Study Title: Vestibulopathy, imbalance and gait disturbances in Parkinson disease

VA PI: Nicolaas Bohnen, MD, PhD

VA Study ID: 1604643

NCT#: NCT05446194

Protocol Version VA IRB Approval Date: 12/18/2025

VA INFORMED CONSENT CHECKLIST

Complete this checklist for each consent obtained and file with the original informed consent document

RESEARCH STUDY IDENTIFICATION (Required information)
STUDY TITLE: _____
PI: _____
NAME OF STUDY TEAM MEMBER OBTAINING CONSENT:_____
ROLE OF STUDY TEAM MEMBER OBTAINING CONSENT: _____

RESEARCH SUBJECT IDENTIFICATION: (Required information)

Last Name	First Name	Mid. Init.	Last-4 SSN	Todays Date (mm/dd/yy)
			| | |	/ /

A.	Date ALL required SIGNATURES (Subject, Witness (If required by IRB) and Person Obtaining Consent), their PRINTED NAMES and the DATES they signed the informed consent document (ICD) have been Checked and Verified Accurate and appear in the proper location
B.	DATE AND TIME (ICD) WAS REVIEWED AND DEEMED COMPLETE AND VALID **Must be prior to date/time of Subject's First Study Activity**
C.	DATE AND TIME OF THE SUBJECT'S FIRST STUDY ACTIVITY OR INVOLVEMENT
	Verify and Initial each requirement below.
1.	Informed consent and HIPAA Authorization, if required by VA-IRB was obtained from this subject prior to study participation.
2.	A VA Scope of Practice Form has been signed by the PI and approved by the VA IRB which designates me as an authorized agent of the PI and qualified to obtain consent for this study.
3.	This prospective subject was given adequate time necessary to carefully and fully read the Informed consent document (ICD) and all questions were answered to his/her satisfaction.
4.	All aspects of this subject's study involvement, including the purpose of the study, known and potential risks, possible benefits and alternatives to study participation were explained and discussed prior to subject signing the ICD.
5.	If required, a scanned image of the Research Enrollment Note, Consent Form and/or HIPAA Authorization will be entered into the subject's electronic medical record (CPRS).
6.	*Subject has been consented using the most recently approved, VA date-stamped version of the consent form (VA Form 10-1086) and HIPAA Authorization Form (VA Form 10-0493).*
7.	A copy of the completed and signed, original informed consent document has been issued to this subject and the subject was instructed to retain that copy for reference and to ask any and all questions that might arise throughout their study involvement.
8.	The subject has been shown where in the ICD to locate study team phone number(s) and the phone number of the VAAAHS IRB Coordinator. The subject has been reminded to call with any questions or concerns. Cathy Kaczmarek @ 734.845.3439
9.	The subject has been informed that participation is entirely voluntary and that they may withdraw their participation at any time and for any reason.
10.	Original ICDs and all copies are printed and issued as single-sided documents and that the original signed ICD must be kept in the investigator's project files on VA property.
11.	Upon completion of the Informed Consent Process, this subject's name was added to the Master List of All Subjects. [Per revised VHA Handbook 1200.05 (11/12/14) a MLS is no longer required, but a list of all enrolled participants is considered good research practice.]
12.	I know I can contact the VAAAHS IRB Coordinator at 734.845.3439 or the Research Compliance Officer at 734.845.4013 if I have questions or concerns regarding the consent of this or any individual considering study participation.

Department of Veterans Affairs **Research Consent Form**		
Title of Study:	**Vestibulopathy, imbalance and gait disturbances in Parkinson disease**	
Principal Investigator:	**Nicolaas Bohnen, MD, PhD**	VAMC: **VA Ann Arbor Healthcare System**

Key Information

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

The study is looking at performing detailed clinical assessments and brain imaging in subjects with Parkinson Disease (PD). This study is being funded by the Ann Arbor VA. By doing this study, we hope to investigate Parkinson Disease and balance issues.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

Your participation in this research will involve visits for clinical testing and imaging. We expect each visit to take 1 day. You will fill out a fall diary for 6 months as part of this study. Your total study participation time will last approximately 6 months. You may be asked to return for 2 optional follow-up visits up to 5 years after your initial study participation.

