

**Role of microglial activation and norepinephrine transporter abnormalities in pathogenesis
of MS-related fatigue**

NCT04144257

Informed Consent Form 12.21.20

Partners HealthCare System Research Consent Form

General Consent Form Template
Version Date: January 2019

Subject Identification

Protocol Title: Role of microglial activation and norepinephrine transporter abnormalities in pathogenesis of MS-related fatigue

Principal Investigator: Tarun Singhal, M.D.

Site Principal Investigator: Georges El Fakhri, Ph.D. (MGH)

Description of Subject Population: Individuals diagnosed with Multiple Sclerosis

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as “Partners.”

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won’t change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about the cause of fatigue in multiple sclerosis (MS) using positron emission tomography (PET) imaging.

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How long will you take part in this research study?

If you decide to join this research study, it will take you up to 8 weeks to complete. During this time, we will ask you to make 3 study visits to Brigham and Women's Hospital (BWH) and 1 study visit to Massachusetts General Hospital (MGH).

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen: blood sample collection/testing, physical exam and medical/MS history intake, administration of questionnaires, PET imaging, and MRI imaging.

Why might you choose to take part in this study?

You will not benefit from taking part in this research study. Others with multiple sclerosis may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include radiation exposure during the PET scans.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

Other things to consider are the time commitment and travel requirements. The screening visit at BWH will take approximately 1-2 hours to complete. Each PET scan will take approximately 2 hours to complete. One PET scan will take place at BWH; the other PET scan will take place at MGH. The MRI scan at BWH will take approximately 1 hour to complete.

As part of the study procedures, if you are currently taking certain medications to treat fatigue, you will be asked to withhold taking this medication 24 hours prior to the PET scan at MGH only. You may experience a temporary increase in your fatigue as a result.

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What other treatments or procedures are available for your condition?

You will not receive treatment for your condition as part of this study. The research PET/CT scans will be done in addition to the treatment that you receive for your condition. The 24 hour “washout” of your fatigue medication, if applicable, is strictly for the purposes of this research study and not part of your routine care. If, for whatever reason, you are unable to withhold taking your medication, you cannot participate in this study. You may have clinical PET/CT and/or MRI scans as a part of your routine care.

Please talk to your doctor and the study doctor about your options before you decide whether you will take part in this research study.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Tarun Singhal, MD is the person in charge of this research study. You can call him 24/7 at 617-732-5566 or email him at tsinghal@bwh.harvard.edu with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Jack Ficke at 617-264-3044.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

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Detailed Information

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.

Why is this research study being done?

We are doing this study to learn more about fatigue in multiple sclerosis (MS) using positron emission tomography (PET) imaging. We are investigating the use of two special PET dyes called 11C-MRB (MRB) and 18F-PBR06 (PBR06). We aim to see if PET/CT scans using MRB and PBR06 can detect ongoing brain injury in MS in better ways than MRI scans. Currently, doctors use MRI scans for this purpose.

We will take pictures of your brain using PET scanners, which allow us to see proteins in your brain. MRB and PBR06 bind to specific proteins in your brain which are involved in the MS disease process. Because MRB and PBR06 contain a small amount of radioactivity, the sites at which they bind can be seen by the PET scanners. Although certain types of PET scans are used clinically, MRB and PBR06, and their use for PET scans, are not approved by the U.S. Food and Drug Administration (FDA). This means that MRB and PBR06 can only be used in research studies. They have already been safely tested in other research studies in the United States.

This is a pilot study. Pilot studies are done on a small group of subjects to learn if a larger study would be useful.

Who will take part in this research?

We are asking you to take part in the research study because you are diagnosed with Multiple Sclerosis (MS).

We plan to enroll up to 20 subjects for this study and all subjects will be enrolled from the Partners MS Center, Brigham and Women's Hospital (BWH), 60 Fenwood Road, Boston, MA.

The Department of Defense (DOD) is paying for this study to be done. Representatives of the DOD are authorized to review research records.

What will happen in this research study?

We will ask you to sign this consent form before we begin any study procedures.

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VISIT 1 – SCREENING VISIT

At the first visit, the study will be explained to you in detail. You will be asked to review this consent form, and any questions you may have will be answered. After we have reviewed the study with you, and you have signed the consent form, you will undergo a further assessment using standardized questionnaires to evaluate your symptoms. This would take approximately 90 minutes. Your medical record will be reviewed at the onset of the study and before each scan to assess any interval changes.

