VA Portland Health Care System (VAPORHCS) Informed Consent Form

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: __06/15/2021

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

About the research, call Brenna Lobb at (503) 220 – 8262 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

DO THE RESEARCHERS HAVE A PERSONAL, FINANCIAL OR OTHER INTEREST IN THIS STUDY?

Dr. McNames is an employee of APDM, a company that is involved in this research. The nature of this financial interest and the design of the study have been reviewed by two committees at OHSU. They have put in place a plan to help ensure that this research study is not affected by the financial interest. If you would like more information, please contact the OHSU Research Integrity Office at (503) 494-7887.

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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 3 months (after this visit).

WHAT WILL HAPPEN DURING THIS STUDY?

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

The screening visit can be done virtually which means that you will need to have access to a computer, tablet, or smart phone and the internet. The procedures done virtually will be similar to the in-person screening visit (described in the next paragraph), only you will not have your blood drawn or have the electrocardiogram (ECG).

The screening visit will last approximately 2 hours. 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 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 3 months of your screening visit. You will complete some questionnaires at home prior to this 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	*prior to day visit*
Total time	2 hours

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 suing 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 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, allergies, 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.

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

Lloyd Center Pharmacy
2606 NE Broadway St Ste B
Portland, OR 97232

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

Pharmacokinetics Core (Dr. Koop)
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
Oregon Health & Science University
3181 SW Sam Jackson Park Road
Portland, Oregon 97239

James McNames, PhD
APDM Wearable Technologies
2828 SW Corbett Ave Ste 135
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.

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.

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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).

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.

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.

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 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.

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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.

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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My signature below indicates that I have read, or had read to me, all of the above information about the study, and that my rights as a research subject have been explained to me. I authorize the use of my information and blood as described in this form.

In the future, if I decide that I no longer wish to participate in this research study, I agree that my blood and information, which were already collected, may continue to be used only for this research by removing all identifying information. However, identifiers may be stored separately and held in accordance with the VA records control schedule.

I voluntarily consent to participate in this study. I have been told that I will receive a copy of this consent form.

_____
Printed Name of Subject

_____ _____ _____
Signature of Subject Date Time

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Date Time

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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.

- 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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I agree to the following regarding future uses including genetic research of my

contact information _____ (initial)

coded data _____ (initial)

and/or blood: _____ (initial)

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

_____ In person/When you come to the VA

_____ By Letter

_____ By Phone

_____ Not applicable (no contact information storage)

I agree to the following <u>future</u> 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.

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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

Signature

Kathryn Chung, MD and any authorized member(s) of the study team has explained the banking of my information, data, and blood for future research to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the banking.

I have been told that I may refuse permission for banking of my blood, data, and/or information for future research and that refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are problems or questions, I have been told I can call Joseph Quinn, MD at (503) 721 – 1091.

By consenting to participate, I authorize the use of my blood, data, and/or information.

My signature below indicates that I have read, or had read to me, all of the above information about the banking of my blood and/or information, and that my rights as a research subject have been explained to me.

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I voluntarily consent to allow the blood, data, and/or contact information (address, last four of social security number, phone number(s), gender, veteran status, contact preferences, and Parkinson's disease information) from this study to be stored in a repository and used for future research, as described in this form. I have been told that I will receive a copy of this consent form.

_____
Printed Name of Subject

_____ _____ _____
Signature of Subject Date Time

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Date Time