This study is being conducted at both the Ann Arbor VA and the University of Michigan.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

This study may benefit others in the future by obtaining data that may become important in the development of improved methods of reducing walking and balance problems in PD. More information will be provided later in this document.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

The most important reason(s)/risk(s) why you may NOT want to volunteer for this study is the risk of loss of data confidentiality, anxiety, and fatigue. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

You can decide not to be in this study, but if you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Nicolaas Bohnen MD, PhD, of the VA Ann Arbor Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: 734-998-8400.

RESEARCH SUBJECT IDENTIFICATION: (Required information)

			| | |	/ /
Last Name	First Name	Mid. Init.	Last-4 SSN	Todays Date (mm/dd/yy)

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

The study is looking at performing detailed clinical assessments and brain imaging in subjects with PD, especially freezing of gait (FoG) and imbalance. This study is being funded by the Ann Arbor VA. By doing this study, we hope to investigate Parkinson Disease and balance issues.

HOW LONG WILL I BE IN THE STUDY?

A maximum of 84 subjects with PD will be studied at The University of Michigan and Ann Arbor VA in this protocol.

The main research study is expected to take approximately four years. Your participation in this research will consist of two or three visits and will last approximately 6 months. You may be asked to return for 2 optional follow-up visits. The first follow-up visit will occur 3 years (± 1 year) after your first visit. The second follow-up visit will take place 2 years (± 1 year) from the first follow-up visit.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

This study involves a maximum of three visits: a screening/baseline visit which includes imaging and 2 optional follow-up visits. Below are some assessments or information that will be collected during your study participation.

Disease information: Basic clinical information will be asked of you. For example, we will collect age and specific details about the symptoms you experience with your PD.

Thinking and memory tests: These tests are designed to get an overall estimate of your memory, concentration, and ability to think. These functions will be measured with standard tests.

Motor assessments: These assessments will involve using some equipment to evaluate your balance and walking abilities. We will place small sensors at your wrist, ankles, and around your chest to measure your body movements while you perform different balance and walking tasks. Some of the walking may be tested while on an electronic gait mat. For participants that are taking dopaminergic medications, some of these assessments will be performed while you are “on” and “off” your dopaminergic (PD) medications. After motor testing has been completed you can take your medication.

Vestibular testing: These assessments will involve evaluating your inner ear system called the vestibular system. We will perform an ear exam prior to the vestibular testing to assess your ear canal. The vestibular testing may involve using multiple pieces of equipment. You may wear some goggles and follow some lights with your eyes. Also, you may be put into a chair that will spin. You may perform multiple tasks during the spinning. You may also have additional vestibular tests where you will look at a rotating black/white striped

drum or figure, or a test where warm or cool air or water will be administered in your outer ear canal or a test where an examiner will move your neck in left to right directions while you are wearing the eye goggles.

You will also be asked to sit in a comfortable chair and wear virtual reality goggles connected to a laptop computer controlled by the test administrator. When wearing the goggles, you will see one or more dots of light moving in different directions. You will be asked to follow these dots with your eyes in a specific way by a computer-generated voice. The test administrator will monitor your progress on a laptop computer and will ensure that you understand the directions for each test. These tests are designed to evaluate eye tracking, balance, reaction times, attention, and memory abilities. This will take approximately 20 minutes, including instructions and calibration.

Magnetic Resonance Imaging (MRI) scan: MRI scans allow the researchers to visualize all the structures in the brain in great detail by using a large magnet. An MRI scan of the brain involves lying on a table, which slides into a scanner. You will be instructed to remove all jewelry and other metal-containing objects for the MRI scan. During the MRI scan loud noises may be heard. The MRI scan will be performed in an FDA-approved MRI scanner at the Department of Radiology at the University of Michigan Hospital.

