

# VA Portland Health Care System (VAPORHCS) Informed Consent Form

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Subject Name: \_\_\_\_\_ Date: \_\_\_\_\_

Title of Study: STAT-PD: Preventing Levodopa Induced Dyskinesia in Parkinson's disease with HMG-CoA Reductase Inhibitors (MIRB # 3869; eIRB # 17302)

Principal Investigator: Kathryn Chung, MD ICF Version Date: 10/05/2018

## **WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?**

About the research, call Brenna Lobb, MS MPH at (503) 220 – 8162 extension 51871.

If you become sick or injured or if you feel your privacy or confidentiality may have been violated (e.g., someone without authorization has received personal information about you), call Kathryn Chung, MD at (503) 721 - 1091.

To speak with someone not connected with this research study about your rights, discuss problems, concerns and questions, obtain information and/or offer input, please call the VA Portland Health Care System Research Office at (503) 273-5125, or the VA Regional Counsel at (503) 412-4580.

## **WHAT IS THE PURPOSE OF THIS STUDY?**

This is a research study. The purpose(s) of this study is to learn about movements in Parkinson's disease. Nearly all Parkinson's disease patients eventually develop involuntary, abnormal, and unwanted movements over time after they are treated with levodopa, the main treatment for Parkinson's disease. These movements can range from subtle to extremely debilitating and may or may not affect activities of daily living such as brushing your teeth. The purpose of this study is to look at these involuntary movements by measuring movement with a force plate, which is a platform on which you stand. You have been invited to be in this research study because you have Parkinson's Disease and have been on levodopa for more than five years.

## **WHO IS PAYING FOR THIS STUDY?**

Clinical Science Research and Development, Department of Veterans Affairs

## **HOW MANY PEOPLE WILL PARTICIPATE?**

Approximately 60 people will participate in this research study at the VA Portland Health Care System, 32 at Oregon Health & Science University in Portland Oregon, and 28 at the VA Puget Sound Health Care System in Seattle, Washington. With a total enrollment of 120 people.

## **HOW LONG WILL I BE IN THIS STUDY?**

If you agree to join and do not withdraw from the study before all procedures are complete, your participation in this study will last for approximately 2 months (after this visit).

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## **Do NOT Change Anything below this line, including bottom margin.**

Subject's Identification (I.D. Plate or complete below)

\_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_  
LAST FIRST SSN (last 4 digits)

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### WHAT WILL HAPPEN DURING THIS STUDY?

You will have one screening visit at the Portland VA and one full day visit at the Oregon Clinical and Translational Research Institute (OCTRI) at Oregon Health & Science University.

The screening visit will last approximately 1 hour. The investigator will ask you about your medical history, including your current and past medications. We may ask you to sign a release of information form so that we may verify your medication history. The investigator will perform a brief neurological exam to measure how your body is affected by Parkinson's disease. You will undergo a short test of your mental function such as memory, naming objects, copying figures and repeating a sentence. Your blood pressure and heart rate will be measured. An electrocardiogram (ECG) will be done to check electrical signals that control the rhythm of your heartbeat. Small discs will be attached to your chest, arms, and legs with a paste. Electrodes are connected to these discs that measure the electrical impulses of your heart. This procedure is painless and takes about 5 to 10 minutes to finish. You will be asked to hold still and breathe normally during the test.

If you are a woman who can get pregnant, a urine pregnancy test will be done. If you are pregnant, you will not be able to continue in the study.

The full day visit at OCTRI will occur within 2 months of your screening visit. Visit procedures are described in the OHSU Consent Form. You will need to arrange your own transportation to OHSU (have someone drive you or take alternative means of transportation such as bus, taxi, tram, Uber, or Lyft). The medications you will receive as part of the study during the all-day visit are not the same as standard healthcare for Parkinson's disease because you will receive the drug levodopa through an IV (intravenously) in your arm and it is usually taken in pill form.

The procedures, questionnaires, blood draws will be done for research purposes and will not be completed if you decide not to take part in the study.

	Screening - VA Portland
Screening tests and medical history	X
Parkinson's & Movement Examinations	X
Tests of thinking and memory	X
Blood draw (1 teaspoon.)	X
Heart Monitoring	X
Quality of Life & Parkinson's Questionnaires	X
Total time	1 hour

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During the screening visit, your blood will be used only for this research and will be destroyed immediately after they are analyzed.

### **WHAT ARE THE RISKS and POSSIBLE DISCOMFORTS of PARTICIPATION?**

Information that identifies you will be used in this study and shared with research staff, the National Institutes of Health, federal agencies including by not limited to: the Food and Drug administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), and the VA Office of the Inspector General (OID), the VA Portland Health Care System committees that oversee research, including the Institutional Review Boards that oversees the safety and ethics of VA studies, as well as the Institutional Review Board at OHSU. The research team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. It also could carry other risks, such as embarrassment or affecting ability to get insurance, current or future job status, plans to have a family, relations with your family, immigration status, parental rights or responsibilities, credit history or status in the community.

As a result of participation in this study, you may learn information about your Parkinson's disease and Parkinson's disease caused movements that could be upsetting to you. If you are upset about the results learned during the course of the research study, Dr. Kathryn Chung, MD may refer you to a counselor.

The following research procedures are in addition to those you would receive for your current health care.  
Blood draws

**Blood draw:** During a blood draw, you might feel discomfort at the site where the blood sample is being collected. Removal of blood by a needle and syringe poses a small risk of pain or bruising at the site of the needle stick, but this is temporary. Infrequently, people may experience fainting or dizziness and there is also a slight risk of infection at the site of the needles stick. However, we will take all available precautions to prevent an infection using sterile techniques.

Some of these questions may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions. If the questions make you very upset, we will help you to find a counselor.

**Stopping your PD medication, the night before the visit:** You may experience some discomfort or an increase in your Parkinson's disease symptoms by being "off" your medications during the night before testing. There is a rare possibility (less than 1%) that withholding your medication could cause something called neuroleptic malignant syndrome. This could include symptoms of high fever, high blood pressure, and/or

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confusion and should be treated as a medical emergency. If you feel you may be having any of these symptoms or cannot tolerate being off your PD medications, please go to the ER.

**For Women:** You should not become pregnant while participating. If you are or become pregnant, IV levodopa could affect a fetus in ways that we do not yet know about. If you are sexually active and at risk of getting pregnant, you and your male partner(s) must use one or two methods of birth control that work well, like birth control pills, a patch, long-acting progestins, an IUD, a diaphragm or condom with spermicide, or abstinence. You will have to do this the whole time you are in this study. If you become pregnant during the research study, please tell the investigator and your doctor immediately.

