STUDY TITLE: Preparing for the Prevention of Huntington's Disease (PREVENT-HD)

ICF VERSION DATE: 06/20/2024

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Research Subject Consent Form
and
Authorization to Use and/or Disclose Identifiable Health Information for Research

TITLE OF THE STUDY: PREVENT-HD (Statistical disease modeling and clinimetrics to prepare for preventive trials in Huntington Disease.)

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INVITATION

You are invited to take part in a research study about Huntington Disease (HD) because you have the gene causing HD or because you are a healthy control. A healthy control is a person who does not carry the genetic mutation that causes HD. Participants in this study must be 18 years-old or older and may or may not have the gene causing HD. If you choose to participate, activities that you complete as part of this study may include: a clinical interview, questionnaires about your mood and health, tests assessing your cognition, brain scans, blood and/or saliva collection and lumbar punctures. Your involvement will consist of two in-person visits over the next 1-2 years, with remote assessments done as needed to reduce participant burden. Some participants may be asked to return within 8-12 months of their baseline visit. This is due to a request from the study's sponsor (the National Institute of Health) to accelerate study enrollment and accommodate as many study visits as possible.

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 how you think, feel, and behave. Willing to give blood and other biological samples for research tests. Willing to participate in the study for a few years. Interested in contributing to scientific knowledge even though you won't benefit directly from the study.	Want to be in a study that might help improve your own health Are unable to give a blood sample or a brain fluid sample. Are unable to obtain a brain scan possibly due to having metal in the upper body. May not have time to complete all parts of the study including up to 2 in-person visits over the next few years.

Important things to know:

1) **Taking part in research is voluntary. You can choose not to be in this study or stop at any time.**
2) **If you decide to stop or not be in this study, your choice will not affect your healthcare or any services you have or will receive. There will be no penalty to you. You will not lose medical care or any legal rights.**

WHAT IS THE PURPOSE OF THIS STUDY?

This study is designed to look at a person's body, brain, and behavior to better detect early Huntington Disease (HD) before they experience changes in motor abilities (e.g., physical movement) and/or any loss of function. Now that experimental treatments are being conducted to slow progression or delay the onset of HD, we need to determine when treatments should begin and how we can show that a new treatment is working in people before they receive a motor diagnosis of HD. Specifically, we want to investigate whether measuring your blood and spinal fluid can reveal early changes of HD before you have symptoms that decrease the quality of your life.

This study is being done at University of Wisconsin-Madison (UW-Madison). A total of about 258 people will participate in this study.

Funding for this study is provided by the National Institutes of Health. This means that the University of Wisconsin-Madison is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team has or will receive a direct payment or increase in salary from NIH for conducting this study.

HOW IS RESEARCH DIFFERENT FROM HEALTH CARE?

When you take part in a study, you are helping to answer a research question. Test results will not be used for your health care. This is not a treatment study.

WHAT WILL HAPPEN IN THIS STUDY:

You will be asked to complete 2 in-person visits over the next 8-24 months. You will also have to opportunity to complete some assessments remotely as needed, to help reduce the length of your onsite visit. This study has three parts: clinical assessment, brain scan, and biomarkers (blood draw, lumbar puncture). If you are eligible to participate, you will be invited to complete all three parts. These data are critical for developing methods for preventive clinical trials among people with the HD gene mutation. If your research visit includes a lumbar puncture, your visit may be a 2-day visit and may range from 3-6 hours each day. By completing some items remotely, you make reduce this timeframe onsite. You may also be asked to complete some items remotely in the event that items are skipped or missed during your onsite visit.

The following timeline shows how your visits in this study might take place:

Table 1. Study Visit Summary & Timeline		
	Baseline	Follow-Up (approx. 8-24 months)
Clinical assessments	X	X
MRI scan	X	X
Lumbar puncture	X	X
Wearable	X 1 month	X 1 month

Procedures

When you arrive, we will discuss all of the details of this study with you and review this consent form. You will have the opportunity to ask any questions you may have about this study.