Positron Emission Topography (PET) scan: The PET scans will allow the investigators to “see” the specific marker of dopamine transportation in the brain. To establish this a chemical tracer will be injected into your vein through an i.v. (intravenous line or plastic “tube” inserted in an arm vein). A tracer refers to a small amount of a radioactive substance that does not alter body function, but that can be detected (imaged) in the PET scanner. The tracer will be injected as you lie on a table, which will move into a hollow machine resembling an X-ray scanner (CT or CAT). Images of your brain will be obtained over a period of time. Women of childbearing potential may be required to provide a urine sample for a urine pregnancy test within 48 hours prior to the PET scan. For the PET scan you will be asked to withhold taking your dopaminergic medications, such as Sinemet (levodopa) or Mirapex (pramipexole), on the morning of your testing.

Please refer below for more detailed information regarding these assessments and your study participation.

While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

This study is occurring in association with the University of Michigan. Some of the data collected from this project will be collected at the University of Michigan and all data will be combined between the Ann Arbor VA and the University of Michigan.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

The known or expected risks will be defined as: **Likely** - occurring in more than 25% of people (more than 25 out of 100 persons); **Common** – occurring in 10% - 25% of people (in 10 to 25 out of 100 persons); **Infrequent** - occurring in 1 - 10% of people (1 to 10 out of 100 people); **Rare** - occurring in less than 1% of people (fewer than 1 out of 100 persons); or **Very Rare** - occurring in less than 0.1% of people (fewer than

1 in 1,000 persons).

The known or expected risks will be described in normal script.
The actions that the researchers take to minimize these risks will be described in italic script, as demonstrated in this paragraph.

General risks:
There is a **very rare** risk of breach of confidentiality, which may affect privacy, self-esteem, social standing, employability, and insurability.
In general, study records will be kept in databases maintained by the researchers. These databases are kept separate from medical records, are protected by passwords, and can only be accessed by personnel involved in the study. If you withdraw from the study at any time, a record of the withdrawal and the reasons given for withdrawing may be kept as part of the study record.

There is a **rare** risk that you may experience some minor anxiety ('test anxiety'), become worried, or have an anxiety reaction in response to any of these tests and procedures. For example, you may become worried about your health, or you may experience a sudden fear of the confined space while in the scanner.
Trained research staff will conduct all tests and procedures. The staff will be prepared to respond to your anxiety, concerns, and behavioral changes by temporarily suspending testing, breaking up testing sessions into several brief visits if needed, and/or answering your questions. During the PET and MRI scans you will be able to talk to technologists throughout the scan and indicate right away if you wish to stop the study and leave the scanner. At the option of your personal physician, (s)he may prescribe sedation with lorazepam (Ativan) or diazepam (Valium) to be taken before the scan in accordance with the prescription directions.

In most patients, temporary withdrawal of dopaminergic medication can be accomplished safely on an outpatient basis and may result in reduction in functional abilities, but not result in inability to conduct essential activity of daily living. There is an **infrequent** chance that you may develop "freezing" symptoms, which is caused by stiffening of your muscles making movements more difficult. You may require additional assistance from your caretaker during this time.
Any risk of adverse effects will be minimized by careful supervision during the morning after the overnight withdrawal of the dopaminergic medications. You will be instructed to resume taking your dopaminergic medications after the completion of the testing. If the withdrawal of medication is intolerable, you may resume taking medication and withdraw from this study at any time.

There is an **infrequent** risk of boredom, frustration, and/or mental and physical fatigue during the thinking and memory testing.
Trained research staff will conduct all the tests and administer all the questionnaires. The staff will be prepared to respond to your concerns by temporarily suspending testing and/or breaking up testing sessions into several brief visits if needed.

None of the test results, brain images, and procedures in this study will be reviewed or interpreted for making a medical diagnosis. Any result or abnormality that would be indicative of current or future disease

will most likely not be discovered. However, if we do find a clinically relevant result or abnormality that deserves additional medical attention we will communicate this to you and you will be urged to visit your primary health care provider. Such a finding might require additional studies, and maybe even treatment, which would not be paid for by the investigators, the sponsor, the Ann Arbor VA, or the University of Michigan. The research results of the brain images will NOT be communicated back to you.