### **WILL I BENEFIT BY PARTICIPATING?**

You may or may not personally benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

### **DO I HAVE TO PARTICIPATE IN THIS STUDY?**

No. You may choose not to be in this study.

### **HOW WILL MY CONFIDENTIALITY BE PROTECTED?**

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Your identity will not be disclosed unless you give specific, separate consent or if required by law. All VA research records will be held in accordance with the VA records control schedule.

Identifiers related to you (i.e. information that can identify you) will be used in this research study and will include: your name, your social security number, your date of birth, your medical record numbers, your complete address, visit and any other dates, and your diagnosis codes. These identifiers may be used to obtain information about you and your health history from VA records and from the health information sources listed on the HIPAA authorization.

Your name, complete address, social security number, and date of birth will be disclosed to OHSU for scheduling purposes. If you do not have a medical record number at OHSU, one will be obtained for you.

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Prior to your day-long visit, your name, date of birth, and date of visit will be disclosed to the Lloyd Center Compounding Pharmacy in order to obtain the intravenous levodopa.

Lloyd Center Pharmacy  
438 E Burnside St  
Portland, OR 97214

Your information and specimens will be shared with other researchers as part of this study. A code number will be assigned to your information and specimens. Only personnel for this study will be authorized to link the code number to you. Other researchers who may receive your information and specimens will be given only the code number and will not be given any other information to link the code back to you.

Your blood samples will be coded with your study number, month and year of collection and will be sent to:

Flow Cytometry Shared Resource (FCSR)  
Oregon Health & Science University  
3181 SW Sam Jackson Park Road  
Portland, Oregon 97239

The sensor data and some of the questionnaire responses will be sent to:

Gait & Balance Lab (FoG), Fay Horak, PhD	James McNames, PhD
Oregon Health & Science University	APDM Wearable Technologies
3181 SW Sam Jackson Park Road	2828 SW Corbett Ave Ste 135
Portland, Oregon 97239	Portland, Oregon 97201

The data set will contain dates and times as recorded by the sensors as well as dates contained on the questionnaires.

In addition, a dataset will be sent to:

c/o Biostatistician  
Oregon Health & Science University  
3181 SW Sam Jackson Park Road  
Portland, Oregon 97239

This dataset will have a code and not contain any information to directly identify you. All dates will be removed.

All other parties, including employers, insurance companies, personal physicians and relatives, will be refused access to the information and specimens, unless you provide written permission or unless otherwise required by law.

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Ownership of a copy of the following information identifiers, including name, address, date of birth, medical record number, gender, information from the freezing questionnaire, sensor data, and specimens with the date of visit will be transferred to Oregon Health & Science University and will be the responsibility of Deborah Golden-Eppelein, Associated VP of Research for Office of Proposal and Award Management (OPAM).

By signing this informed consent, you give permission for the transfer of a copy of this information to OHSU. Oregon Health & Science University and Deborah Golden-Eppelein will be responsible for maintaining the security and confidentiality of the transferred data. VAPORHCS will continue to have ownership of your research data for this research study. All original research records, both hard copy and electronic, will be maintained at the VAPORHCS in accordance with current records retention requirements. Any information shared with OHSU may no longer be protected under federal law. Research records may be reviewed and/or copied by the sponsor.

**Mandatory reporting of suspected child or elder abuse.** Under Oregon Law, suspected child or elder abuse must be reported to appropriate authorities.

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.

This study involves a drug (intravenous levodopa) regulated by the US Food and Drug Administration (FDA), the FDA may choose to inspect research records that include identifiable medical records, identifying you as a subject of this study.

### **Possibility of Disclosure and Notice of Privacy Practices.**

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it may no longer be protected. Our Notice of Privacy Practices provides more information on how we protect your information. If you do not have a copy of the notice, the research team will provide one to you. (Notice of Privacy Practices available online at [http://www.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=3048](http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3048)).

If you are a non-Veteran, we will provide you with the VA Notice of Privacy Practices and ask you to sign the acknowledgment (VA Form 10-0483) you received the document. This acknowledgement may be scanned into your medical record.

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### **WILL I BE ABLE TO SEE MY RESEARCH DATA?**

During this research study, you will not be able to see the research data collected about you. After the study is complete and the study results are determined or published, you may request your health information.

### **WILL I BE TOLD ABOUT THE STUDY RESULTS?**

We will contact you with results of this study after the study is completed.

### **WILL IT COST ME ANYTHING TO BE IN THIS STUDY?**

**Participants.** A VA participant will not be required to pay for care and services received as a subject in a VA research project.

None of the participants will pay for any of the following because they are only for research study purposes: ECG, pregnancy test, IV levodopa infusion, blood draw, carbidopa dose, physical examinations including neurological and Parkinson's exams.

Some Veterans are also required to pay co-payments for medical care and services provided by VA **that are not part of this study** (e.g., normal hospital and prescription expenses that are not part of the research study, any treatment that is standard clinical treatment for your condition).

Non-veterans will be required to pay or have insurance billed for medical care and services provided by the VA that are not part of this study (such as standard of care costs).

### **WILL I BE PAID FOR PARTICIPATING?**

You will be paid \$10 for completing the screening visit, and \$50 for completing the all-day visit at OHSU. You will receive the check payment at the end of each visit. If you drop out of the study before completing all the all-day visit, you will be paid for the \$10 for the screening visit that you completed. If you complete all of the scheduled visits, you will have received a total of \$60.

An Internal Revenue Service (IRS) Form 1099 may be generated, which will use your Social Security Number. This payment is considered taxable income. If you owe money to the government, this payment may be garnished to satisfy the debt.

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### **WHAT WILL HAPPEN IF I AM HURT?**

Every reasonable effort to prevent any possible injury from this study will be taken. In the event the study results in any physical, mental or emotional injuries to you, the VA will provide necessary medical treatment (not just emergency care) at no cost to you. This does not apply to treatment for injuries that result from if you do not follow the study procedures. Additional compensation, beyond paying for treatment, has not been set aside. The VA will also provide all necessary assistance in the event of any violation of confidentiality or privacy (for example, identity theft resulting from the loss of a social security number by anyone associated with this study). For eligible Veterans, compensation damages may be payable under 38 United States Code 1151. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with the provisions of the Federal Tort Claims Act. For additional information concerning claims for damages, you may contact VA Regional Counsel at (503) 412-4580. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

### **WHO SHOULD I CONTACT IF I AM INJURED DUE TO THE RESEARCH?**

If you believe that you may have suffered a research related injury (physical, mental or emotional injury or injury caused by loss of confidentiality or privacy), contact Kathryn Chung, MD at (503) 721 - 1091.