Clinical Assessments: These are activities and/or interviews to help us get a clear picture of your life and experiences. You may have an interview that will ask you about your medical history (e.g., current medications, history of surgeries, etc.) and basic demographics (e.g., education, marital status, racial and cultural identification, handedness, etc.). Some other assessments will cover things like language, motor skills, and memory. The surveys include questions about your thoughts, feelings, and behavior. You do not have to answer any questions you are not comfortable answering. You will be asked to wear a device on your finger to record your movements while completing motor assessments.

You will also have a neurological exam with a clinician where you will complete tasks that are designed to measure your motor abilities (e.g., movement), perception and/or sensations (e.g., touch, smell), and some physical tasks like finger tapping or walking toe-to-heel.

To reduce the time of your visits, you will have the option to complete the clinical interview and some surveys from your home prior to your visit.

Video Recordings*:* Two of the tests that you will complete as part of this study will be video recorded. The recorded videos will be used to ensure all research staff are administering these tests the same way. Every video recording will be stored in a password-protected database and labeled with a coded study identification number. Recordings will be destroyed at the end of the study.

Blood Draw*:* You will be asked to provide up to 20 ml of blood (2 tubes; less than 1 ½ Tablespoons) to be sent to a repository in Indiana (National Institute of Neurological Disease and Stroke) to identify potential biological markers of disease. This repository will store your blood for development of future HD biomarker assays.

Saliva Sample/Genetic Testing**:** If you know your CAG (cytosine-adenine-guanine) repeat status but do not have documentation of it, we will ask that you provide a saliva sample using a take-home kit to confirm the results. The amount of saliva needed for the CAG test is less than four Tablespoons. The number of CAG repeats determines whether you have Huntington's Disease. Because this analysis is for research purposes, the results will not be reported to you or placed in your medical record.

If you do not know your CAG repeat status, we have partnered with a company called InformedDNA to help. They provide genetic counseling and results for participants who may not have a CAG test already in their medical history. InformedDNA will provide a separate consent to obtain your permission to run the

necessary tests. The genetic results will only be provided to you or others with your permission. If you choose to not receive the findings, they will be sent only to the data management team of the PREVENT HD team so you can participate in research. If you choose to receive the genetic results yourself, you will receive pre- and post-test genetic counseling from licensed genetic counselors in your state. This genetic consultation will be completed over the telephone.

Please list a phone number we can share with InformedDNA so they can contact you for a genetic consultation. Phone:__ _____.

After you give permission, InformedDNA will contact you to sign a general HIPAA consent form. This will allow permission for the genetic counselor to collect personal and family history information for the purposes of the genetics consultation. All of your identifiable reported information, including but not limited to HIPAA Personal Health Identifier demographics, will only be maintained in the InformedDNA secure electronic medical record database (GE Centricity).

InformedDNA will discuss your family health history and determine whether or not to complete a genetic test. If you choose to proceed, they will order the appropriate tests from a company called Prevention Genetics. These DNA results are Clinical Laboratory Improvement Amendments (CLIA) certified, meaning they are governed by the federal government to assure they are accurate and safe. Specialists will help interpret the results and explain what they may mean. You are not required to learn your results and instead may choose to only have them shared with the PREVENT HD team through COINS, a secure online encrypted system that is being used for study data.

Genetic counselors will discuss applicable genetic information laws as well as limitations to federal protections, such as potential life insurance and/or long-term care discrimination. The genetic counselor will review what you can do if you receive a positive result such as screening if symptoms arise.

These results will not be put into your medical record; they will only be kept in COINS and the secure Prevention Genetics system. They will only be shared with you and persons you choose to inform.

