Interest Disclosure:**
A member of this research team has a personal interest in or might profit financially from the results of this study. This is called a "conflict of interest." The University of Wisconsin-Madison manages conflicts of interest so that they do not affect study participants or the quality of the data collected. We are telling you about the conflict of interest in case it affects whether you want to take part in this study.

**Will my data be used for future research?**

This study is collecting data from you. We would like to make your data available for other research studies that may be done in the future. The research may be about emotion and thinking patterns, similar to this study. However, it could also be about other types of research. Because data from this research study can be useful for many different kinds of research, organizations like the National Institutes of Health (NIH) have created large databases that collect data from research studies. We will put data from this study in a public database or in other public scientific resources to make the information broadly available. We cannot predict how this information will be used in the future. Because it can be used for many kinds of research, your information may be used for research that you disagree with or would not choose to be involved in. These studies may be done by researchers at this institution or other institutions, including commercial entities. Your data may be shared with researchers around the world. Our goal is to make more research possible. We plan to keep your data indefinitely. To get your data, future researchers must seek approval from this institution and review by an IRB may be required.

Your name and identifying information will be removed from any data you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data.

We will do our best to protect your data during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that people who are not supposed to might access your data. In either case, we cannot reduce the risk to zero.

Participating in this study means you agree to share your data. You can change your mind later, but researchers might still use your data if they have already been shared. If you do not want your data used for other research studies, you should not participate in this study.

**Future Contact:**
Are you interested in being contacted about future opportunities (e.g. research studies, focus groups, media requests) or to address questions or concerns you may have about the study? If yes, only your name and contact information (e.g. phone number and address) will be maintained in our contact list, separate from your study data. You do not need to join our contact list to be in this study.

- **YES,** I would like to be contacted in the future.
- **NO, I do NOT** want to be contacted about future opportunities.

## Agreement to participate in the research study

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.

| | |
|---|---|
| Signature of participant | Date |
| Printed name of participant | |
| Signature of person obtaining consent | Date |
| Printed name of person obtaining consent | |