**In the event of a life-threatening emergency, call 911 or go to the Emergency Department (ED).**

### **WHAT ARE MY RIGHTS?**

**You may ask questions about research or about your rights as a subject.** Brenna Lobb at (503) 220 – 8262 extension 51871 will answer any questions you may have about this research study. If you have any questions regarding your rights as a research subject, you may contact the VA Portland Health Care System Research Office at (503) 273-5125, or VA Regional Counsel at (503) 412-4580.

**Participation is voluntary.** Your participation in this research study is voluntary. The VA Authorization for Use and Release of Individually Identifiable Health Information (Collected) for VHA Research to use your protected health information is also voluntary. You may refuse to sign this consent form and the authorization. However, in order to participate in this study, you must sign this consent form and the authorization.

Dr. Kathryn Chung is a researcher on this study and may also be your health care provider. They are interested in both the clinical welfare of their patients who participate in this study and in the conduct of this study overall. Before entering this study or at any time during the research, you may ask for a second opinion

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about your care from another provider who is in no way associated with this study. You are not under any obligation to participate in any research study offered by your health care provider.

**What if I decide not to participate?** You do not have to join this or any other research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or if you drop out of the study at any time, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

### **CAN I DROP OUT (WITHDRAW) AFTER I SIGN THIS CONSENT FORM?**

You may withdraw from this study at any time. This will not affect your rights as a VHA patient or your eligibility for medical care and benefits for which you are otherwise eligible with this institution or with the VHA.

To withdraw, you must write to Kathryn Chung, MD at P3-PADRECC, VA Portland Health Care System, 3710 SW US Veterans Hospital Road, Portland, Oregon 97239, or ask a member of the research team to give you a form to withdraw your consent and authorization. If you withdraw your consent and authorization, you may not be able to continue to participate in the study.

Revocation of authorization form is available at: <http://www.portland.va.gov/research/documents/hrpp/revoke-authorization.pdf>

If in the future you can decide you no longer want to participate in this research, you may request to have your blood destroyed by contacting Brenna Lobb at (503) 220 – 8262 extension 51871. If your blood is still identifiable, you may withdraw consent to use them at any time, and Brenna Lobb will assure that the specimens that you have given will be destroyed.

If you do withdraw, we will not look at your medical record for purposes of the research anymore and will not collect any more information about you. However, we will keep and use the data that we already collected before you withdrew your consent.

### **Can someone else stop me from being in the study?**

The investigator may stop your participation in this study at any time, without your permission, based on their judgment. She may decide to do this to improve your medical care or because you cannot follow instructions. Some examples of why you may be withdrawn by the investigator are: missed visits or inability to follow directions.

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### **WILL I BE TOLD IF THERE IS NEW INFORMATION THAT MIGHT CAUSE ME TO WANT TO QUIT THIS STUDY?**

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

### **Signature**

The research staff has explained the study to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I have been told I do not have to take part in this study and refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are medical problems or questions, I have been told I can call Dr. Kathryn Chung, MD at (503) 721 - 1091 from 08:00 am – 04:00 pm, Monday through Friday, and after hours and on weekends please call and ask for the neurologist on call at (503) 494 - 8311. If any medical problems occur in connection with this study, the VA will provide emergency care.

By consenting to participate, I authorize the use of my blood.

If you wish to provide consent to allow your blood and information to be used in research for future studies, you will be asked to sign the banking addendum portion of this consent form.

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### Addendum: Banking your blood, data, and contact information for future research

#### WHAT IS THE PURPOSE AND WHAT WILL HAPPEN?

We are asking you to allow your contact information (including last four of your social security number, date of birth, address, gender, veteran status, phone numbers, Parkinson's disease information, and contact preferences, your blood and data, including any identifiers, such as date of study visit or specimen collection to be stored ("banked") in a repository located at the Portland VA Health Care System. By signing this form below, you agree to allow your contact information and data listed above to be made available to researchers for the purpose of contacting you about future research studies. The repository may then release your blood and study information for use in future research, which may include research about neurological disorders, including Parkinson's disease. The future research may include genetic research. The blood that will be stored in the repository will be drawn at the all-day visit at OHSU.

#### WHAT ARE THE RISKS?

Information that could be used to identify you will be banked for the purpose of use in future research. The repository team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. It could also carry other risks, such as embarrassment or affecting ability to get insurance, current or future job status, plans to have a family, relations with your family, immigration status, parental rights or responsibilities, credit history or status in the community.

Some members of your family may not want research done on your tissues to understand the genetics or possible inherited disorders of you and your family. This may cause conflict with your family members and could affect your decision or the decisions of family members to have children. You may want to hold a discussion with your family members before deciding to participate in this study and signing this consent form.

The Genetic Information Nondiscrimination Act (GINA), a federal law, generally makes it illegal for health insurance companies, group health plans, and employers of 15 or more employees to discriminate against you based on your genetic information.

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote or fire you or when setting the terms of your employment.

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- However, there is a serious risk, if there is a loss of confidentiality and certain genetic information reaches your current or future life, disability or long-term care insurance carrier, your employer (if s/he employs fewer than 15 employees), or others, that you or members of your family may experience some type of discrimination resulting in (1) **loss of life insurance, disability insurance, or long-term care insurance coverage and/or** (2) **loss of job**. All researchers associated with this study and the repository will make every reasonable effort not to disclose any of this information, but it is important for you to understand that the possibility of this information being disclosed exists despite every reasonable effort. If you have any questions, please ask Joseph Quinn, MD, who can be reached at (503) 721 - 1091.
- The VAPORHCS also abides by the Oregon Genetic Privacy law (ORS 192.531 through ORS 192.549) and its requirements concerning confidentiality and the legal remedies provided by that law for breach of its requirements. You have not waived your legal rights by signing this form. For clarification on this subject, or if you have further questions, please call the VA Regional Counsel office at (503) 412-4580.

### **HOW LONG WILL YOU KEEP MY INFORMATION?**

Your blood and information will be stored indefinitely.

### **WILL I BE TOLD ABOUT ANY FUTURE RESEARCH RESULTS?**

If you give your permission for your blood and/or information to be used in future studies, the results of those studies involving the use of your specimens will not be made available to you because your contact information including your name and address will not be retained with the information in the repository.

### **CAN I WITHDRAW MY PERMISSION TO USE MY BLOOD AND/OR INFORMATION?**

If your blood and/or information are still identifiable, you may withdraw consent to use them at any time. To withdraw your consent for such use, you must write to Kathryn Chung, MD at Portland VA Health Care System, 3710 SW US Veterans Hospital Road, P3-PADRECC, Portland, Oregon 97239, or you may ask a member of the research team to give you a form to withdraw your consent and authorization. You will still receive all the medical care and benefits for which you are otherwise eligible. This will not affect your rights as a VHA patient.

