VA Puget Sound Health Care System
RESEARCH INFORMATION STATEMENT

TITLE OF STUDY: Washington State Parkinson Disease Registry

Researchers:

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If you have any questions about this form,
please feel free to contact us at 206-277-6080 or 888-365-9901

RESEARCHERS' STATEMENT

You are being invited to participate in a research study. The purpose of this Information Statement is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide whether you want to be in the study. This process is called "informed consent." You may keep this form for your records.

PURPOSE OF THE STUDY

The purpose of this research study is to create and maintain a database registry of information from people who are willing to participate in Parkinson's disease research. Eligible people who can participant in this study can be part of the following groups:

- People with Parkinson's disease or related disorders.
- People with an increased risk of developing Parkinson's disease or related disorders.
- People without Parkinson's disease (controls).

People with a diagnosis of atypical parkinsonism, including progressive supranuclear palsy (PSP), multiple system atrophy (MSA), corticobasal degeneration (CBD), and dementia with Lewy bodies (DLB), are also eligible to participate in the Registry.

The database will consist of information about the subject's disease and contact information to make it easier for researchers to enroll people into new research studies. Different investigators from the University of Washington and non-University of Washington affiliated institutions will conduct these research studies. By creating this Registry, we hope to improve access to those who are willing to participate in research studies and to facilitate the recruitment process for researchers.

We are asking you to give us verbal consent in order to obtain details of your disease (if any), your biographical information, and your permission to be contacted for future research studies. Your

participation is completely voluntary and there is no cost to participate in these research studies. If you consent to these terms, we will include you in the Washington Parkinson Disease Registry and contact you in the future when suitable research studies arise.

STUDY PROCEDURES

We will follow these procedures:

Screening Process. If you express an interest in participating, you will be asked 15 questions to determine your eligibility for the Registry. These include questions about diagnosis, medications, and symptoms. If you meet the basic criteria for inclusion in the study, we will explain the purpose, procedures, benefits, and risks of participation outlined in this Information Statement.

Consent Process. While most Consent Forms require your signature, we will be asking for verbal consent either over the phone or in person. This process is described as a Waiver of Written Consent. Other than the difference in asking for verbal consent, there is absolutely no difference in the degree of security or confidentiality in this process. You might not be able to provide verbal consent for several reasons, including:

- You might have diminished decision-making capacity.
- Your disease might have affected your ability to communicate (for example, you may have a soft voice or slurred speech).

Under these circumstances, we will ask your legally authorized representative (guardian, durable power of attorney, spouse, or other next of kin) to provide verbal consent. In addition, we will need to establish your willingness to participate in the Registry by asking your permission to be included in the Registry.

Data Acquisition. Once we verify that you have provided verbal consent, a Registry Coordinator will collect the following information:

- Biographical information such as name, address, phone number, date of birth, ethnicity, and email address
- Medical information such as initial and current symptoms related to Parkinson's disease, medications, complications from medications, history of deep brain stimulation (if applicable) and family history of Parkinson's disease
- Your interest in participating in various types of studies such as drug trials, genetics research, studies on environmental exposures, and "biomarker" research

We will also ask for your legally authorized representative's contact information (phone number, address, email) if different from yours. This is necessary since it will facilitate the follow-up / update process.

The interview process will occur over the phone or in person and should take no more than one hour. The interview can be made shorter and easier if you can prepare a list of medications and doses, physician names, and Parkinson's disease symptoms beforehand.

We will keep the information obtained during the interview process indefinitely unless you choose to withdraw from the Registry (see below).

We will ask for updates to both your biographical and medical information every year. This will ensure that we have the most up-to-date information on file. These one-year updates can be done by mail-in questionnaires, phone, e-mail, or a secure online form.

Operation of the Registry. An Executive Board will review all requests to use the Registry. The main function of the Executive Board, which consists of researchers from the University of Washington and the VA Puget Sound Health Care System, is to make sure that only quality studies are allowed to utilize the Registry. The Registry is also overseen by an Advisory Board which consists of representatives from the American Parkinson Disease Association, Northwest Parkinson's Foundation, and Northwest Collaborative Care.

Once a suitable research study arises, we will contact you by mail, e-mail or phone and provide you with further details and contact information for the study's Research Coordinator. If you agree to participate in any study, you will be asked to sign a specific Consent Form that describes that particular study in detail. Certain studies may not appeal to you. You are free to decide not to participate in any study and remain in the Registry. You are encouraged to call us at any time if you have questions or concerns about your participation in a particular study.

Some of the information obtained from your participation in other research studies will be given back to us and we will store this information in your Registry records. We will take a number of measures to ensure the confidentiality of this transferred information. Information given to us by outside research groups will not be available to you through the Registry. You may inquire about this information directly by contacting the research group that conducted the study.

RISKS, STRESS, OR DISCOMFORT

During the interview process, you may feel uncomfortable answering some questions. You may skip any question that you do not want to answer. We will make sure that the entire interview process is as stress-free as possible.