At the conclusion of the first genetics consultation, the following will occur:

1. The genetic counselor will place an order for CAG testing in the HD gene, and order a test kit through Prevention Genetics. The following demographics will be sent to Prevention Genetics:
    a. Name, date of birth, home address, sex
    b. A saliva collection test kit will be sent directly from Prevention Genetics to you at your home address.
2. You will receive a ‘How To’ instruction sheet in the test kit. It should take between 2 to 5 minutes to fill the tube with saliva. Before spitting in the tube, you will be asked to do the following:
    a. Do NOT eat, drink (even water), smoke, or chew gum for 30 minutes before spitting in the tube
    b. Do NOT remove the plastic film from the funnel lid.
3. You will send your saliva sample in the enclosed, prepaid package back to Prevention Genetics via the approved, prepaid mail service (Fedex, UPS, etc) for genetic testing.
4. Genetic testing will be completed by Prevention Genetics.
5. Results will be sent directly back to InformedDNA through the Prevention Genetics secure online portal.
6. InformedDNA will contact you again following receipt of genetic test results (regardless of whether positive, unknown, or negative) to schedule the disclosure of the results, if you asked to learn the results. Ideally, the consultation will be scheduled via telephone with your original genetic

counselor, if schedule availability allows. A follow-up genetic consultation will also be offered within the following two weeks.

It is important to note that not all participants will be offered this option. If you already have a genetic test on file, you will not need a second test. Study staff will determine whether you are eligible for testing or not, based on your responses to the screening questions. You may still participate in this study even if you do not receive your results.

Brain Scan: You will be asked to complete an MRI scan lasting approximately 1 hour. The MRI scan will be done at one of the Brain Imaging Centers (WBIC, WIMR), or similar facility at UW-Madison. An MRI scanner is a large machine that contains a hollow tube and takes pictures by producing a magnetic field that passes through your body without disturbing any of its parts. While you are in the scanner, you will hear tapping noises as the MRI machine works. Ear plugs or headphones will be provided to minimize any potential discomfort from these noises, and small cushions to keep you comfortable and help hold your head still during the scan. You will be able to talk to study staff while you are in the scanner and you can end or pause the scan at any time if you do not wish to continue.

We would like to store your MRI images for future analyses, after this study is over. The types of brain analyses we may use them in may not even exist at this time. Scans will be uploaded to the Collaborative Informatics and Neuroimaging Suite (COINS) data system in Atlanta, Georgia, and the NIH repository at the National Data Archives in Bethesda, Maryland. They will store the MRI scans indefinitely and may use and share them with other researchers at academic institutions, hospitals, and biotechnology/pharmaceutical companies. All brain scans are de-identified (no one will be able to know the scan is associated with your name, face, or identifying information) but additional data from this research will accompany the scan.

The MR images for this study are for research purposes only, they will not be reviewed by a radiologist and the results will not be shared with you. 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.

PREGNANCY STATUS (FEMALE PARTICIPANTS ONLY)

Although there is no evidence that MRI scans can cause harm to a fetus, there may be risks that are not known at this time. For these reasons you will not be allowed to have an MRI if you are pregnant. Due to the additional risks involved with having a lumbar puncture (LP), you will also not be allowed to have a LP if you are pregnant. You should only take part in the MRI scan and the LP if you are sure that you are not pregnant.

Baseline. I confirm that I am not pregnant at this time:

_____ _____
Signature Date

Follow-up Visit. I confirm that I am not pregnant at this time:

_____ _____
Signature Date

Procedures continued:

Spinal Fluid Draw*:* You will be asked to undergo a lumbar puncture (LP). A LP is a procedure that involves inserting a needle in the lower back, below the spinal cord, to collect a small amount of the spinal fluid that cushions the brain and spinal cord, called cerebrospinal fluid (CSF).

If you agree to the LP, you will need to stay an additional day as you will need to fast the night before. You will be asked to fast from midnight prior to coming to our clinic for the LP. This means no food or drinks such as coffee, tea, milk or juice (water is OK). You should drink extra water the two days before your LP to reduce the risk of dehydration and potential headache. You will be instructed to discontinue any blood thinning medication for up to 14 days prior to your LP, depending on which medication you are taking.