If you agree, your name, last four of your social security number, address, date of birth, phone number, veteran status, gender, contact preferences, and Parkinson's information may be used by VAPORHCS researchers to contact you regarding future research studies.

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## How do you want to be contacted about future research opportunities?

- In person/When you come to the VA  
 By Letter  
 By Phone

## I agree to the following future uses of my contact information:

- Only Research on Neurologic Disorders  
**OR**  
 Research on Any Disease or Disorder  
 Only Investigators for this study  
**OR**  
 Any Investigators

If you agree, your data may be used in future research as described below. A code number that doesn't contain any personal identifiers (such as your initials or date of birth) will be assigned to your study data. Only personnel working on this study will be authorized to link the code number to you. However, some of these personnel also work for the repository. Other researchers who may receive your data for future studies will be given only the code number, and will not be given any other information allowing them to link back to you or your family.

## I agree to the following future uses of my blood and research data:

- Only Research on Neurologic Disorders  
**OR**  
 Research on Any Disease or Disorder  
 Only Investigators for this study  
**OR**  
 Any VA or Non-VA Investigators

Do not change anything below this line, including bottom margin.

VAPORHCS Research Service Template Date: 3/1/2018





<b>Subject Name</b> (Last, First, Middle Initial):	<b>Subject SSN</b> (last 4 only):	<b>Date of Birth:</b>
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**VA Facility** (Name and Address):  
 VA Portland Health Care System  
 3710 SW US Veterans Hospital Road  
 Portland, Oregon 97239

<b>VA Principal Investigator</b> (PI): Kathryn Chung, MD	<b>PI Contact Information:</b> 503.721.1091
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**Study Title:**  
 STAT-PD: Preventing Levodopa Induced Dyskinesia in Parkinson’s disease with HMG-CoA Reductase Inhibitors

**Purpose of Study:**  
 The purpose of this study is to look at involuntary abnormal movements in persons with Parkinson's disease (PD). Almost all PD patients will develop these movements overtime with treatment of levodopa.

**USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):**

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization.

Your individually identifiable health information used for this VA study includes the information marked below:

- Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings
- Specific information concerning:
  - alcohol abuse       drug abuse       sickle cell anemia       HIV
- Demographic Information such as name, age, race
- Billing or Financial Records
- Photographs, Digital Images, Video, or Audio Recordings
- Questionnaire, Survey, and/or Subject Diary
- Other as described: 0

**Authorization for Use & Release of Individually Identifiable Health Information for  
Veterans Health Administration (VHA) Research**

<b>Subject Name</b> (Last, First, Middle Initial):	<b>Subject SSN</b> (last 4 only):	<b>Date of Birth:</b>
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**USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH:** (Instruction: When banking or further analysis is an **optional** research activity, complete page 5 and leave this section blank. If banking is a required research activity to store "Data" and/or "Specimen" for future use or if "Not Applicable" is selected, remove page 5 in its entirety.)

Not Applicable - No Data or Specimen Banking for Other Research

An important part of this research is to save your

Data

Specimen

in a secure repository/bank for other research studies in the future. If you do not agree to allow this use of your data and/or specimen for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.

**DISCLOSURE:** The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

Non-VA Institutional Review Board (IRB) at Oregon Health & Science University  
who will monitor the study

Study Sponsor/Funding Source: VA Office of Research & Development (CSR&D)  
VA or non-VA person or entity who takes responsibility for; initiates, or funds this study

Academic Affiliate (institution/name/employee/department): Oregon Health & Science University  
A relationship with VA in the performance of this study

Compliance and Safety Monitors: VA Office of Research & Development (CSR&D)  
Advises the Sponsor or PI regarding the continuing safety of this study

Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO):  
Food and Drug Administration (FDA), Department of Health & Human Services (DHHS), Office of Human Research Protections (OHRP), Government Accountability Office (GAO), Internal Revenue Service (IRS)

A Non-Profit Corporation (name and specific purpose):

Other (e.g. name of contractor and specific purpose):  
Flow cytometry shared resource (FCSR) @ OHSU - analysis of blood  
Gait & Balance Lab (FoG) - Fay Horak PhD @ OHSU - analysis of inertial sensor data  
NeuroNext Biostatistician @ OHSU - Analysis of study data

**Authorization for Use & Release of Individually Identifiable Health Information for  
Veterans Health Administration (VHA) Research**

<b>Subject Name</b> (Last, First, Middle Initial):	<b>Subject SSN</b> (last 4 only):	<b>Date of Birth:</b>
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**Note:** *Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may also have access to your information in the performance of their VA/VHA job duties.*

**Access to your Individually Identifiable Health Information created or obtained in the course of this research:**  
While this study is being conducted, you

- will have access to your research related health records
- will not have access to your research related health records

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

**REVOCAATION:** If you sign this authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:

Kathryn A Chung, MD  
VA Portland Health Care System  
P3-PADRECC  
3710 SW US Veterans Hospital Road  
Portland, Oregon 97239

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

**EXPIRATION:** Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will:

- Expire at the end of this research study
- Data use and collection will expire at the end of this research study. Any study information that has been placed into a repository to be used for future research will not expire.
- Expire on the following date or event:
- Not expire

**Authorization for Use & Release of Individually Identifiable Health Information for  
Veterans Health Administration (VHA) Research**

<b>Subject Name</b> (Last, First, Middle Initial):	<b>Subject SSN</b> (last 4 only):	<b>Date of Birth:</b>
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**TO BE FILLED OUT BY THE SUBJECT**

**Research Subject Signature.** This permission (authorization) has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.

I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this form. I will be given a signed copy of this form for my records.

\_\_\_\_\_  
Signature of Research Subject Date

\_\_\_\_\_  
Signature of Legal Representative (if applicable) Date

To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State Law)

\_\_\_\_\_  
Name of Legal Representative (please print)

**Authorization for Use & Release of Individually Identifiable Health Information for  
Veterans Health Administration (VHA) Research**

<b>Subject Name</b> (Last, First, Middle Initial):	<b>Subject SSN</b> (last 4 only):	<b>Date of Birth:</b>
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**VA Facility** (Name and Address):

VA Portland Health Care System  
3710 SW US Veterans Hospital Road  
Portland, Oregon 97239

**VA Principal Investigator** (PI):

Kathryn Chung, MD

**PI Contact Information:**

503.721.1091

**Study Title:**

STAT-PD: Preventing Levodopa Induced Dyskinesia in Parkinson's disease with HMG-CoA Reductase Inhibitors

**Optional Authorization Supplement for Placing My Data or My Biological Specimens in a Repository or for Conducting Optional Analysis of My Specimens for Future Use in Research**

**Purpose.** This supplement to the authorization is for either banking of data and/or biological specimens (for example blood, urine, tissue) collected during the study for future research or for conducting optional analysis for this study. You are not required to provide this permission and not providing this permission will have no impact on your participation in this study, i.e., granting this permission is not a condition of participating in this study.

