PRINCIPAL INVESTIGATOR: Debra Ehrlich, M.D.

STUDY TITLE: Phase II Trial of Non-invasive Intermittent Theta Burst Stimulation of the Dorsolateral Prefrontal Cortex in Functional Movement Disorders

STUDY SITE: NIH Clinical Center

Cohort: People with functional movement disorders

Consent Version: 04/29/2025

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Debra Ehrlich, M.D. Phone: 301-443-7888 Email: Debra.Ehrlich@nih.gov

Study coordinator: Vivian Koo, R.N. Phone: 301-435-8518 Email: vivian.koo@nih.gov

KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. Taking part in research at the NIH is your choice.

What are Functional Movement Disorders (FMD)?

- Functional movement disorders (FMD) are characterized by unwanted involuntary movements that are not due to a recognized neurological or medical cause. FMD cause significant disability just as other neurological diseases such as Parkinson's disease or multiple sclerosis. Currently there is no effective treatment for FMD other than cognitive and physical therapy. The goal of this study is to evaluate whether non-invasive brain stimulation using transcranial magnetic stimulation (TMS) improves FMD symptoms.

What is Transcranial Magnetic Stimulation (TMS)?

- TMS is a non-invasive brain stimulation that uses a magnetic field to stimulate nerve cells in your brain. TMS can increase or decrease brain activity in particular area of your brain. In this study, we will use the TMS to see if it helps with FMD symptoms. TMS operates completely outside of the body and is generally very well tolerated.

Random Group Assignment:
If you join this study, you will be assigned by chance (like flipping a coin) to one of 2 groups:

- Active brain stimulation group
  - If you are randomized to this group, TMS will be delivered to your brain.
- Sham stimulation group

- If you are randomized to the sham stimulation group, a sham or "fake" coil, will be used. You will not get TMS delivered to your brain. It will look and sound the same as TMS, so you and the study doctor examining you don't know what group you are in.

Neither you nor your study doctor will be able to choose which group you are assigned to.

What will I be asked to do for this study?

- First, you will come to the NIH Clinical Center for a screening visit. You will have a physical exam. The doctor will ask questions about your medical history. Your vital signs will be taken. Your height and weight will be measured. This visit will be done on the same day as the baseline visit if possible.

- Within 4 weeks you will have your baseline visit. You will have a neurological exam and research MRI. This baseline visit will take up to 4 hours.

- Within 2 weeks after the baseline visit, you will come to the NIH Clinical Center every day for 5 days of outpatient visits. You will have brain stimulation with TMS or sham each day. Each session will last 1-2 hours.

- After completing 5 daily sessions of TMS or sham stimulation, you will have three more follow-up visits about 1 month, 2 months and 6 months later. We will evaluate your FMD symptoms and you will be asked to answer some questionnaires at each visit. These visits can be done in the clinic at the NIH Clinical Center or via Telemedicine visit at your home.

If you have any questions or concerns about this study, please do not hesitate to contact the study team at any time.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to see whether non-invasive brain stimulation using TMS improves FMD symptoms. We are asking you to join this research study because you have been diagnosed with FMD by your neurologist.

TMS is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA) to treat FMD. However, the use of TMS is approved to treat depression and obsessive-compulsive disorder. We are testing it in this research study to see if TMS treatment improves FMD symptoms compared to control (sham stimulation).

WHAT WILL HAPPEN DURING THE STUDY?

If you decide to take part in this study, you will be asked to come to the NIH clinical center for 6-9 outpatient visits.

Random Group Assignment

You will be randomly assigned either to active brain stimulation (TMS) group or sham brain stimulation group. Randomization means that you are assigned by chance (like pulling a number from a hat) into one of the groups described below. Neither you nor your study doctor will be able to choose which group you are assigned to.

- Active brain stimulation group: If you are randomized to this group, TMS will be delivered to your brain.
- Sham stimulation group: If you are randomized to this group, a sham or "fake" coil will be used. You won't have TMS delivered to your brain. It will look and sound the same as TMS, so you and the study doctor examining you don't know what group you are in.

Screening Visit*

- You will have a physical exam. The doctor will ask questions about your medical history.
- Your vital signs will be taken.
- Your height and weight will be measured.

*This visit will be done on the same day as the baseline visit if possible.