In addition, a blood sample will be drawn (approximately 2-5 mL of blood, or 1 teaspoon) for testing to identify if you are a good candidate to undergo one of the PET scans. Some people (approximately 10% of general population) do not produce proteins in the brain that bind to the PBR06 dye sufficiently to obtain a good quality PET scan. The result of this blood test will be known in 1-2 weeks after your screening visit. The result of this test is relevant only for this PET scan and has no relation to your underlying disease or treatment options/choices. Blood will also be drawn for serum assays.

If you are currently on certain medications (methylphenidate, modafinil or amphetamine salts) for your fatigue, you and your treating physician will discuss with Dr. Singhal if it is safe for you to withhold taking the medication for 24 hours prior to the scan at Mass General and if you're comfortable doing so.

For females, if you are pregnant or breastfeeding you cannot participate in the study.

VISIT 2 – BWH PET SCAN VISIT

- Test your blood for pregnancy if you are a woman of child bearing potential. Pregnant women cannot take part in this research study.
- You will undergo positron emission tomography PET imaging of your brain at 75 Francis Street, Boston, MA.
- Before the PET/CT scan, we will ask you to drink plenty of water. You may eat and drink as you normally would before you have the PET scan.
- You will lie down on a padded table with your head in a special head rest so that you can keep your head still throughout the scanning session. When you are comfortable, we will place one intravenous cannula into a vein in one arm. The catheter will be used to inject the PBR06 dye.

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- You will then have the PET/CT scan while lying on a table that moves through a large machine. The machine is quiet. You may play music during the scan if you like or you may also sleep. The scans will show where the PBR06 is in your brain and take some pictures.
- PET/CT scan will take up to 120 minutes. After 45 minutes of scanning, you will have the option of taking a break for up to 15 minutes and then proceed with the remaining 60 minutes of scanning. We will ask you to lie as still as you can during this time. You may feel uncomfortable from lying on a hard surface during the scan. Let us know if you become too uncomfortable and we will do our best to help you feel better.
- After the PET/CT scan is completed, the catheter will be removed, and study staff will be available to answer any questions before you finish with your study visit.
- We will ask you to drink plenty of water to help the PBR06 dye get out of your system. PBR06 leaves the body through your urine.
- We will follow up with you via telephone within 24-72 hours after your PET scan and again within 2 weeks after your PET scan.

VISIT 3 – MGH PET SCAN VISIT

- We will test your blood for pregnancy if you are a woman of child bearing potential. Pregnant women cannot take part in this research study.
- You will undergo positron emission tomography PET imaging of your brain at Massachusetts General Hospital, 55 Fruit Street, Boston, MA.
- Before the PET/CT scan, we will ask you to drink plenty of water and if applicable, skip your fatigue medication dose 24 hours in advance. You may eat and drink as you normally would before you have the PET scan.
- You will lie down on a padded table with your head in a special head rest so that you can keep your head still throughout the scanning session. When you are comfortable, we will place a cannula (plastic tube with a needle on the end) into a vein in one arm. This will be used to inject the MRB dye.
- You will then have the PET/CT scan while lying on a table that moves through a large machine. The machine is quiet. You may play music during the scan if you like or you may also sleep. The scan will show where the MRB is in your brain and take some pictures.
- PET/CT scan will take up to 120 minutes. We will ask you to lie as still as you can during this time. You may feel uncomfortable from lying on a hard surface during the scan. Let us know if you become too uncomfortable and we will do our best to help you feel better.

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- After the PET/CT scan is completed, the catheter will be removed, and study staff will be available to answer any questions before you finish with your study visit. You will be advised on how to resume taking your fatigue medication safely, if applicable.
- We will ask you to drink plenty of water to help the MRB dye get out of your system. MRB leaves the body through your urine.
- We will follow up with you via telephone within 24-72 hours after your PET scan and again within 2 weeks after your PET scan.

VISIT 4 – 7T MRI VISIT

You will undergo magnetic resonance imaging of your brain at Brigham and Women's Hospital, 60 Fenwood Rd, Boston, MA. Before you have your 7T MRI scan, you will be asked to complete a questionnaire, to make sure that it is safe for you to have an MRI. We will ask you if you are pregnant and may test your urine for pregnancy, if you are a female able to become pregnant. During the MRI scanning session, you will be asked to lie as still as possible on a padded table. The table will slide into a narrow cylinder of the magnet, and images of your brain will be taken. The scan may take 45-60 minutes. There is very little room in the MRI cylinder. However, you will be able to hear and communicate to the research staff that will be in the scanning room. You should expect to hear very loud knocking noises during the scan. Earplugs will be given to you to reduce this noise.