**Research Subject Signature.** This additional permission (authorization) has been explained to me and I have been given the opportunity to ask questions about this activity. By signing below, I am giving my permission for VHA to:

Store my health information in a research data repository at  
Portland VA Health Care System, Neurologic Disorders Repository (MIRB # 3129)  
and sponsored/run by Joseph Quinn, MD

Store my biological specimens (blood, tissue, urine, etc.) in a research biological specimen/tissue repository at Portland VA Health Care System, Neurologic Disorders Repository (MIRB # 3129)  
and sponsored/run by Joseph Quinn, MD

Further optional analysis of my specimens for the current study occurring below:

Future research of data maintained within a research data repository will only occur after further Institutional Review Board and/or other applicable approvals of the new research to ensure the protection of your individual privacy. Future use of my biological specimens will only occur after the new research has been approved by all required committees.

Signature of Research Subject

Date

Signature of Legal Representative (if applicable)

Date

To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State law)

Name of Legal Representative (please print)





IRB#: e17302

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## Research Study Informed Consent Document

**Study Title for Participants: STAT-PD: Preventing Levodopa Induced Dyskinesia**

### Overview and Key Information

The purpose(s) of this study is to learn about movements in Parkinson's disease. Nearly all Parkinson's disease patients eventually develop involuntary, abnormal, and unwanted movements (levodopa-induced dyskinesia) over time after they are treated with levodopa, the main treatment for Parkinson's disease. These movements can range from subtle to extremely debilitating and may or may not affect activities of daily living such as brushing your teeth. You have been invited to be in this research study because you have Parkinson's Disease and have been on levodopa for more than five years.

### What am I being asked to do?

We are asking you to take part in a research study. We do research studies to try to answer questions about how to prevent, diagnose, and/or help patients with diseases like Parkinson's disease.

We are asking you to take part in this research study because you have a risk of developing levodopa-induced dyskinesias (abnormal movements) because you have Parkinson's Disease.

### Do I have to take part in this study?

**Taking part in this study is your choice.** You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered.

### Why is this study being done?

This study is being done to answer the following question[s]:

- o Does levodopa-induced dyskinesia (abnormal involuntary movements) vary depending on whether a person took a statin before or after levodopa?

- o Is there a biomarker in your blood that indicates levodopa-induced dyskinesia?

We are doing this study because we want to find out if there is a way to improve medical care for your Parkinson's disease.

We are asking you to provide blood and information for a blood and data bank, also called a repository. These samples will be stored indefinitely and may be used and disclosed in the future for research which may include genetic research. The repository components are optional.

### **What are my choices if I decide not to take part in this study?**

- You may choose not to be in this study. If you choose not to be in this study, your medical care will not be affected and there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services

### **What will happen if I decide to take part in this study?**

If you agree to join and do not withdraw from the study before all procedures are complete, your participation in this study will last for a maximum of 2 months. You will have one screening visit at the Portland VA (VHAPORHCS) or the Puget Sound VA (VHAPUGHCS) and one full day visit at the Oregon Clinical and Translational Research Institute (OCTRI) at Oregon Health & Science University (OHSU).

The screening visit will be performed at the Portland VA and last approximately 1 hour. The day-long visit at OHSU's OCTRI will start at 08:00 am and last until 03:00 pm. The night before the visit, you will stop any Parkinson's medication (such as Sinemet, carbidopa/levodopa, ropinirole, or amantadine) at 10:00 pm. You will continue to take medications for any conditions other than Parkinson's. You will receive a low-protein breakfast and lunch while at OCTRI for this visit. We will perform various tests examining your movements which include standing on a plate much like a bathroom scale while counting backwards, walking down a hallway, and pressing buttons as quickly as possible.

The medications you might receive as part of the study are not the same as standard healthcare for your Parkinson's disease because you will receive the drug levodopa through an IV (intravenously) in your arm (it is usually taken in pill form by mouth). The study procedures are experimental.

If you decide to take part in this study, you will have the following procedures performed during the study:

- IV levodopa Infusion
- Oral carbidopa
- PD and Movement Evaluations
- PD Questionnaires
- Blood draw
- Heart Monitoring

### **What are the risks and benefits of taking part in this study?**

There may not be benefits to taking part in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future. It is important for you to think carefully about these as you make your decision.

## **Risks**

We want to make sure you know about a few key risks right now. We give you more information in the “WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?” section.

Some of the most common risks or side effects that the investigators know about are:

- During a blood draw, you might feel discomfort at the site where the blood sample is being collected. Removal of blood by a needle and syringe poses a small risk of pain or bruising at the site of the needle stick.
- During the IV levodopa infusion, you may have nausea and vomiting with or without stomach pain and distress
- You may experience some discomfort or an increase in your Parkinson’s disease symptoms by being “off” your medications during the night before testing.

There may be some risks that the investigators do not yet know about.

## **Benefits**

This study is not likely to help you. However, it may help the investigators understand how to help other people in the future.

### **If I decide to take part in this study, can I stop later?**

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let the investigator know as soon as possible. If you stop, you can decide if you want to keep letting the investigator know how you are doing.

The investigator will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

### **Are there other reasons why I might stop being in the study?**

Yes. The investigator may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- For women: You become pregnant while on the study.
- The study is stopped by the Institutional Review Board (IRB), or study funder (VA Clinical Science Research and Development).

**It is important that you understand the information in the informed consent before making your decision.** Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the investigator or nurse.



IRB#: e17302

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### Research Consent and Authorization Form

**TITLE:** STAT-PD: Preventing Levodopa Induced Dyskinesia in Parkinson's disease with HMG-CoA Reductase Inhibitors (MIRB # 3869; eIRB # 17302)

**PRINCIPAL INVESTIGATOR:** Kathryn Chung, MD (503) 721 - 1091

**CO-INVESTIGATORS:** Brenna Lobb, MS MPH (503) 220 – 8262 x 51871  
Susan O'Connor, RN (503) 220 – 8262 x 55336

**WHO IS PAYING FOR THE STUDY?:**

Clinical Science Research and Development, Department of Veterans Affairs

**WHO IS PROVIDING SUPPORT FOR THE STUDY?:**

- Parkinson's Disease Research, Education, and Clinical Center at:
  - VA Portland Health Care System
  - VA Puget Sound Health Care System
- Parkinson's Center of Oregon, Oregon Health & Science University (OHSU)
- Oregon Clinical and Translational Research Institute, OHSU
- Flow Cytometry Shared Resource (FCSR), OHSU
- Gait & Balance Lab (FoG), OHSU
- APDM Wearable Technologies, Inc

**WHY IS THIS STUDY BEING DONE?:**

You have been invited to be in this research study because you have Parkinson's disease and have been on levodopa for more than five years. The purpose(s) of this study is to learn about movements in Parkinson's disease called levodopa-induced dyskinesia (LID). Nearly all Parkinson's disease patients eventually develop involuntary, abnormal, and unwanted movements over time after they are treated with levodopa, the main treatment for Parkinson's disease. These movements can range from subtle to extremely debilitating and may or may not affect activities of daily living such as brushing your teeth.