Visit 1 (Baseline)

- First, we will perform neurological exam. We will evaluate your FMD motor symptoms, and you will be asked to complete some questionnaires about your health.
- We will ask you to take a urine pregnancy test if you are able to become pregnant.
- We will perform a brain MRI.
    - The first part of the MRI will be a structural MRI, to look at things like your brain's shape and size. If you had a structural MRI at the NIH in the last 12 months, we can use that instead.
        - An MRI makes pictures of the inside of your body using strong magnets instead of x-ray energy.
        - At the time of each scan, you will be asked to fill out a screening form to verify that it is safe for you to have the scan.
        - You will also be asked to remove any metallic objects you are wearing (for example, watches, earrings, or piercings). We may ask you to change into a hospital gown.

- Then you'll be asked to lie on a narrow bed that will move into the MRI scanner. Before moving you into the scanner, special padding will be placed around your head to help keep your head still. The scanner is a long, narrow tube that is open at each end. Once you are comfortable, the table will be moved into the scanner. You will need to lie still on the table during the scan. The total scan time for both parts will take about 45 to 90 minutes to complete. You will hear normal "hammering" or clicking and squealing noises during the scan. We will give you earplugs or earmuffs to muffle the sound. You will be able to communicate with the technician running the scan the entire time. We will also give you an emergency button to squeeze at any time if you want the scan to stop.

- The second part of the scan is functional MRI. Functional MRI lets us see what parts of your brain are used when you do a task.
  - In this part of the MRI, you may be asked to do study tasks. At other times you will lie still just like the first part of the scan.
  - You will look at a mirror in the MRI. We will project instructions onto the mirror to tell you when to do a task.
  - You will be able to communicate with the MRI staff during your scan and you may ask to be moved out of the machine at any time.

Visits 2-6 (within 2 weeks after Visit 1)

During visits 2-6 we will perform the stimulation procedure based on the group you are randomly assigned to. The brain stimulation may be active (TMS) or sham (fake). You will come to the NIH Clinical Center one time a day for 5 days straight. Each visit will last about 1-2 hours. You will need to get a good night sleep each night. During this time, you cannot drink more than 1 alcoholic drink a day.

- We will ask you to take a urine pregnancy test prior to each TMS session if you are able to become pregnant.
- Active stimulation group: If you are in this group, you will have TMS.
  - TMS uses a a brief, pulsed magnetic field to affect brain activity. During the TMS sessions, a device called a "coil" will be put on your head. A brief electrical current will then pass through the coil and create a magnetic field. You will hear a click and you may feel a tapping or pulling sensation on your skin under the coil. You may feel a twitch in your face, neck, arm, or leg muscles. You will be given hearing protection that must be worn during TMS because the clicking noise can be loud enough to damage your hearing. We may ask you to tense certain muscles or do simple actions or tasks during TMS.
  - A series of repeated TMS pulses can lead to brain and behavior changes even after you stop getting TMS. This type of TMS is called "repetitive TMS" or "rTMS" and can be used to study the brain or as a treatment. We will use a type of rTMS called "intermittent theta burst stimulation (iTBS)" to deliver brain stimulation.
  - During the iTBS you will get 2 bursts (30 pulses) of stimulation every 10 seconds in a cycle of 190 seconds (about 3 minutes). A total of three cycles (600 pulses) will be done at each visit. You will have at least a 15 minutes break between the cycles.

  - Electromyography (EMG) may be used with TMS to measure the effects of TMS on your brain and body. We will use the surface EMG, which is a sticker type of electrode that measures muscle activities in response to TMS.
  - You will be able to talk with the study staff at all times during the TMS session.
  - You may ask to stop the session at any time.
- Sham stimulation group: If you are in this group we will use the sham coil that looks, sounds, and feels the same as the real TMS coil. You won't have any active electrical pulses.
  - Neither you nor your doctor who will evaluate before and after TMS will know if you receive active or sham stimulation until the study is completed.
  - A total of three cycles will be done at each visit. You will have at least a 15 minutes break between the cycles.
- Exam: Your study doctor will examine you after each TMS or sham session to check you for any side effects.
  - Functional Brain MRI (Visit 6 only): After the last TMS or sham session is complete, you will have another functional MRI.

Visit 7 (around 30 days after Visit 6)

We will evaluate your FMD symptoms, and you will be asked to fill in some questionnaires about your health. This can be done in the clinic at the NIH Clinical Center or via a Telemedicine visit at your home.

Visit 8 (around 60 days after visit 6)

We will evaluate your FMD symptoms, and you will be asked to fill in some questionnaires about your health. This can be done in the clinic at the NIH Clinical Center or via Telemedicine visit at your home.