If you participate in other research studies, those researchers will protect the privacy of the information they collect about you. However, there is always a risk that someone could find out that you are a research participant and could learn private information about you.

BENEFITS OF THE STUDY

We do not expect you to directly benefit from being in this study. However, the facilitation of research studies and the improved access to these studies might provide future benefits to individuals with Parkinson's disease and related disorders.

CONFIDENTIALITY

Security Measures. Your confidentiality is one of our primary concerns. All telephone interviews are conducted in a secure private office. Information obtained in the Registry will be accessible only to those individuals and groups listed in this Information Statement. All of your research records will be kept in locked cabinets and protected computer files. If you complete your one-year update online, your research data will be temporarily stored in VA REDCap (VA Research Electronic Data Capture) - a secure web application for research data collection. Your information will never be given or sold for advertisement or fund-raising.

We will not place your name on any research data. Instead, we will assign a code number to your information. We will keep the master list that links your name to your code number in a locked cabinet. We will not share your information with anyone unless you ask us to. The only exception is if there is a risk of possible harm to others or to yourself. Your name will not appear in any reports about the Registry. All information and results from the Registry will be kept indefinitely unless you withdraw from the Registry.

Oversight Committees. In some cases, the following people or groups might ask to review our records to make sure that we are following all the regulations properly:

- The VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies
- Seattle Institute for Biomedical and Clinical Research (SIBCR). SIBCR is the nonprofit institute that works with the VA to conduct research and administers our research funds
- Other government oversight agencies that oversee research, such as the Department of Veterans Affairs, Department of Health and Human Services, and National Institutes of Health
- REDCap, a secure web application for research data collection

ALTERNATIVES

This study is voluntary and for research purposes only. If you are in this study, you can withdraw at any time. You will not be penalized for your decision to not participate or withdraw, nor will you lose your VA or other benefits if you decide to do so.

WITHDRAWING FROM THE REGISTRY

You can withdraw from the Registry at any time by notifying us in writing. All information except for your responses to the screening questionnaire will be deleted. This questionnaire will not contain any personal identifying information and cannot be linked to you. For regulatory reporting purposes, we will also retain gender, veteran status, and racial and ethnicity information.

Your decision will not affect the quality or level of care provided by your physician.

If we are notified that a Registry subject has died, we will retain all of his/her information for regulatory reporting and statistical purposes.

If a legally authorized representative requests to remove information, we will remove personal identifying information and retain responses on the screening questionnaire, as well as gender, veteran status, and racial and ethnicity information.

FOR SUBJECTS PARTICIPATING IN OTHER PARKINSON'S DISEASE STUDIES

If you are a current participant in Parkinson's disease-related studies conducted here at the University of Washington and the VA Puget Sound Health Care System (*Alzheimer's Disease Research Center: Participant Registry and Sample Repository, The PaGeR Study, or PANUC Clinical Core and Data Management), w*e are asking you to give us verbal consent in order to obtain the following:

- Your permission to provide the Registry with personal information:
  - Name
  - Date of birth
  - Home address
  - Phone number
  - Gender
  - Ethnicity/race
  - Email address (if applicable)
  - Legally authorized representative's contact number (if applicable)
- Your permission to transfer your medical information about your Parkinson's disease or related disorders from the above-mentioned studies to the Registry, such as your:
  - Age and year of first symptoms
  - Age and year of diagnosis
  - Current symptoms
  - Hoehn & Yahr stage
  - Results of available tests related to Parkinson's disease such as the *Unified Parkinson's Disease Rating Scale* (UPDRS), Montreal Cognitive Assessment (MoCA), detailed neuropsychological testing data, depression scales, and sleep scales/studies
  - Use of, response to, and complications from anti-Parkinson medications
  - Family history of Parkinson's disease and related disorders
  - Relevant medical/surgical history (for example, history of deep brain stimulator placement, low blood pressure, and damage to nervous system outside the brain or spinal cord)
- Your permission to provide the Registry with yearly personal and medical updates
- Your permission to be contacted for future research studies

If updates to your research records occur after we transfer your information to the Registry, we might also transfer this updated information to the Registry whenever this occurs.

OTHER INFORMATION

You will not be paid or otherwise receive compensation for taking part in the Registry.

If you have any questions regarding the diagnosis or treatment of Parkinson's disease, we can refer you to the appropriate agencies (such as the American Parkinson Disease Association and the Northwest Parkinson's Foundation) that can provide lists of support groups and physicians in your area.

We will not provide any medical advice.

Information generated by utilizing this Registry may be published in medical literature or used for medical education. Your identity, however, will never be included.

RESEARCH SUBJECT'S RIGHTS

After reading this Information Statement, if you have any questions about the study purpose, procedures, possible risks or discomfort, possible benefit, choices available to you, or your rights as a research subject, please discuss them with one of the researchers, study staff, or IRB staff listed above before agreeing to participate in this research study.

We appreciate your time and consideration of this study!