WCM IRB #1711018740

NCT03675282

Quantitative Mapping of Substantia Nigra Iron in Parkinson's Disease (Stages I-IV, REM Sleep Behavior Disorder) and Controls

PI: Alexander Shtilbans, MD, PhD

Approved for use: 12/06/2021 – 12/05/2022

WEILL CORNELL MEDICAL COLLEGE

Informed Consent and HIPAA Authorization for Clinical Investigation

Project Title: Quantitative Mapping of Substantia Nigra Iron in Parkinson's Disease (Stages I-IV, REM sleep behavior disorder) and Controls

Project #: 1711018740

Principal Investigator: Alexander Shtilbans, MD

Subject Name/Number: _____

MRN: _____

INSTITUTION: Weill Cornell Medical College

Hospital for Special Surgery

INTRODUCTION

You are invited to consider participating in a research study. You were selected as a possible participant in this study because you have either Parkinson's disease (Stages 1 through 4) or REM Sleep Behavior Disorder (RBD).

Please take your time to make your decision. It is important that you read and understand several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary.

(b) Personal benefit to you may or may not result from taking part in the study, but knowledge gained from your participation may benefit others.

(c) You may decide not to participate in the study or you may decide to stop participating in the study at any time without loss of any benefits to which you are entitled.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other information about the study are discussed below. Any new information discovered which might affect your decision to participate or remain in the study will be provided to you while you are a participant in this study. You are urged to ask any questions you have about this study with members of the research team. You should take whatever time you need to discuss the study with your physician and family. The decision to participate or not to participate is yours. If you decide to participate, please sign and date where indicated at the end of this form.

The research study is being funded by the National Institute of Neurological Disorders and Stroke.

Alexander Shtilbans, MD is the principal investigator from Department of Neurology and primary contact for your participation and progress while on study.

The study baseline/screening visit will take place at the Weill Cornell Parkinson's Disease & Movement Disorder Institute, 428 East 72nd Street, Suite 400, New York NY 10021, or at Hospital for Special Surgery.

Some portions of this study may take place at:
Weill Cornell Citigroup Biomedical Imaging Center, 516 E72nd Street, New York NY 10021
Weill Cornell Imaging at NewYork-Presbyterian
Nuclear Medicine, New York Presbyterian Hospital, 525 East 68th Street, STARR 2, New York NY 10065
Cornell University - Ithaca Magnetic Resonance Imaging Facility (CMRIF), Martha Van Rensselaer Hall, 116 Reservoir Ave, Ithaca, NY 14853

WHY IS THE STUDY BEING DONE?

The purpose of this study is to establish a noninvasive accurate imaging method for measuring and quantifying iron changes in the brain of subjects with Parkinson's disease or REM Sleep Behavior Disorder (a condition which could start many years prior to the onset of the motor symptoms in Parkinson's Disease). This study will evaluate the rate of iron accumulation throughout different stages of the disease and compare it to controls (group of individuals who do not have Parkinson's Disease or REM Sleep Behavior Disorder who are participating in this study). Thus, we will be able to see if iron starts to accumulate in patients with Parkinson's Disease or REM Sleep Behavior Disorder, potentially before motor symptoms develop.

In this study we hope to monitor you over a period of 24 months to observe any long-term changes in your imaging (MRI) test results and clinical symptoms. Subjects who are enrolled with either Parkinson's Disease or REM Sleep Behavior Disorder will undergo the same clinical and imaging assessments. For a detailed description of the different assessments please refer to the schedule of activities in the "**What's Involved in the Study?"** section.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as subjects.

About 100 subjects will take part in this study. There will be six groups of participants based on diagnosis, these groups include:
Parkinson's Disease Stage 1 (20 subjects)
Parkinson's Disease Stage 2 (20 subjects)

Parkinson's Disease Stage 3 (20 subjects)
Parkinson's Disease Stage 4 (20 subjects)
REM Sleep Behavior Disorder (10 subjects)
Healthy Controls (10 subjects)

All of the subjects will be recruited here at Weill Cornell Medicine or Hospital for Special Surgery.

WHAT IS INVOLVED IN THE STUDY?

If you decide to participate in this study, you will be asked to sign this consent form and you will undergo a Screening/Baseline visit to make sure that you meet the criteria to be in the study.