The day before your LP, safety screening questions will be asked, and additional blood work will be collected (up to 20ml; a little more than a tablespoon) to determine that your current health status ensures safety to collect the CSF. Also, a medical doctor will provide a brief physical/neurological exam and review your lab results to ensure that it is safe to proceed with the procedure. If it is determined that you are eligible to continue, we will continue with the CSF collection for the following morning. Ifyou are not eligible, we may ask you to return at a later date.

On the morning of the LP we will confirm the following:
1. You did not eat or drink (other than water) since midnight
2. You did not take any blood thinners for the time period directed by the medical doctor
3. You have no allergies to the numbing medication used

On the morning of the procedure, prior to the LP, you will have a blood draw (up to 80 mL; about 5 ½ Tablespoons) and nursing staff will check your vitals. These will be stored for future research to develop blood and/or spinal fluid assays. During the LP procedure, you will lie on your side curled up into a ball or you will sit on the edge of a chair or bed and lean forward. An ultrasound may be conducted to determine needle insertion site. The lower part of your back will be cleaned with an antiseptic. A local anesthetic (1% Lidocaine) will be injected into the skin of your lower back at the area of the LP. When the area is numb, a very thin needle will be inserted into the spinal canal in the lower back, well below the level where the spinal cord ends. The doctor may need to move the needle slightly or try again if he/she isn't able to collect enough fluid. About 22 mL (less than 1 ½ Tablespoons) of spinal fluid will be removed for analysis and storage. Your body replaces this spinal fluid within 2 hours.

We will want you to tell the doctor if you aren't feeling well during the LP, so he/she can add more numbing medicine and make you more comfortable or stop the procedure if necessary. In most cases, the collection of the spinal fluid only takes 15-20 minutes.

After the LP is completed, you will remain in the clinical room for 30-60 minutes so you can rest. The entire procedure should take about 2 hours, including the resting period.

You should avoid any strenuous physical activity for 24 hours following your LP. This includes lifting, bending, housework and gardening, exercise such as jogging or bicycle riding and engaging in any sexual activity. You will be able to travel home in a car or plane. You will be given an instruction sheet to take home which includes this information. Study staff will contact you 1-3 days following your LP to discuss how you are feeling.

Please initial below if you AGREE to the collection of Cerebral Spinal Fluid (CSF) at your baseline and 8-24 month follow-up visit:

_____Yes, I agree to participate in the collection of Cerebral Spinal Fluid (CSF) that may be analyzed and stored for future research and shared with other researchers for the purpose of biomedical research.

Additional information regarding your visits:

De-identifying your data: If you have been seen at the University of Wisconsin Hospital and Clinics (UWHC) before, we may obtain information from your medical records for more accurate data and to eliminate redundant procedures and questions. This information is collected for purposes of conducting our research only.

Your biological samples and collected information/data will be stripped of identifiers (Ex. Name, birthdate, address, etc.) and you will be assigned a numeric study id that will be used in all subsequent study activities to protect your identity (for more information, see below). Other researchers who obtain proper permission from the PI may gain access to your sample and/or data for use in other approved research studies.

Genetic Testing: Some of your blood/saliva samples will be sent to the NIH Genome Database for future genetic testing, which is done on your DNA. DNA, or deoxyribonucleic acid, carries the genetic instructions for the cells that make up your body. Genes tell your body how to do things like form your spine, or what color your eyes should be.

HOW IS MY 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
- Things you tell the researchers about your health
- Information currently in your medical records as well as information added to your medical records during the course of this study. This information could include your medical history; your diagnosis; lab test results, MRIs, CTs or other kinds of medical imaging. We will get this information from your health care providers such as UW Health.

HOW LONG WILL MY PERMISSION TO USE MY HEALTH INFORMATION LAST?