You should consult your personal doctor if you have any health concerns.

Fall diary study:

There is a **very rare** risk that confidentiality will be breached when the diary, fall-event information sheet, or the activity questionnaires are returned to us by mail.

You will be asked not to write your name on neither the envelope nor on any of these test materials. We will write a code on the test materials that will allow us to connect these test materials with your name. This code is securely monitored and behind lock and key, only accessible by the research staff

Clinical tests:

There is a **very rare** risk of physical fatigue during the clinical examination.

Trained research staff will conduct all the tests. The staff will be prepared to respond to your concerns by temporarily suspending testing and/or breaking up testing sessions into several brief visits if needed.

Motor testing:

Many of the tests are comparable to normal standing and walking conditions that you may experience in everyday-life. Nonetheless, there is an **infrequent** risk of falling or near-falling during these tests which may result in fall-related injuries.

Trained research staff will remain in close proximity to you at all times and observe ('spot') you to prevent you from falling.

There is a **very rare** risk that the sensors used may become detached and that you may trip. You may also trip on the walking mat.

We will regularly check the sensors for appropriate attachment, and you will be closely monitored.

Eye movements will be measured with video eye goggles while you are making small eye movements. There is **rare** risk that this may cause some eye strain or discomfort.

Rest breaks will be provided if needed. Any minor eye strain will disappear shortly after the test.

There is a **very rare** risk that you may experience some minor eye strain when doing the visual tracking tests.

Rest breaks will be provided if needed. Any minor eye strain will disappear shortly after the test.

Vestibular testing:

There is an **infrequent** risk that you may experience dizziness, nausea, headache, feeling off balance, feeling unsteady on feet, blurry vision or having a warm or cold feeling in the ear, and there is a **rare** risk of vomiting.

Rest breaks will be provided if needed. Any dizziness, nausea, headache, feeling off balance, feeling unsteady on feet, blurry vision or having a warm or cold feeling in the ear will disappear shortly after the test.

There is an **infrequent** risk that during vestibular testing a piece of ear wax may become loose and may plug up the ear that could result in hearing and balance changes.

This typically resolve within days but when persistent may require ear cleansing by your physician.

There is an infrequent risk that while wearing the virtual reality goggles you may experience minor discomfort around your eyes, forehead, and nose. There is a rare risk that the virtual reality goggles may cause mild nausea or dizziness.

Rest breaks will be provided if needed. Any discomfort or nausea will disappear shortly after the test.

MRI scan:

There is a **likely** risk of discomfort or anxiety from being in the confined space of the MRI scanner.

We will provide pads and blankets to make you as comfortable as possible. You will be able to talk to us throughout the study, and you will be able to let us know right away if you want to stop the study and get out of the scanner.

The MRI scanner makes loud, vibrating noises.

You will wear foam earplugs to reduce the loud noises made by the scanner and to prevent any hearing damage.

Some studies, like this one, have the potential to cause "peripheral nerve stimulation" (PNS). PNS is a light touching sensation on the skin surface, lasting only for a few seconds. It may cause mild discomfort, but is not harmful to you.

The MRI machine is operated within FDA guidelines so the potential for inducing PNS is low.

In **very rare** situations, subjects report a temporary, slight dizziness, light-headedness or nausea during or immediately after the scanning session.

If you feel dizzy or light-headed, we will have you get up slowly from the scanner.

Because the strong electromagnetic fields can move metal objects and cause heating, there is a risk that loose objects (jewelry, keys) outside your body could be accelerated by the magnetic field and strike you, causing you injury. There is also a risk that the magnetic fields could disturb a metal fragment in your body, interfere with an implanted device, such as a pacemaker or neurostimulator, or cause metal (including foil-backed medication patches) on or in your body to heat up, causing you harm.

We keep the environment around the MRI scanner completely free of loose metal objects that could be moved by the magnetic field, and we will make sure that you have no metal on your body that could be affected by the MRI scanner. We will also ask you questions and have you complete an MRI screening form to make sure that you have no metal inside your body that would cause you harm during the MRI scan.