Questionnaires: At each study visit, you will complete paper-based questionnaires about your general health, physical activity, and your ability to complete daily activities. These questionnaires are being administered for research purposes only.

Magnetic Resonance Imaging (MRI) - Brain Imaging: MRI is a commonly performed medical procedure. In fact, about 30 million MRI scans are performed in the United States each year. It takes about 45 minutes to obtain these pictures. You will need to lie still inside a big machine. The machine will make noise, but otherwise you will not feel anything. The machine will use magnets and radio signals to gather information about your brain. This information will be used to construct a picture of how your brain looks, how much blood is flowing to different parts of your brain, and how much some parts of your brain are communicating with each other. You will undergo a MRI exam at Screening/Baseline and 24 Months. If you receive a baseline MRI exam as part of your standard of care imaging for your disease, this MRI exam will be used to satisfy the MRI screening/baseline requirement and will be considered performed for standard of care purposes and billable to you/your insurance company. If a baseline MRI exam needs to be performed for the purposes of this research study only (i.e. you have previously received an MRI for standard of care purposes outside the screening window and the exam must be repeated for research purposes or if you do not have an MRI exam on file within the screening window and this exam must be performed for the purposes of this study only) it will be billable to the study. The subsequent MRI exam performed at 24 Months is considered performed for research purposes only and billable to the study.

PE2i Positron Emission Tomography (PET) Scan - Brain Imaging: The PE2i PET procedure will begin by placing an intravenous (IV) catheter in a vein in one of your forearms. A small amount of a specialized PET chemical (drug) will be injected into your blood stream through an IV catheter. The chemical has a radioactive atom on it that gives off radiation. This radiation, cannot be seen with the human eye, but it can be seen by PET camera. The radiation makes it possible for the PET camera to watch where ever the chemical goes, and see how it interacts with your brain. The chemical, called "PE2i" helps us see how your dopamine system is working and

will bind to dopamine transporters (DaT) on the neuron. PE2i is an investigational chemical. This means that it has not been approved by US Food and Drug Administration (FDA) for general use. It has only been approved for use in research studies like this one.

DaT (iuflopane) Single Photo Emission Computed Tomogrpahy (SPECT) Scan – Brain Imaging: The DaTSCAN procedure will begin by placing an intravenous (IV) catheter in a vein in one of your forearms. A small amount of a specialized SPECT chemical (drug) will be injected into your blood stream through an IV catheter. The chemical has a radioactive atom on it that gives off radiation. This radiation, cannot be seen with the human eye, but it can be seen by SPECT camera. The radiation makes it possible for the SPECT camera to watch where ever the chemical goes, and see how it interacts with your brain. The chemical, called "iuflopane" helps us see how your dopamine system is working. This scan has been approved by US Food and Drug Administration (FDA) for the indication it is being used for in this study.

Lugol's Solution: If you are receiving the DaT scan, before the scan occurs subjects will ingest a small amount of Lugol's solution which is a saturated solution of potassium iodide. The purpose of Lugol's before a DaT scan is to protect the thyroid from radioactive iodine.

You will undergo either a PE2i PET Scan with PE2i or DaT scan at Screening/Baseline and 24 Months. The PE2i PET scan or DaT scan performed as part of this study will be performed for research purposes only.

Please see the schedule of events below for a summary of what to expect at each study visit:

Screening/ Baseline Visit:

During this visit we will:

- Review the study, answer any questions you may have and ask you to sign this consent document if you wish to be a part of the study
- Give you a subject identification number

If you meet all of the requirements of the study, the tasks listed below will be done:

- Review your medical history including your age, sex, major health events (e.g. hospital admissions)
- Review your current medication use, including over the counter medications and herbals
- Perform a physical and neurological exam
- Ask you to fill out questionnaires about quality of life and other PD symptoms
- Ask you to complete a Montreal Cognitive assessment (MoCA) test
- If you are a woman who can get pregnant, a pregnancy test will be done using a urine sample**.**
- Perform MRI of the brain