By signing this form, you are giving permission for your health information to be used by and shared with the individuals, companies, or institutions described in this form. Unless you withdraw your permission in writing to stop the use of your health information, there is no end date for its use for this research study. You may withdraw your permission at any time by writing to the person whose name is listed below:

Dr. Jane S. Paulsen
Department of Neurology, MFCB
1685 Highland Ave
Madison, WI 53705-2281

Beginning on the date you withdraw your permission, no new information about you will be used. Any information that was shared before you withdrew your permission will continue to be used. If you withdraw your permission, you can no longer actively take part in this research study.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last between 8 months and 2 years. If you agree to complete the lumbar puncture procedure and brain scan, your visits will be 2-day visits and will range from 3-6 hours of study activities each day.

The researchers may take you out of the study, even if you want to continue, if:
- your health changes and the study is no longer in your best interest, and/or
- you do not follow the study rules or no longer meet the requirements to be in the study, and/or
- the study is stopped by the sponsor or researchers

HOW IS BEING IN THIS STUDY DIFFERENT FROM MY REGULAR HEALTH CARE?

This study is not part of your health care.

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 HD and how to develop treatment studies to prevent the onset of HD. If, however, you receive genetic results from InformedDNA during this study, those results may help you prepare for the future with more certainty.

WILL I RECEIVE THE RESULTS OF RESEARCH TESTS?

You and your doctors will not be told the results of the research tests with the exception of the genetic results from InformedDNA. If you chose to learn the results of that test, you may share it with your doctor and others.

ARE THERE ANY RISKS TO ME?

Your chance of developing HD will not be influenced by participating in this study. However, if you have inherited the HD genetic mutation, there is a chance that you may develop clinical signs of HD during the course of this research study.

Personal Information. One of the risks 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. To keep this

from occurring, all records which contain personally identifying information are kept in locked file cabinets and our computer systems have controlled access. When reporting results of the study all personal identifiers are removed. In most cases only analysis of group data is presented or published; individual subject data is rarely the focus of reports or data presentation.

Clinical Assessments*.* Some people may experience anxiety, fatigue, or boredom during the cognitive and functional testing portion of the visit. Frequent breaks can be provided during the testing, and the study coordinator will offer assurances throughout the visit. You may skip questions that you prefer not to answer.

Please note that if we have reason to believe that you pose a risk to yourself or others, confidentiality may be breached in the interest of safety. If this happens, we may need to disclose information about you without your consent to protect you or others around you. If possible, we will discuss our concerns and actions with you before making such disclosures.

Orbital Xray**:** Certain participants will be asked to do an orbital x-ray as an MRI screening procedure. Participants will be exposed to a small amount of "ionizing radiation." Studies have shown that getting a lot of radiation at one time or getting many small amounts over time may cause cancer. The risk of getting cancer from the radiation in this procedure is very small and does not pose more than minimal risk for adults.

Methods for reducing risks: Participants will be instructed to tell the x-ray technologist if they are or may be pregnant. Women who are pregnant should not be in this study. A protective shield may be used should it be requested by the participant. If the participant has imaging records on file they should discuss with the technician to avoid unnecessary duplication of x-rays.

MRI Safety**.** Some people should not participate in MRI studies. These include people with metallic implants. The magnetic field generated by the MR machine can cause displacement of metallic implants or malfunction of electronic implants, such as cardiac pacemakers. There are no known risks or adverse effects from the magnetic signals used in this study. In previous studies, participants have reported some anxiety or claustrophobia in the MR scanner. If you experience any of these symptoms, or are otherwise uncomfortable during the scan, you are free to stop and be brought out at any time.

Some people have reported tingling or tapping sensations, or muscle twitches in different parts of their body during MR imaging. 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 discomfort you should not clasp your hands together during the scan. 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.

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 enables newly developed features that are not yet FDA approved for clinical use. Although not approved by the FDA, the systemis being operated under the FDA safety specifications.

Women who are pregnant must not participate in this study. Potential risks to a fetus from a MR scan

are not known. If you have any reason to suspect that you might be pregnant, you must not participate.

Risks of Blood Draw. During the collection of blood samples, you may experience pain and/or bruising at the insertion site. Fainting or feeling lightheaded may occur during or shortly after having blood drawn. A rare risk of infection at the insertion site is possible. Our study staff use all practices to assure the least amount of discomfort from the blood draw by using only staff members who are specifically trained for these procedures.