PET scans:
There is an **infrequent** risk of bruising, bleeding, infection, or soreness associated with intravenous (IV) and/or arterial catheter placement during the PET scan, similar to the risks associated with routine blood testing. Also, you may feel dizzy or lightheaded or may rarely even faint when the tube is put in or taken out.

We will use highly trained personnel for placement and removal of the IV.

There is a **very rare** risk that you could experience an allergic reaction to the PET tracer. This could involve itching, skin rash or shortness of breath shortly after injection. However, because of the very small tracer amounts used in PET imaging, the risk is very rare.

A physician will be available and an emergency cart is located in the PET Facility for treatment of any adverse reactions that may occur.

During the course of this study, you will be exposed to radiation from the PET transmission scan and the [11C]PE2I PET radiotracer.

The biological effect of radiation in humans is measured in terms of Sieverts (Sv) or mSv (1/1000 Sv), which is a unit of uniform whole body exposure. All subjects will undergo a [11C]PE2I scan. The exposure for a single [11C] PE2I *PET scan is 3.6 mSv. Each scan will also require a head CT scan which adds 0.17 mSv per scan. Thus you will be exposed to a total of about 3.8 mSv for the PET scan. Your life-time radiation risk includes the background radiation you are exposed to naturally like everyone else living on this planet, which is on the average 3 mSv per year. The exposure resulting from this PET scan in a single year is about 1.3 times higher than the natural background exposure. In case of a technical failure of the scan, you may be asked to undergo a repeat [11C]PE2I PET scan.*
Due to the possible repeat scans, your total exposure may be 9.6 mSV or less. The effects on the body of this radiation exposure will be added to your overall lifetime radiation risk. The US Federal Government requires that the annual amount of radiation exposure of radiation workers does not exceed 50 mSv per year; the radiation you will be exposed to in this study is a maximum of 20% of this amount.

Your lifetime radiation risk also includes any radiation you may have received in the past for diagnosis or treatment, and any such radiation you may be exposed to in the future.

Please inform the investigators if you have had any major radiation exposure in the past, particularly in the past year, such as medical treatment with X-rays or radioactivity, or diagnostic X-rays, CT scans or nuclear medicine scans.

No PET studies will be performed on pregnant, nursing, or potentially pregnant women.

A urine pregnancy test will be performed on all women of childbearing potential within 48 hours prior to the PET scanning session.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Data obtained from this research may support the future development of improved methods for treating symptoms of Parkinson disease.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Your research records will be stored in a secure location to which only the research team has access. All research records will be stored under code numbers, without attached names or other identifying information. The "key" linking these records to your name will be stored in a separate, locked (electronic) file.

The data will be collected and stored securely on the VA server. The data collected at the University of Michigan will be securely transferred to the Ann Arbor VA, following a Data Use Agreement between the Ann Arbor VA and The University of Michigan.

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.

Identifiers will be removed from the identifiable private information that is collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medications.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Ann Arbor VA Institutional Review Board, University of Michigan Institutional Review Board, Food and Drug Administration Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO), the Parkinson's Foundation, or the University of Michigan.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to

the Principal Investigator at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the study team receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

To revoke your authorization please write to the address below:

Functional Neuroimaging, Cognitive and Mobility Laboratory
Domino's Farms, Lobby B Suite 1000, PO Box 362
24 Frank Lloyd Wright Drive
Ann Arbor, MI 48106

If you revoke this authorization, Nicolaas Bohnen, MD, PhD and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

You or your insurance will not be charged for any treatments or procedures that are part of this study. If you usually pay co- payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I BE PAID FOR PARITICIPATING IN THIS STUDY?