- Perform PE2i PET scan of the brain with PE2i or DaT scan with iuflopane

24 Month Visit:

- Review your current medication use, including over the counter medications and herbals
- Perform a physical and neurological exam
- Assess/Monitor your PD symptoms using various rating scales.
- Ask you to fill out questionnaires about quality of life and other PD symptoms
- Ask you to complete a Montreal Cognitive assessment (MoCA) test
- If you are a woman who can get pregnant, a pregnancy test will be done using a urine sample**.**
- Perform MRI of the brain
- Perform PE2i PET scan of the brain with PE2i or DaT scan with iuflopane

During the period of time between your screening/baseline visit and the 24 Month visit, you may return to the clinic for monitoring of your disease as part of your standard of care follow up prescribed by your treating physician. As part of this research study, we will collect clinical information relating to your diagnosis which is located in your medical record. This is called a research chart review, clinical information which will be collected for research purposes may include new medications prescribed, imaging results, and information relating to disease progression.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for 24 Months.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study team first.

If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with WCMC, New York-Presbyterian Hospital, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

WHAT ARE THE RISKS OF THE STUDY?

Risks and discomforts include:

1. PE2i PET scans: You may experience discomfort from lying still on your back for each scan; some people feel claustrophobic in the PET scanner. If this happens we would stop the scan immediately. PE2i-PET scans are experimental studies that may be conducted only for medical research purposes. PE2i-PET involves exposure to radiation, and that exposure is increased the more often such imaging tests are done. The PE2i tracers are radioactive because one of the atoms (Carbon-11) that make up the drugs has been man-made in such a way that it will spontaneously decompose. When it does, it will give off a type of radiation in the form of rays. These special type of rays are a form of radiation that cannot be seen with the human eye, but the camera has sensors that can detect where it is coming from inside your body. These rays will be used to make pictures of your brain. In this study, you may have either 2 PET scans over a 24 Month period. The total amount of radiation that you will be exposed to from the PET scans in this study is a little less than the amount of radiation exposure allowed for occupational workers over a period of one year. There are always theoretical risks associated with exposure to radiation of any kind. These risks are considered within acceptable limits for human subjects who will not personally benefit from their participation in the research study. Tell the study doctors if you have participated in other research this past year that involved exposure to radiation.

2. Radiation Exposure. Tests included in this study, PET (positron emission tomography) or SPECT (single photo emission computed tomography) nuclear medicine scans, are employed routinely in the care of patients with medical conditions. They involve exposure to radiation and that exposure is increased the more often such tests are done. Radiation exposure at certain doses can potentially cause cancer. Any possible increase in cancer risk associated with participation in this study is within acceptable limits for human research subjects.

3. Allergic reactions.
   With any drug (radioactive chemical substance used in PE2I PET scans or DaT scans), there is a possibility of an allergic reaction. Allergic reactions most commonly are mild such as a rash, cough, dizziness or fainting, hives, itching, chest tightness, shortness of breath, or wheezing. Rarely, a more severe and possibly even life-threatening reaction can occur, such as anaphylaxis (a reaction which may involve shortness of breath, swelling or closing of the airway and/or drop in blood pressure). In the event of an allergic reaction, medical treatment will be immediately available from the study staff. The risks of an allergic reaction from imaging exams in this study are very low.

4. IV catheter. Before each PE2i PET scan or DaT scan study begins, a catheter will be placed in a vein of your forearm. Catheter placement may cause bleeding, bruising, redness, swelling discomfort, and/or pain at the needle site or dizziness and fainting. The bruising and discoloration at the areas where the venous catheters are inserted may last for several days after the study. On rare occasions, they may cause clot formation and infection. You

should discuss these risks with your study doctor. You must notify the study physician right away if you have any symptoms from the catheter in your arm.

5. DaT scans. The most common side effects of DaT imaging are headache, increased appetite, and dizziness. However, it is important for you to know that the injection of DaTscan may include risks that cannot be predicted, although for the purposes of this study, it is being used in accordance with its FDA approved usage. The insertion of the IV may feel uncomfortable and may leave a bruise. You will need to lie very still under the camera for up to 1 hour, which may be uncomfortable. The DaT scan included in this study is employed routinely in the care of patients with medical conditions. It involves exposure to radiation and that exposure is increased the more often such tests are done. Radiation exposure at certain doses can potentially cause cancer. Any possible increase in cancer risk associated with participation in this study is within acceptable limits for human research subjects.