Potential changes due to COVID-19

During this study we may need to make changes to study visits and procedures to comply with public health efforts to address COVID- 19 (coronavirus). We may need to adjust the study visit schedule and/or research procedures as a result of study site restrictions on research visits. We may conduct some of the study screening procedures remotely until the restrictions are lifted. Remote visits will be conducted by zoom video conferencing platform or telephone. During these visits, someone from the study staff will contact you via zoom video call platform or telephone and conduct the following types of research activities:

- Clinical review of symptoms and past medical history
- Review of study procedures
- Clinical questionnaires for assessment of disability, depression, anxiety, cognition and fatigue.

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Study staff will provide you information on how to access the video conferencing platform. We will launch the video conferencing in a private and secure area. To protect your privacy we ask that you do not take screenshots, photographs, or recordings of any kind with any electronic equipment. We would like to remind you that a video meeting is similar to us visiting you at home. We may learn more about your home and the people living with you than we would during a visit at the hospital. For example, we may learn information from you that must be reported to public health or public safety authorities. We are required by law to report known or suspected child or elder abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies. Please ask the research staff if you have any questions about this prior to your video visit.

Partners Alert System

Partners Healthcare has an electronic system that lets your study doctors know if you are admitted to a Partners Hospital, or if you visit a Partners Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side effects you experience while you are taking part in the study.

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).

Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

How may we use and share your samples and health information for other research?

The samples and information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

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At the completion of this research study, we would like to store and be able to use and share your identifiable samples and health information with researchers at Partners for other research related to multiple sclerosis. If we share your samples and/or health information with other researchers outside of Partners, we will label the samples and information with a code instead of your name or other directly identifying information. The key to the code connects your name or other identifiers to your sample and/or information. We will keep the code in a password protected computer/locked file.

Because these samples and/or health information are identifiable, we are asking your permission to store, use and share them for other research. You can still take part in the research study whether or not you give permission for the storage, use, and sharing of the samples and health information for other research.

Do you agree to let us store and use your samples and health information for other research related to multiple sclerosis?

☐ YES ☐ NO Initial _____

Will you get the results of this research study?

No. The research study we are doing is only a stepping stone in understanding multiple sclerosis. Therefore, no information about the results of this research study or the results of your individual participation in the research study will be given to you or your doctor. Tests done for the research using your samples will not be useful in directing your medical treatment. The results of the tests will not be placed in your medical record.

What are the risks and possible discomforts from being in this research study?

Risks of PET/CT Scans

Risks of Radiation Exposure

As a result of your participation in this study, you will be exposed to radiation from PET scans of your brain. Please note that this radiation is not necessary for your medical care and is for research purposes only.

The total amount of radiation exposure you will receive from taking part in this study is equal to a whole body exposure of about 7.49 milliSieverts (mSv). A mSv is a unit of radiation dose. For comparison, everyone receives radiation exposure from natural background sources from the earth

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and the sky. The dose that you could receive from participation in this research study is about the same as you would normally receive in 30 months from these natural sources. Scientists disagree on whether radiation doses at these levels are harmful. A possible effect that could occur at doses associated with this study is a slight increase in the risk of developing cancer later in life. There may be other risks of PET/CT that are not known at this time.

If you are pregnant or breast feeding, you will not be able to participate in this research study.

Since the effects of radiation can add up over time, it is important that you tell the study doctor about your past clinical imaging and research-related radiation exposure. If you have taken part in other research studies in the past 12 months that have involved radiation exposure, please tell us. If it appears that your earlier radiation exposure is more than our current guidelines, it is possible that you will not be allowed to participate in this study. Please initial next to your choice below:

_____ I have participated in other research studies (not including this study) involving radiation exposure within the last 12 months.

_____ I have not participated in other research studies (not including this study) involving radiation exposure within the last 12 months.

Risks to a Fetus or Embryo, or to a Nursing Infant:

Radiation exposure may be harmful to an embryo or fetus (developing baby still in the womb). Because of this risk, women cannot be in this study if they are pregnant or nursing.