The medications you might receive as part of the study are not the same as standard healthcare for your Parkinson's disease because you will receive the drug levodopa through an IV (intravenously) in your arm (it is usually taken in pill form by mouth). The study procedures are experimental.

This study requires 2 visits (one to the Portland VA and one to OHSU) and will take a maximum of 8 weeks to complete.

Another purpose of the study is to understand the development of levodopa-induced dyskinesia (LID). If a gene or genes that cause LID can be found, the diagnosis and treatment of LID may be improved.

Genes are the units of DNA--the chemical structure carrying your genetic information--that determine many human characteristics such as the color of your eyes, your height, and whether you are male or female.

The samples provided by you will be analyzed in the laboratory to determine if a protein is present that shows whether there are differences in the genes of people with and without LID.

We are asking you to provide blood and information for a blood and data bank, also called a repository. These samples will be stored indefinitely and may be used and disclosed in the future for research, which may include genetic research. This is optional for this study.

A total of approximately 120 people will participate in this research study at Oregon Health & Science University in Portland Oregon.

The study procedures that will occur at VA Portland and/or the VA Puget Sound will be discussed in detail in the VA Consent Form.

### **WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?:**

You will have one screening visit at the VA and one full day visit at the Oregon Clinical and Translational Research Institute (OCTRI) at Oregon Health & Science University. You will need to arrange your own transportation to OHSU (have someone drive you or take alternative means of transportation such as bus, taxi, tram, Uber, or Lyft).

The screening visit will last approximately 1 hour and is described in the VA Consent Form.

The full day visit at OCTRI will occur within 2 months of your screening visit. The night before the visit, you will stop any Parkinson's medication (such as Sinemet, carbidopa/levodopa, ropinirole, or amantadine) at 10:00 pm. You will continue to take medications for any conditions other than Parkinson's.

You will arrive at OCTRI unit at 08:00 am. You will receive a low-protein breakfast and lunch while at OCTRI for this visit. We will provide your meals because we want to control your protein intake. High protein meals are known to reduce the absorbency of levodopa, and therefore, would not provide an adequate change in your Parkinson's disease state (from "off" to "on"). You will not be allowed to consume any foods brought with you during these visits. All study procedures will start at 08:30 am.

If you were screened at the VA Puget Sound, we may ask you to sign a release of information form so that we may verify your medication history. We will review your medications, and past medical history. We will draw a tube of blood at 08:00 am.



You will wear six sensors during the entire day of the visit. The sensors are about the size of a watch and have a Velcro strap attached to them. We will place a sensor around your wrists (with the sensor on top), around each of your feet, around your sternum, and one around your waist.

Every half hour from 09:00 am to 03:00 pm, you will perform three main tasks. You will arise from a chair, walk 25 feet, turn around and sit down. You will stand on the force plate for 30 seconds while completing a mental task. The force plate is a 2-foot square device that will take measurements of your balance and movement while you stand on top of it. There will be a mark on the plate showing you where to place your feet. You will do 1 minute of finger tapping. The investigator will rate your tremor during these tasks.

The medications you might receive as part of the study are not the same as standard healthcare for your Parkinson's disease because you will receive the drug levodopa through an IV (intravenously) in your arm (it is usually taken in pill form by mouth). The study procedures are experimental.

Below is the list of study procedures and each timepoint in the study for the full-day visit:

08:00 am – Arrive at OCTRI. If you were screened at the Puget Sound VA, you will have a blood draw. You will be served breakfast. The breakfast is low in protein and will help us to control your “on/off”. You will take a dose of carbidopa to prevent nausea that can occur when levodopa is taken alone. Carbidopa is routinely given to patients who take levodopa for Parkinson's disease.

08:30 am – An intravenous (IV) line will be placed in your forearm. This line will be used to deliver intravenous levodopa for two hours. Levodopa is given by vein because it is not always absorbed by the stomach and intestines in the same way. We are giving you IV levodopa in order to control your “on” (when the drug is effective and your Parkinsonism is reduced). Nurses will place electrodes on your chest for heart monitoring. This will be like the ECG from the screening visit, but will show active monitoring of your heart activity before, during, and after the levodopa infusion. Monitoring of your heart and measuring your vital signs (blood pressure, heart rate, etc.) will be done to watch for side effects of the infusion. You will put on the sensors.

The following describes what you will do at each ½ hour time point in addition to the 3 main tasks (finger tapping, standing on a plate to measure movement, and arising from a sitting position and walking down a hallway for about 7 feet) in addition to having your vitals and heart rate monitored by the OCTRI staff nurses.

09:00 am – You will do two extra minutes of finger tapping and we will perform an additional assessment of your movements. This assessment will involve putting on a jacket, drinking from a cup, telling a story, and walking down a hallway. You will also undergo a Parkinson's exam that looks at your stiffness, slowness, and balance.

09:30 am – The IV infusion of levodopa will start. The infusion will last for two hours. You will complete some questionnaires with and without the rater about your movements.

10:00 am – You will complete some additional questionnaires about your movements and your Parkinson's disease.

10:30 am – You will complete just the main tasks (finger tapping, standing on a plate to measure movement, and arising from a sitting position and walking down a hallway for about 7 feet).

11:00 am – You will have an additional assessment of your movements. This assessment will involve putting on a jacket, drinking from a cup, telling a story, and walking down a hallway. You will also undergo a Parkinson’s exam that looks at your stiffness, slowness, and balance.

11:30 am – The IV infusion will be stopped. You will have a blood draw of approximately 1 tsp of blood. You will complete a questionnaire about your Parkinson’s disease. You will complete a short test of thinking and memory.

12:00 pm – You will complete just the main tasks and take another carbidopa pill.

12:30 pm – You will complete just the main tasks. The nurse will remove the heart rate monitor. You will be served lunch.

1:00 pm to 3:00 pm or until you turn “Off” – You will complete the main tasks. Once you have turned “Off”, the investigator will repeat the testing of your Parkinson’s disease and your movements with the test including putting on a jacket, telling a story, or walking down a hallway.

The procedures, questionnaires, blood draws will be done for research purposes and will not be completed if you decide not to take part in the study.