Visit 9 (around 6 months after visit 6)

We will evaluate your FMD symptoms, and you will be asked to fill in some questionnaires about your health. This can be done in the clinic at the NIH Clinical Center or via Telemedicine visit at your home.

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study, your involvement is expected to last for about 6 months. You will have a total of 9 study visits. Each visit will range from 1- 4 hours in length.

- Screening Visit: About 1 hour.
- Visit 1: up to 4 hours.
- Visit 2 - 6 (TMS or Sham visits): about 1-2 hour.
- Visit 7- 9 (follow-up visits): about 30 – 60 minutes.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have 30 people take part in this study at the NIH.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

TMS

- The effects of TMS on a developing fetus are not known. You will not be able to have TMS if you are pregnant. People who can get pregnant will have a pregnancy test before their first TMS session.
- Most people do not find TMS painful, but sometimes strong contractions of scalp muscles can cause discomfort or headache. If you find the procedure too uncomfortable, you may discontinue it at any time. Headaches usually go away on their own.
- The loud noise of the machine can damage hearing, especially if you already have hearing loss. You will be fitted with earplugs that must be worn during the session. If your hearing protection comes loose during the session, tell us right away. Tell the study staff if you know you have hearing loss.
- It may not be safe for you to get TMS if you have certain kinds of metal in your body including:
  - metal staples or screws in the head or neck,
  - pacemakers or other implanted electrical devices,
  - brain stimulators,
  - aneurysm clips (metal clips on the wall of a large artery),
  - cochlear implants,
  - an implanted delivery pump, or
  - shrapnel fragments. Welders and metal workers may have small metal fragments in the eye.
- Also, it may not be safe for you to get TMS if you have a history of certain medical conditions, are withdrawing from alcohol, or if you are taking certain drugs. You will be asked to complete a screening form before you get TMS. This screening form will be updated at each session. If you have questions about metal in your body or other potential risks mentioned on the screening form, you should let us know.
- Very rarely, TMS has led to seizure (abnormal activity in the brain that can cause muscle spasms and can happen with or without losing consciousness). Also rarely rTMS may lead to a short-term change in your ability to remember, your ability to pay attention, or your mood. If these effects happen, they do not usually last long and will go away without treatment. If you have bipolar disorder, the risk of mood and behavior changes is a little higher.
- A safety plan is in place and a licensed clinician is available during each TMS session in case you have a seizure or other side effect. There may be other risks that we don't currently know about. There are no known long-term risks of TMS.
- We will be using the TMS System and the coil for research purposes. This means that we are using it to study brain function. We are not using it to treat patients. However, all sessions done under this protocol will be done within safety guidelines. There is no increased risk in the use of these research techniques compared with clinical uses. The use of the TMS system and coil for research has not been approved by the FDA and is considered investigational.

MRI

You may be at risk for injury from the MRI magnet if you have some kind of metal in your body. It may be unsafe for you to have a MRI scan if you have:

- a pacemaker or other implanted electrical device,
- brain stimulator,
- some types of dental implants,
- aneurysm clips (metal clips on the wall of a large artery),
- metallic prostheses (including metal pins and rods, heart valves, and cochlear implants),
- permanent eyeliner,
- certain tattoos,
- an implanted delivery pump,
- or shrapnel fragments. Welders and metal workers may have small metal fragments in the eye.

You will be screened for these things before having any scan. If you have any, you will not have an MRI scan. If you have a question about metal in your body, you should tell us. You will be asked to fill out an MRI screening form before each MRI scan.

All magnetic objects must be removed before entering the MRI scan room. This includes items like watches, coins, jewelry, and credit cards.

People with fear of confined spaces may become anxious during an MRI. Those with back problems may have back pain or discomfort from lying in the scanner.

The noise from the scanner is loud enough to damage hearing, especially in people who already have hearing loss. We will give you hearing protection. If the hearing protection comes loose during the scan, you should let us know right away.

Clinical and research rating scales

There is no medical risk or discomfort associated with clinical and research rating scales. However, it may be frustrating or stressful. You may refuse to answer any question or to stop participating at any time and for any reason.

The questionnaires and researcher rated scales may reveal problems with depression or anxiety. They may reveal another condition of which you were unaware. If they do, we will tell you and refer you to an appropriate health care providers.

Risks of Storage and Sharing of Data

Even though we will remove information that could identify you from data that are sent to repositories or shared, there is a very small chance that the data could be identified as yours.