If you are a menopausal woman and have not had a period for the past 12 months or more, you will not need to have a pregnancy test. Also, if you have had any well-documented method of surgical sterilization, you will not need to have a pregnancy test. The documented methods of surgical sterilization include having had a hysterectomy (removal of the uterus with or without the ovaries), bilateral oophorectomy (removal of both ovaries), a tubal ligation (having your tubes tied), or transvaginal occlusion (plugging the opening of the tubes with a coil).

If you are a woman who can become pregnant, you must have a negative blood pregnancy test before the research PET scans.

Aside from the risk of radiation exposure, there are no known risks of MRB or PBR06. The investigators and your neurologist will monitor (check) your blood tests that are obtained medically before and after each scan.

Risks of Having an IV Catheter:

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Putting in an IV catheter can cause pain, bleeding, or bruising at the place where the needle enters the vein. There is a very small risk of an infection or a bruise at the spot where we place the IV catheter. We will treat an infection with antibiotics. Bruises usually go away without treatment.

Risk of MRI Scans:

MRIs use powerful magnets to make images. There are no known radiation risks associated with MRI. However, persons with metal implants, such as surgical clips, or pacemakers should not have an MRI. All credit cards and other items with magnetic strips should also be kept out of the MRI room. People who feel uncomfortable in confined spaces (claustrophobia) may feel uncomfortable in the narrow tube. The MRI makes loud banging noises as it takes images. Earplugs can be used to reduce the noises. The MRI can be stopped at any time at your request. If you are or suspect you are pregnant, you should not participate in this study. The MRI has the potential, during normal routine use, to cause localized warming of your skin and the underlying tissues. You should immediately inform us if you experience discomfort due to warming and the procedure will be stopped.

Some people experience dizziness or rarely nausea when going into an MRI scanner and these sensations may be more common in scans with higher magnetic fields. In most cases, these symptoms only last a short time. However, some people may experience them throughout the scan and/or continue to experience them for a short period of time after; generally, less than half an hour. No case of permanent problems is known.

The 7 Tesla MRI may cause dizziness, ringing in the ears, and less commonly nausea, especially as entering the magnet. However, these symptoms are temporary and disappear completely after scanning.

The switching of the magnetic field gradients can, under some circumstances, cause peripheral nerve stimulation that may be experienced as a mild twitching reaction in certain muscles. Such effects are rare and the switching rates are kept well below the levels at which such effects are known to occur frequently. The MR examination can and will be stopped at any time upon request by the subject, should he or she experience any of the above explained discomforts.

The information created by this study will not usually become part of your hospital record. If we see something that looks like a medical problem on the PET/CT scans or MRI scan, we will ask a radiologist (a doctor who specializes in x-rays/scans/test results of this sort) to review the results. If the radiologist thinks there might be a problem, we will tell your neurologist and

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help you get follow-up care. If the radiologist thinks that you might have a medical problem, but it turns out that you don't, we may have caused you to worry needlessly about your health.

Potential Effects Related to Stopping Fatigue Medications Temporarily:

During the 24 hour washout period when you stop taking your fatigue medication, your feelings of fatigue may increase. If you experience significant changes in your symptoms, tell the study doctor right away.

What are the possible benefits from being in this research study?

You will not benefit from participating in this study. Patients with MS may benefit in the future. The results of the study will be made available to your physician if you wish.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will be paid for taking part in this study as it follows:

- If you complete the screening visit, you will be paid \$50

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- For each PET scan you complete, you will be paid \$200
- If you complete the MRI, you will be paid \$100

The total amount you may receive for taking part in all study visits is \$550.

If you have to stop any visit early for any purpose, you will still receive \$25 for your time.

Meals and parking in the hospital will be provided.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

What will you have to pay for if you take part in this research study?

The PET/CT scans, MRI scan and blood testing that will be done only for the research will be paid for by study funds. Charges for any ongoing or routine medical care you receive outside this study will be billed to you or to your insurance company in the usual way. You will be responsible for any deductibles or co-payments required by your insurer for your routine medical care.

If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

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If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as “identifiable information.”

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)

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- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

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Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject

Date

Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent

Date

Time (optional)

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**Consent of Non-English Speaking Subjects Using the “Short Form” in the
Subject’s Spoken Language**

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter

Date

Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject’s own language, and that the subject was given the opportunity to ask questions.

Name

Date

Time (optional)

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