	Day Visit
Screening tests and medical history	X <sup>1</sup>
IV Levodopa Infusion	X
Parkinson’s & Movement Examinations	X
Tests of thinking and memory	X
Blood draw (1 teaspoon.)	X <sup>1</sup>
Heart Monitoring	X
Quality of Life & Parkinson’s Questionnaires	X
Total time	8-9 hours

*<sup>1</sup>Puget Sound participants will have an extra teaspoon of blood drawn at 08:00 am and have a review of your medical and Parkinson’s history.*

The medications you will receive as part of the study are not the same as standard healthcare for Parkinson’s disease because you will receive the drug levodopa through an IV (intravenously) in your arm and it is usually taken in pill form.

In the future, your samples and/or information may be given to researchers for other research studies. These studies may include genetic research. The samples and

information will be labeled as described in the **WHO WILL SEE MY PERSONAL INFORMATION?** section.

### **WILL I RECEIVE RESULTS FROM THE TESTING IN THIS STUDY?**

We do not plan to share your *research or genetic*, test results with you. However, if we discover information that is important for your health care, either in this study or in the future, we will contact you and ask if you want to know the results. If you choose to receive the results, you may need to have the test repeated in a non-research laboratory. You may learn information about your health that is upsetting or that impacts your *family relationships*.

The results of research tests will not be made available to you because the research is still in an early phase and the reliability of the results is unknown.

### **WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?:**

Information that identifies you will be used in this study and shared with

- Research staff,
- The National Institutes of Health,
- Federal agencies including by not limited to:
  - the Food and Drug administration (FDA),
  - the Office for Human Research Protection (OHRP),
  - the VA Office of Research Oversight (ORO),
  - the VA Office of the Inspector General (OID),
  - the VA Portland Health Care System committees that oversee research, including the Institutional Review Boards that oversees the safety and ethics of VA studies,
- the Institutional Review Board at OHSU.

The research team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. It also could carry other risks, such as embarrassment or affecting ability to get insurance, current or future job status, plans to have a family, relations with your family, immigration status, parental rights or responsibilities, credit history or status in the community.

As a result of participation in this study, you may learn information about your Parkinson's disease and Parkinson's disease caused movements that could be upsetting to you. If you are upset about the results learned during the course of the research study, Dr. Kathryn Chung, MD may refer you to a counselor.

The following research procedures are in addition to those you would receive for your current health care.

- Blood draws
- IV levodopa infusion

**Blood draw:** During a blood draw, you might feel discomfort at the site where the blood sample is being collected. Removal of blood by a needle and syringe poses a small risk of pain or bruising at the site of the needle stick, but this is temporary. Infrequently, people may experience fainting or dizziness and there is also a slight risk of infection at the site of the needles stick. However, we will take all available precautions to prevent an infection using sterile techniques.

Some of these questions may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions that you do not wish to answer. If the questions make you very upset, we will help you to find a counselor.

You may have some side effects we do not expect because we are still learning about intravenous levodopa.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- *Some side effects may be serious and may even result in death.*

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- *The study doctor may adjust the study drugs to try to reduce side effects.*

### **COMMON, SOME MAY BE SERIOUS**

In 100 people receiving **IV levodopa**, more than 20 and up to 100 may have:

- Loss of appetite
- Nausea and vomiting with or without stomach pain and distress
- Dry mouth
- Difficulty swallowing
- Excessive flow of saliva
- Clumsiness
- Increased hand tremor
- Headache
- Dizziness
- Numbness (generalized)
- Weakness (generalized)
- Fainting
- Grinding teeth while sleeping
- Confusion

- Sleeplessness
- Nightmares
- Exaggerated sense of well-being
- An infection where the IV tube is placed causing swelling, redness, and pain
- You may bleed or get a bruise
- Your arm may become irritated by the levodopa infusion

### **OCCASIONAL, SOME MAY BE SERIOUS**

In 100 people receiving **IV levodopa**, from 4 to 20 may have:

- Muscle twitching
- Involuntary movement of the eyelids
- Lockjaw
- Burning sensation of the tongue
- Bitter taste
- Diarrhea, constipation, and/or gas
- Flushing
- Rash
- Increased sweating
- Unusual breathing patterns
- Inability to urinate
- Double vision, blurred vision, and/or dilated pupils
- Hot flashes
- Weight gain or loss
- Dark sweat and/or dark urine
- Urinary retention
- Agitation
- Anxiety
- General body discomfort
- Bleeding
- Bruising
- There is a small chance of getting an infection in your blood stream or heart valves
- You may experience leakage out of the vein and into the muscle
- You may get a blood clot that could go to your lungs.

### **RARE, AND SERIOUS**

In 100 people receiving **IV levodopa**, 3 or fewer may have:

- Occasional uncontrollable movement
- Heart irregularities
- Pounding the in chest
- Lightheadedness or dizziness when standing or sitting up
- Sudden swings from improved condition to worsened condition
- Lightheadedness
- Low blood pressure
- An irregular heart beat
- Nausea
- Vomiting
- Heavy sweating

- Confusion
- Hallucinations.

The IV levodopa infusion can cause lightheadedness, low blood pressure, and an irregular heartbeat. This side effect is a potentially serious (even life-threatening) complication that also happens when levodopa is given by mouth. We will do tests before the infusion to check that your heart is healthy. We will also take your blood pressure and watch your heart rhythm closely during the infusion. Drugs to treat the heart irregularities, if necessary, are immediately available during the study. Resting flat in bed until the effects wear off (which may take minutes to hours) treats the low blood pressure caused by levodopa.

**Carbidopa.** Carbidopa is only taken with levodopa to help decrease the levodopa side effects. There is no information on what carbidopa's side effects are if not taken with levodopa. Carbidopa and levodopa when used together have the following side effects:

### **COMMON, SOME MAY BE SERIOUS**

In 100 people receiving levodopa and carbidopa, more than 20 and up to 100 may have:

- Anxiety, confusion, nervousness, depression

### **OCCASIONAL, SOME MAY BE SERIOUS**

In 100 people receiving levodopa and carbidopa, from 4 to 20 may have:

- Low blood pressure
- Rapid or slowing of the heartbeat
- Sleep loss, tiredness
- Hallucinations
- Inability to coordinate movements, muscle contractions
- Nausea, vomiting, bleeding of the stomach
- Blurred vision

### **RARE, AND SERIOUS**

In 100 people receiving levodopa and carbidopa, 3 or fewer may have:

- Ulcer which is a burning and pain around your stomach area
- Anemia caused by destruction of red blood cells, symptoms are dark urine, fatigue, pale skin color, rapid heart rate, shortness or breath, and yellow skin color
- High blood pressure.