What are the risks related to pregnancy?

If you are able to become pregnant, we will ask you to have a pregnancy test before starting this study. Although TMS and MRI are considered minimal risk for pregnant women, it is not known if TMS and MRI are completely safe for the developing fetus. You must tell the study doctor if your birth control method fails while you are in the study. If you think or know you have become pregnant while participating in this research study, please contact the study team as soon as possible.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You might not benefit from being in this study.

However, you may have improvement in FMD symptoms and mood from active brain stimulation.

Are there any potential benefits to others that might result from the study?

In the future, other people might benefit from this study because we may learn things from this study that will help us understand more about FMD.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Before you decide whether or not to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could use cognitive behavioral therapy with a psychologist. You could also use rehabilitation therapy with a physical therapist.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

Most of the results we obtain in this study are for research purposes only. We will not discuss the results of research tests with you or your physician. However, we may obtain information that could be important for your health or well-being or that could affect your decision to continue in the study. We will share with you any new information that may relate to your willingness to continue to participate in this study or that are important for your health. With your approval, we will share with your physician any new information that may impact on his/her care of you.

EARLY WITHDRAWAL FROM THE STUDY

We may discontinue or withdraw you from the study if:

- you develop adverse events or other medical condition such that continuing in the study would not be in your best interest, or
- you become pregnant during the study or
- you are unable to receive 3 or more brain stimulations.

We will ask you to complete a safety visit approximately 30 days following the last session of brain stimulation.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR DATA

Will your data be saved for use in other research studies?

As part of this study, we are obtaining data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding FMD, or other diseases or conditions. This could include studies to develop other

research tests, treatments, drugs, or devices, that may lead to the development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my coded data to be stored and used for future research as described above.

_____ Yes _____ No

Initials Initials

Will your data be shared for use in other research studies?

We may share your coded data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas that are similar to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

I give permission for my coded data to be shared with other researchers and used by these researchers for future research as described above.

_____ Yes _____ No

Initials Initials

If you change your mind and do not want us to store and use your data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your data. For example, if some research with your data has already been completed, the information from that research may still be used. Also, for example, if the data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. We might do this even if you answered "no" to the above questions. If we do this, we would not be able to remove your or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your data.

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. Usually, these researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number; and your data will be labeled with only a code. We cannot offer you a choice of whether your data to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

How long will your data be stored by the NIH?

Your data may be stored by the NIH, possibly indefinitely.

Risks of storage and sharing of data

When we store your data, we take precautions to protect your information from others that should not have access to it. When we share your and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your data.

PAYMENT

Will you receive any type of payment for taking part in this study?

Study participants will be paid approximately $1,290 for their time and effort.

Compensation for time	
First hour outpatient visit	$20
Additional hours	$10
Compensation for inconveniences	
Research MRI	$100 per visit
Questionnaires	$25 per visit
Surface EMG	$20 per visit
TMS, repetitive	$150 per visit

If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

If you are unable to finish the study, you will receive the payment for the parts you completed. If you have unpaid debt to the federal government, please be aware that some or all of your compensation may be automatically reduced to repay that debt on your behalf.

With few exceptions, study compensation is considered taxable income that is reportable to the Internal Revenue Service (IRS). A "Form 1099-Other Income" will be sent to you if your total payments for research participation are $600 or more in a calendar year.

We will need to collect your social security number in order to compensate you. You can withhold your social security number and still participate in the research study; however, you will not be able to receive compensation if you do so.

REIMBURSEMENT

Will you receive reimbursement or direct payment by NIH as part of your participation?

If your travel to the NIH Clinical Center (e.g. flight, hotel) is arranged and paid for by the NIH, the agency making the reservations and their representatives will have access to your identifiable information.

COSTS

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center. Subjects are not expected to pay any costs for the study. However, you will be responsible for payment if hospitalization or transfer to other hospitals is required due to unexpected complications.

CONFLICT OF INTEREST (COI)

The NIH reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.

No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies
- National Institutes of Health Intramural Institutional Review Board

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical information that we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. Sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Debra Ehrlich, MD, Debra.Ehrlich@nih.gov, 301-443-7888. Other researchers you may call are: Vivian Koo at 301-435-8518.

You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness should sign below if either:

1. **A short form consent process has been used to enroll a non-English speaking subject or**
2. **An oral presentation of the full consent has been used to enroll a blind or illiterate subject**

Signature of Witness	Print Name of Witness	Date

NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____ .