6. Lugol's Solution. Lugol's Solution is 10 drops of saturated solution of potassium iodide. You may experience a metallic or bitter taste in your mouth from iodine. **If you have allergies to iodine,** you must inform your study doctor. Patients with iodine allergies may experience itching, a rash, bloating, severe blood pressure changes (shock), or death if given iodine. If you are allergic to iodine, you will be administered potassium perchlorate instead of Lugol's solution.

7. MRI scans. The MRI scan involves the use of a magnet and radiofrequency waves (much like an ordinary shortwave radio.) There are no known risks or adverse effects resulting directly from exposure to magnetic fields and radiofrequency signals used in this study, other than the potential risks associated with the scanning procedure summarized below:
   A. Claustrophobia. Some people feel claustrophobic in the MR scanner. If this happens we would stop the scan immediately.
   B. Metallic Foreign Body Risks. You may not be able to undergo MRI scanning if you have a pacemaker, an implanted defibrillator or certain other implanted electronic or metallic devices. It is important for you to advise the MRI staff if you have had brain surgery for a cerebral aneurysm, or if you have implanted medical or metallic devices, shrapnel, or other metal fragments or objects in your body, such as metal in your eye

8. There may be unforeseen risks that cannot be anticipated.

9. Incidental Findings. The PET or DaT scans and the MRI scans will be interpreted by a WCMC Department of Radiology faculty radiologist. The report of the findings will be provided to the study PI. The PET scans, DaT scans, or the MRI scans could show unexpected findings that seem unusual. These findings could suggest that we have accidentally discovered a disease that you didn't know you had. If this situation occurs, we might recommend that you have these findings investigated in collaboration with a physician who is not involved in this study. This could result in anxiety, risks unrelated to the research

procedures, and health care costs. These costs are not covered by the study or WCMC, and therefore are the sole responsibility of the subject and or the subject's insurance company.

10. Frustration and Anxiety during clinical testing: You may feel frustrated while completing the study questionnaires. You are free to stop a test at any time if you feel frustrated, embarrassed, or if you choose not to continue.

11. Loss of Confidentiality: Participation in this research carries a small risk of loss of confidentiality. We will code the information we collect from you rather than using your name or other information that can directly identify you. Every effort will be made to maintain your confidential information and protect personal information obtained as a result of this study. Therefore the possibility of someone obtaining your confidential information is low.

12. Risks related to pregnancy: Women who are pregnant or nursing will not be included in the study. Women who can get pregnant must confirm to the best of their knowledge that they are not pregnant or intending to become pregnant during this study. Women who can get pregnant will have a pregnancy test before the start of the study. If the test is positive during your Screening/Baseline visit, you will be excluded from the study. The risk associated with undergoing a PE2i PET or DaT scan while pregnant are unknown. There are no known risks from MRI imaging during pregnancy. However, there may be risks that are currently unknown. Therefore, the study team will take all precautions to verify that you are not pregnant at the time of undergoing this imaging test. If you decide you wish to become pregnant you must notify the study team immediately.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

We cannot and do not guarantee that you will receive any benefits from the study. We hope the information learned from this study will benefit other patients with Parkinson's disease and RBD and improve inclusion criteria for future clinical trials.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have these options:

You may choose not to participate. Choosing not to participate will not impact your care at New York Presbyterian Weill Cornell Medicine.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to legal requirements and may be part of your medical record. You will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

- Weill Cornell Medical College and New York-Presbyterian Hospital
- Hospital for Special Surgery
- The Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)
- Department of Health and Human Services and National Institutes of Health
- The Food and Drug Administration (FDA) and/or their representatives
- National Institutes of Health (NIH)

By signing this consent form, you authorize access to this confidential information. You also authorize the release of your medical records to Weill Cornell Medical College and New York-Presbyterian Hospital by any other hospitals or institutions where you might receive medical care of any kind while you are participating in this study.

If information about your participation in this study is stored in a computer, we will take precautions to protect it from unauthorized disclosure, tampering, or damage by requiring a unique ID and password to log into the database. Each participant will have a personal folder containing all relevant documents (consent forms, contact information, etc.), which will be stored locked in the Department of Radiology offices. Data will be entered into a dedicated study research database that is password protected. In addition, only personnel who are associated with the study will have access to the study specific records in the database.