**Stopping your PD medication, the night before the visit:** You may experience some discomfort or an increase in your Parkinson's disease symptoms by being "off" your medications during the night before testing. There is a rare possibility (less than 1%) that withholding your medication could cause something called neuroleptic malignant syndrome. This could include symptoms of high fever, high blood pressure, and/or confusion and should be treated as a medical emergency. If you feel you may be having any of these symptoms or cannot tolerate being off your PD medications, please go to the ER.

**For Women:** You should not become pregnant while participating. If you are or become pregnant, IV levodopa could affect a fetus in ways that we do not yet know about. If you are sexually active and at risk of getting pregnant, you and your male partner(s) must use one or two methods of birth control that work well, like birth control pills, a patch, long-acting progestins, an IUD, a diaphragm or condom with spermicide, or abstinence. You will have to do this the whole time you are in this study. If you become pregnant during the research study, please tell the investigator and your doctor immediately.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease being tested.

Although we have made efforts to protect your identity, there is a small risk of loss of confidentiality. If the results of these studies of your genetic makeup were to be accidentally released, it might be possible that the information we will gather about you as part of this study could become available to an insurer or an employer, or a relative, or someone else outside the study. Even though there are certain genetic discrimination and confidentiality protections in both Oregon law and federal law, there is still a small chance that you could be harmed if a release occurred.

**WHO WILL SEE MY PERSONAL INFORMATION?:**

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy.

We will create and collect health information about you as described in the WHY IS THIS STUDY BEING DONE? and the WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY? sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study and optionally store in a repository.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The funder of this study, CSR&D, and the funder's representatives
- The coordinating center, Portland VA Health Care System
- The Food and Drug Administration
- The Office for Human Research Protections, a federal agency that oversees research involving humans.

Those listed above may also be permitted to review and copy your records.

We may also share your information with other researchers, who may use it for future research studies. This is optional.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

Under Oregon law, suspected child or elder abuse must be reported to appropriate authorities.



Identifiers related to you (i.e. information that can identify you) will be used in this research study and will include: your name, your social security number, your date of birth, your medical record numbers, your complete address, visit and any other dates, and your diagnosis codes. These identifiers may be used to obtain information about you and your health history from OHSU records and from the health information sources listed on the HIPAA authorization.

OHSU complies with Oregon state requirements for reporting certain diseases and conditions to local health departments.

When we send specimens or information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your specimens or information could be used and re-released without your permission.

Data and specimens from this study may be shared with other investigators for future research studies. A code number will be assigned to you, your cells and genetic information, as well as to information about you. Only the investigators and people involved in the conduct of the study will be authorized to link the code number to you. Other investigators who may receive samples of your *blood, genetic information, and medical information* for research will be given only the code number which will not identify you.

Your genetic information may be shared in a public online database for future research. The database will not contain any information that directly identifies you, such as your name, address, or birth date, so it is unlikely that someone would know the genetic information came from you. In the future, people may develop ways to identify you or your blood relatives from this information, but currently, there is not a way to identify you without having additional information to compare to it, such as information from your DNA sample.

We may continue to use and disclose your information as described above indefinitely.

Some of the information collected and created in this study may be placed in your OHSU medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your OHSU medical record. If you have questions about what study information you will be able to access, and when, ask the investigator.

### **WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT?**

Samples and/or information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

### **WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?**

There will be no cost to you or your insurance company to participate in this study.

You will be paid \$10 for completing the screening visit, and \$50 for completing the all-day visit. You may receive payment via a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and FAQ sheet.

If you drop out of the study before completing all the all-day visit, you will be paid for the \$10 for the screening visit that you completed. If you complete all of the scheduled visits, you will have received a total of \$60.

We may request your social security number in order to process any payments for participation.

### **WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?:**

If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact Brenna Lobb at (503) 220 – 8262 extension 51871 or call (503) 721 -1091.

If you are injured or harmed by the study drugs or study procedures, you will be treated. OHSU and the funder do not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance.

However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

### **WHERE CAN I GET MORE INFORMATION?:**

If you have any questions, concerns, or complaints regarding this study now or in the future, contact Kathryn Chung (503) 721 - 1091 or other members of the study team at (503) 220 – 8262 extension 51871.

This research is being overseen by an Institutional Review Board (“IRB”). You may talk to the IRB at (503) 494-7887 or [irb@ohsu.edu](mailto:irb@ohsu.edu) if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.

- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at <https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html> or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

### **DO I HAVE TO TAKE PART IN THIS STUDY?**

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. Some parts of the study are optional. You can choose not to participate in some or all of the optional parts but still participate in the rest of the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

### **IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?**

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. You can choose to withdraw from some or all of the optional parts of this study without withdrawing from the whole study. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study or change which parts of the study you are participating in].

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

*Kathryn Chung, MD, C/O PADRECC, VA Portland Health Care System, P3-PADRECC, 3710 SW US Veterans Hospital Road, Portland, Oregon 97239.*

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If in the future you decide you no longer want to participate in this research, we will remove your name and any other identifiers from your [*samples and information*], but the material will not be destroyed and we will continue to use it for research.

You may be removed from the study if: the investigator or funder stops the study, you do not follow study instructions or miss visits.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

**SIGNATURES:**

**PARTICIPANT OPTIONS**

The optional portions of this study are described in detail throughout this consent form and listed here as a summary. Please read the options and place your initials next to your choices. You can still participate in the main part of the study even if you choose not to participate in the optional parts.

\_\_\_\_\_ I give my consent for my coded data to be stored in a repository at the VHAPORHCS and used for future research studies, which may include genetic research.

I agree to the following future uses of my data:

\_\_\_\_\_ Only Research on Neurologic Disorders

**OR**

\_\_\_\_\_ Research on Any Disease or Disorder

\_\_\_\_\_ Only Investigators for this study

**OR**

\_\_\_\_\_ Any Investigators

\_\_\_\_\_ I give my consent for my contact information (address, last four of social security number, phone number(s), gender, veteran status, contact preferences, and Parkinson's disease information) to be stored in a repository at VHAPORHCS and used for future research studies, which may include genetic research.

How do you want to be contacted about future research opportunities?

\_\_\_\_\_ In person/When you come to the OHSU

\_\_\_\_\_ By Letter

\_\_\_\_\_ By Phone

I agree to the following future uses of my contact information:

\_\_\_\_\_ Only Research on Neurologic Disorders

**OR**

\_\_\_\_\_ Research on Any Disease or Disorder

\_\_\_\_\_ Only Investigators for this study

**OR**

\_\_\_\_\_ Any VA or non-VA Investigators

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

\_\_\_\_\_  
Subject Printed Name                      Subject Signature                      Date

\_\_\_\_\_  
Person Obtaining Consent Printed Name                      Person Obtaining Consent Signature                      Date