Risks of Genetic Research*.* One risk of giving blood/saliva for genetic research may be the release of your name or any other information that could link you to the stored samples and/or the results of the tests run on your samples. To prevent this, all samples will be given a code. Your name will not be associated with any of your research data.

Additionally, the *Genetic Information Nondiscrimination Act* of 2008 is a Federal law that is supposed to prevent health insurance companies and employers from discriminating against people based on genetic information. There are some limits to this law:

- It does not apply to businesses that employ fewer than 15 people. So, if you work somewhere with fewer than 15 employees, your employer could fire you or make other decisions about employment using genetic information.
- Regardless of where you work, it does not apply to life insurance, disability insurance, or long-term care insurance. This means that if you had an abnormal genetic test result, and that result became known, then you could be denied or pay higher rates for life insurance, disability insurance, or long-term care insurance.

Your DNA samples and information will be sent to the NIH Genome Database and will not include personal information like your name or your birthdate. However, even without your name or other identifiers, your genetic information is unique to you, like a fingerprint. Scientists expect that over the next few years, researchers will be able to look at your genetic information and be able to trace the data back to you (and potentially also to your blood relatives).

Research has already shown that some populations are more likely to develop certain diseases than others. For example, sickle cell anemia is more common in people of African, African American, or Mediterranean heritage. By participating in this research, your genetic information could help researchers find out if members of a specific population are at greater risk for specific diseases. Some people have been concerned that this information could be used to stereotype all members of a population group, even if not everyone in that group is at risk for the disease common in their racial or ethnic heritage.

There may be other risks related to genetic testing that we don’t know about right now. This is because the field of genetics is moving forward very quickly.

Risks of Cerebrospinal Fluid (CSF) Collection*.* During the lumbar puncture procedure to collect CSF, you may experience the following risks/discomforts:

1. Stinging from the injection of the local anesthetic
2. Hypersensitivity (allergic) reaction to the anesthetic
3. Pressure sensation when the LP needle is inserted
4. Brief pain, either in the back or down one leg, when the LP needle is inserted
5. Nausea, vomiting or fainting

6. Brief period of double vision, and/or light sensitivity
7. Back pain following the CSF collection, similar to a sore muscle. Up to 3 in 10 people may experience this.
8. Infection caused by the needle going through the skin. This is very rare, much less than 1 in 1000 people will experience this.
9. Bruising at the insertion site
10. Headache following the CSF collection, usually the following day. You can take Tylenol or Ibuprofen and rest is recommended. This risk for mild to moderate headache is 1 in 5 to 1 in 10 people, severe headache risk is much lower. If the headache does not resolve, you may need to go to your local hospital for a procedure called a “blood patch”. A metallic taste in the mouth may also occur typically with the headache and may also indicate the need for a “blood patch”. This risk is rare, less than 1 in 20 chance.
11. Damage to the nerves in the lower back which could cause numbness, pain or altered function in the legs, bowels, bladder or genitals. This may be caused directly by the needle or by blood leaking into the spinal fluid. This is very rare, much less than 1 in 1000.

To minimize these risks, the LP will be performed by a medical doctor or a nurse who is specifically trained in this procedure. Study staff will also follow-up with you 1-3 days after your procedure to discuss how you are feeling.

If you experience any non-emergent medical problems related to the spinal tap, please contact your regular healthcare provider. If it’s an emergency, please seek immediate care from your primary care physician, urgent care, or local emergency room. Please report any sickness or injury to the study at (833) 828-0122 Monday-Friday, 8:00-5:00pm, or contact our 24/7 study line at 319-471-3292.

WILL BEING IN THIS STUDY COST ME ANYTHING?

There will be no cost to you for any of the study activities or procedures.