Visit #	Activities			$30 Travel per day	Total Compensation
1. Screening / Baseline (over 2-3 days)	PET Scan	MRI Scan	History, physical exam, motor tests, vestibular tests, surveys		
Compensation	$100	$100	$200	$60-90	$460-490
2. Optional Follow-Up #1			Physical exam, motor tests, vestibular tests, surveys		
Compensation			$25		$25
3. Optional Follow-Up #2			Physical exam, motor tests, vestibular tests, surveys		
Compensation			$25		$25

Compensation for your time and effort after full study completion may total a maximum of $540.
(Compensation will vary based on number of visits completed)

Overnight accommodations may be provided depending on personal circumstances or if you live far away. We will discuss with you the need for these accommodations as the research appointment(s) are being arranged. If eligible, overnight lodging can be arranged by a study team member and you. However, you may decide to make alternative arrangements. In that case, please discuss with the study team first if you are eligible for reimbursement prior to making any reservations. We can only reimburse for expenses that have been approved in advance by the study team. You will need to provide receipts to the study team before expenses can be reimbursed. Cost for overnight lodging and meals are estimated at $280 per night (3 nights per person maximum). You will receive a voucher for valet parking at the University of Michigan Hospital. Parking at Domino's Farms is free.

You will be paid after your last study visit or, in case you decide to withdraw from the study, you will be paid for the parts that you have completed. You will be paid by direct deposit if applicable.

Payments will be disbursed by the Ann Arbor VA Accounting Obligators. Due to limitations in the Financial Management System, payments made to subjects through Austin Financial Services Center generate Internal Revenue Service Form 1099 regardless of amount. Due to this we will ask you to provide your social security number to disperse payments. Since the study reimbursement is greater than $600 per year filing with the IRS is required.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

As a VA study participant, the VA (not you or your insurance) will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Ann Arbor VA Medical Center or arrangements may be made for contracted care at another facility. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at 734-845-3386.

VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85).

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: DURING THE DAY:
Mr. Robert Vangel at 734-936-1168

AFTER HOURS:
Dr. Nicolaas Bohnen at 734-936-6267 pager 10196

Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

You do not have to participate in this study. You may drop out of the study at any time without penalty. By doing so, you will not lose any benefits that you may be entitled to. If you do not participate in this study, your decision will not affect your eligibility to receive standard health care at the Ann Arbor VAMC. If you decide not to participate or to withdraw from the study, then this decision will not affect the availability of any accepted course of therapy for which you may be entitled to at the Ann Arbor VAMC. If you withdraw, you may be asked to return for a final study visit in order to assure your safety. Even if you withdraw your permission for us to use the information about you, we are required by regulatory agencies to record any information that relates to the safety of any study- related intervention.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Nicolaas Bohnen, MD, PhD
Study Coordinator: Robert Vangel, BS
Mailing Address: UM Functional Neuroimaging, Cognitive, and Mobility Laboratory 24 Frank Lloyd Wright Dr.
Suite B1000, Box #362
Ann Arbor MI 48105
Telephone: 734-998-8400

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the IRB Coordinators at (734) 845-3440 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.
We will let you and your physician know of any important discoveries made during this study, which may

affect you, your condition, or your willingness to participate in this study. If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law.

RE-CONTACT:

You will not be re-contacted, unless you indicate by initialing below that you may be contacted by researchers at the University of Michigan or Ann Arbor VA for studies for which you may eligible. If you agree to be contacted for other studies, we will keep your name and contact information in a separate password-protected database.

_____ (initials) I agree to be contacted about other research studies for which I may qualify. If I cancel my permission for this study, I will not be contacted for other studies. If I do participate in another study, data obtained in this study may also be used for that study.

Department of Veterans Affairs Research Consent Form		
Title of Study:	**Vestibulopathy, imbalance and gait disturbances in Parkinson disease**	
Principal Investigator:	**Nicolaas Bohnen, MD, PhD**	VAMC: **VA Ann Arbor Healthcare System**

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms._____has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name (Print)	_____ Participant's Signature	_____ Today's Date

Person Obtaining Informed Consent		
_____ Name (Print)	_____ Signature	_____ Today's Date

[IF MORE THAN ONE PAGE IS USED, EACH PAGE (VAF 10-1086) MUST BE CONSECUTIVELY NUMBERED.]