Please also note that your MRI and PET or SPECT imaging that are done as part of this study will be read and interpreted by a WCMC Department of Radiology radiologist and the report will be provided to the Principal Investigator. If there are any unsuspected, incidental findings that you should know about, the Principal Investigator will share the findings with you or a physician who you may designate. Incidental findings noted on the MRI and PET or SPECT studies might or might not have clinical significance and might or might not lead to further medical tests or treatments. It will be up to you and your designated physician to determine if any further testing or treatment is necessary on the basis of this information.

A description of this clinical trial will be 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.

HIPAA AUTHORIZATION TO USE or DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Purposes for Using or Sharing Protected Health Information: If you decide to join this study, WCMC researchers need your permission to use your protected health information. If you give permission, Weill Cornell Medical College (WCMC) and/or New York-Presbyterian Hospital

(NYPH) researchers may use your information or share (disclose) information about you for their research that is considered to be protected health information.

Voluntary Choice: The choice to give WCMC and/or NYPH researcher's permission to use or share your protected health information for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for WCMC and/or NYPH researchers to use or share your protected health information if you want to participate in the study. If you decline to sign this form, you cannot participate in this study, because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care from WCMC and/or NYPH.

Protected Health Information To Be Used or Shared: Government rules require that researchers get your permission (authorization) to use or share your protected health information. Your medical information may be disclosed to authorized public health or government officials for public health activities when required or authorized by law. If you give permission, the researchers could use or share with the entities identified above any protected health information related to this research study from your medical records and from any test results, which includes the results of MRI and PET or SPECT scanning.

Other Use and Sharing of Protected Health Information: If you give permission, the researchers could also use your protected health information to develop new procedures or commercial products. They could share your protected health information with the WCMC Institutional Review Board, inspectors who check the research, government agencies and research study staff. The information that may be shared with the sponsor and/or government agencies could include your medical record and your research record related to this study. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule.

Future Research

You may agree to allow your data to be used for future research either within or outside WCMC and/or NYPH. If information goes to an outside entity then the privacy rule may not apply.

RESEARCH REPOSITORY

What is a Research Repository? A research repository (database) is a collection of information from the health and medical records of many individuals. The repository (database) may share the information with researchers who study medical conditions and diseases.

The repository (database) includes codes that identify each person whose information is collected. However, the repository does not share information with researchers unless the researchers promise to keep the information confidential.

RESEARCH PARTICIPANT: Please check the boxes below that describe your wishes:

☐ The WCMC Repository may keep my protected health information and share it with qualified researchers studying the research described above. If information goes to an outside entity then the Privacy Rule may not apply.

☐ The WCMC Repository may not keep my protected health information for a research repository. If you do not allow your PHI to be stored in a repository, you are not eligible for this study. Your health care will not be adversely impacted in any way.

CANCELING AUTHORIZATION

Canceling Permission: If you give the WCMC and/or NYPH researchers' permission to use or share your protected health information, you have the right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used or shared.

If you wish to cancel your permission, you may do so at any time by writing to:

Privacy Officer
1300 York Avenue, Box 303
New York, NY 10065

If you have questions about this, call: (646) 962-6930 or e-mail: privacy@med.cornell.edu

End of Permission: Unless you cancel it, permission for WCMC and/or NYPH researchers to use or share your protected health information for their research will never end.

ACCESS TO RESEARCH RECORDS During the course of this study, you will have access to see or copy your protected health information as described in this authorization form in accordance with Weill Cornell Medical College (WCMC) and/or New York-Presbyterian Hospital (NYPH) policies. During your participation in this study, you will have access to your research record and any study information that is part of that record. You will have access to your clinical medical record, which is kept as part of your health record within the hospital's electronic medical records systems.

WHAT ARE THE COSTS?