WILL I BE PAID FOR MY PARTICIPATION?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

Participants will be reimbursed for each part of the study you complete. The following is the payment schedule:

Clinical assessments: $50 per visit
MRI scan: $50 per scan per visit
CSF collection and blood draw: $50 per visit

If it’s determined you are unable to undergo CSF collection, you will be compensated $25. We may ask you to return within 30 days to attempt the LP again in which case you will be compensated the additional $25.

Travel, lodging, and meal costs incurred by your participation will be provided, or you will be reimbursed at the University of Wisconsin-Madison rates. In addition, airport shuttle, parking, and tolls may be

provided or reimbursed if applicable.

Participants may also receive non-monetary gifts that may include items such as a bag, t-shirt, water bottle, pen, magnetic clip, bookmark, stress reliever squishy or other fidget items.

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

WHAT HAPPENS IF I AM INJURED OR GET SICK BECAUSE OF THIS STUDY?

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, please contact your regular health provider.

To report your sickness or injury to the study, please call (833) 828-0122 Monday-Friday, 8:00-5:00pm or contact our 24/7 study line at 319-471-3292.

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 WILL THE RESULTS BE USED, MY CONFIDENTIALITY BE PROTECTED, AND WHO WILLUSE MY HEALTH INFORMATION?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your health information, 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. We may also have to tell appropriate authorities, such as child protective services or health care providers, if welearn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

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 information and biospecimens that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

Members of the research team
Offices and committees responsible for the oversight of research
Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study

Who outside the UW-Madison may receive my information?

U.S. Office for Human Research Protections
NIH National Data Archives
NINDS biorepository at Indiana University
NIH Database for phenotypes and genotypes
Critical Path Institute, Huntington's Disease Regulatory Science Consortium
Future researchers who consent to confidentiality and privacy practices
Great Lakes Neurotechnologies, the company that makes the Kinesia ONE

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

Will information from this study go in my medical record?

A UW medical record will be created for you if you do not have one. No information collected as part of this study will go into your medical record but your medical record might say that you participated in this study.

WHAT WILL HAPPEN TO MY DATA AND BIOSPECIMENS AFTER MY PARTICIPATION ENDS?

We will keep your data and biospecimens indefinitely, meaning we have no plans of ever destroying your data or biospecimens. Keeping data or samples for future research is called "banking." These will be kept in a secure location for use by researchers. All data collected for this study will be banked. You can request to have your data removed from the bank by contacting the research team at any time.

This is what will happen with your banked data and samples:

- There are no limits on how your samples and data may be used in the future. For example, data and samples could be used for research on heart health.
- The data and samples may be shared with other researchers at the University of Wisconsin-Madison and outside the university.
- The banked data and samples will be labeled with a code instead of your name. When we give your data and samples to other investigators for research projects, they will not be able to use the code to figure out which data and samples are yours.
- The research team will maintain a link between your data and samples and your identifiable information kept by the study team.

This is what will **not** happen with your banked data and samples:

- Banked data will not be shared with health care providers or used in treatment/care outside the study.

WHAT IF I HAVE QUESTIONS?

If you have questions about this research, please contact Jane Paulsen (608) 263-5448. 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.

We are requesting your email address so we can contact you using various methods to accommodate your preferences. Email is generally not a secure way to communicate about private information 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. This research study has a private email box only checked by study staff and Dr. Paulsen. Please email hdresearch@neurology.wisc.edu if you desire communication with staff. You do not have to provide your email address to participate in this study.

IF I START THE STUDY, CAN I CHANGE MY MIND?

Your participation is completely voluntary; you may stop participating at any time during the study. Stopping the study will not affect present or future medical care at this institution in any way.

Agreement to Participate in this Study and Permission to Use and/or Disclose My Health Information

I have read this consent and authorization form describing the research study procedures, risks, and benefits, what health information will be used, and how my health information will be used. I have had achance to ask questions about the research study, including the use of my health information, and I have received answers to my questions. I agree to participate in this research study and permit the researcher to use and share my health information as described above.

You should receive a copy of this form after signing it.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Date

_____ _____
Signature of Person Obtaining Consent Date