You or your insurance company will have to pay for in-office physician visits performed at Baseline, and 24 Months if these visits are performed as standard of care. If the study Baseline/screening in-office visit or the study 24 Month in-office visit does not coincide with a standard of care office visit, these visits will be billable to the study. If you receive a baseline MRI exam as part of your standard of care imaging for your disease within the screening window, this MRI exam will be used to satisfy the MRI screening/baseline requirement and will be considered performed for standard of care purposes and billable to you/your insurance company. If a baseline MRI exam

needs to be performed for the purposes of this research study only (i.e. you have previously received an MRI for standard of care purposes outside the screening window and the exam must be repeated for research purposes or if you do not have an MRI exam on file within the screening window and this exam must be performed for the purposes of this study only) it will be billable to the study.

The following procedures are considered performed for research purposes and will be provided at no cost to you: PE2i PET Brain Scan or DaT scan performed at Baseline, and Month 24 visit; MRI Brain performed at Baseline (see above exception for standard of care MRI exams performed at screening/baseline), 24 Month visits.

If unsuspected, incidental findings are noted in the review of the MRI and PET or SPECT studies and further medical tests and/or treatments are considered, such tests and/or treatments are no longer considered part of the study and therefore would be billed to you or your insurer. You should expect no compensation or reimbursement for these costs or any risks and anxieties associated with any such follow up care. You or your insurance company will also be charged for any continuing medical care and/or hospitalization that are not a part of the study.

The Policy and Procedure for Weill Cornell Medical College are as follows:

We are obligated to inform you about WCMC's policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from WCMC or New York-Presbyterian Hospital. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

COMPENSATION FOR PARTICIPATION

You will receive compensation for participating in this study.

You will receive $25 dollars at the MRI scanning appointment performed at 24 Months. If you are asked to undergo a repeat research MRI at baseline visit, you will not be provided with compensation for this baseline MRI visit. You will receive $100 dollars at each PE2I PET or DaT scanning appointment performed at screening/baseline and 24 Months. The total compensation for participation in this study is up to amount of $225 dollars.

You may be eligible to receive some reimbursement for your travel expenses, depending on the distance you travel to come to the study site. You will be required to obtain approval in advance, and provide the study coordinator with receipts of your travel expenses. Please ask the researchers for additional information.

You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.

COMMERCIAL INTEREST The Cornell Center for Technology Licensing has a patent on the MRI methods being used in this study. Dr. Wang is a named inventor on the patent.

Dr. Wang is a named inventor on the patent on the MRI methods being used in this study. The related QSM technology patents are owned by Cornell University and have been licensed to Medimagemetric. Dr. Wang holds equity in Medimagemetric. Cornell also owns equity in Medimagemetric and thus has a financial interest in the outcome of this study. Dr. Kelly Gillen is a paid consultant for MedImageMetric.

If you have any questions or would like additional information about the financial interests described in this paragraph, please contact Weill Cornell Medical College's Office of Research Integrity at (646) 962-8200.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose to not take part in the study or to leave the study at any time. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with the Weill Cornell Medical College, New York-Presbyterian Hospital, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Dr. Alexander Shtilbans at 212-746-2474 or the Department of Neurology. Be sure to inform the physician of your participation in this study.

If you have questions about your rights as a research participant, contact the WCMC IRB Office. Direct your questions to:

Institutional Review Board at:
Address: 1300 York Avenue
Box 89
New York, New York 10065

Telephone: (646) 962-8200

Consent for Follow-Up Contact

We would like permission to contact you annually to update your contact information. We may contact you in the future should we decide that it is important to continue following your progress or if we open a new study to follow-up on people who take part in this study. Any new studies would go through ethics review (just like this one) and would have a new consent form for you to sign. You can decide at that time whether or not you would like to participate in any additional studies.

Please check **Yes** or **No** to indicate your preference:

☐ **Yes**, I give my consent to be contacted in the future.

☐ **No**, I do not want to be contacted in the future.

Consent for Research Study

Project Title: Quantitative Mapping of Substantia Nigra Iron in Parkinson's Disease (Stages I-IV, REM sleep behavior disorder) and Controls

Principal Investigators:
Alexander Shtilbans, MD (Department of Neurology)

RESEARCHER'S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____	_____	_____
Signature of person obtaining the consent (Principal Investigator or Co-investigator)	Print Name of Person	Date

SUBJECT'S STATEMENT

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with Dr. Alexander Shtilbans and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

_____	_____	_____
Signature of Subject	Print Name of Subject	Date