PDGENE-PF Informed Consent Form and Authorization to Use and Disclose Protected Health Information - PART 1

Sponsor / Study Title:	**Parkinson's Foundation / "Parkinson's Foundation: PD GENEration"**
Protocol Number:	**PDGENE-PF**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

Thank you for expressing an interest in participating in the Parkinson's Foundation PD GENEration Genetic Registry (PDGENE-PF) research study, sponsored by the Parkinson's Foundation.

You may print a copy of this form to consider or discuss with family or friends before making your decision on whether to participate in PDGENE-PF.

KEY INFORMATION:
You are invited to take part in a research study. This research study aims to collect and share Parkinson's disease genetic testing data from up to 500,000 study participants for research use. The Parkinson's Foundation is sponsoring this research study.

Participants will include people with Parkinson's disease (PD), people at-risk for developing PD, and members of the general community who do not have PD. To investigate the genetic link to PD, we will ask participants to contribute a sample of either primarily whole blood or, secondarily, saliva or buccal swab. A participant's sample will undergo genetic testing. Their genetic test results, associated raw data, and residual DNA will be stored for future research use. Participants will receive their genetic test results through a genetic counseling session. The risks associated with this study are potential invasion of privacy, sample failure due to laboratory error, and impact on family relationships. This study is being done to help improve our understanding of PD and help participants and their clinicians understand their genetic status to improve care, which includes determining eligibility for clinical trial participation.

Participation in the study is entirely voluntary. No medical treatments, medical advice or medical interventions will be provided to you as part of this study.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part in this study or not. If you decide to take part in this study, you must sign your name at the end of this form.

WHAT WILL HAPPEN DURING THIS STUDY?
Your participation in this study will last approximately 3 months to a maximum of 1 year and will include approximately 2 study visits.

Visit 1: Baseline

Consent and Survey:
Before any study-related tests and procedures are performed, you will be asked to read and sign this consent document. The following procedures will then be performed at the baseline visit if you qualify to take part in this study and consent to the study:

- Provide your permission to share the results of your genetic test with the Parkinson's Foundation and with your clinician
- Agree to share your de-identified data (stripped of personal information such as your name and date of birth to protect your privacy) to be made available to qualified researchers, who may be employed by non-profit organizations, companies and/or government entities, for future research use
- Agree to bank your DNA for future research use
- Agree to be re-contacted by the Parkinson's Foundation in the future with updated information about PD and other clinically actionable genes
- Agree to undergo genetic testing for PD
- Complete participant survey

Sample Collection:
You will be asked to provide a sample that will undergo genetic testing. Your sample will be labeled with a unique identification code that is different from the one used to identify your clinical information. Your sample will not be labeled with your name, and only the study team will be able to link your information with the unique identification code.

Your sample will be collected at a clinical site, or it will be collected by you at your home (remotely). Blood collected at a clinical site will be collected via venipuncture using a needle in your arm or will obtained using a FDA approved blood collection kit called Tasso+. Blood collected remotely will be obtained via a FDA approved blood collection kit called Tasso+. Tasso+ is a sterile, disposable blood lancing device. When collecting a sample, the device is held onto the skin by a mild adhesive. A sterile lancet punctures the skin with a press of the button, simultaneously this creates a slight vacuum that helps capillary blood flow under gravity into a compatible tube. After a predefined time period, or when the tube is full, the device is peeled off the skin. The tube is removed and capped for transport. The lancet is single use and automatically retracts into the device in a safe position after use.

If the blood sample quality does not meet the requirements of the testing lab, you may be asked to do the following:

- Provide a second sample using a new Tasso+ kit
- Schedule an appointment with a local site that is collecting blood
- Schedule an appointment with a phlebotomy service
- Provide a saliva or cheek swab sample

Whole genome sequencing data from your DNA will be de-identified and kept by the Parkinson's Foundation for storage. This file may be shared in the future with researchers or in managed-access cloud databases. Successful research scientists and other organizations using

the sample or sample data could result in a commercial or therapeutic product with significant value, such as a product for the medical treatment or diagnosis of PD. You will not share in any financial benefits of these uses.

Visit 2: Genetic Counseling
You will be given your genetic test results via a genetic counseling session with a clinician or a genetic counselor either in-person or remotely.

Clinically Relevant Results:
Research results that are clinically relevant, including individual research results, will be disclosed to you in this study.

GENETIC FINDINGS
DNA is the genetic material in our body and DNA segments constitute a gene. A gene is a set of instructions that tells our bodies how to complete certain functions. The genetic testing performed by this study is whole genome sequencing, a technique that reads all the genes from our DNA . Researchers can look closely at large amounts of your genetic information by sequencing, or "reading", every letter in your DNA (your genome). The research will include whole genome sequencing (for example, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Genetic Findings:
Your DNA will be analyzed by a clinically approved (CLIA) lab to look for changes, or different types of genes, within a minimum seven specific PD genes (*LRRK2, GBA1, SNCA, PRKN, PARK 7, PINK1, VPS35*). We will provide a report if you decide you want to receive these results.

Your clinician or genetic counselor will discuss if you have one or more different types of these genes, which we know cause or increase the chance of developing PD. Some PD symptoms, such as cognitive changes or dementia, may be more common among people with PD who carry certain types of genes. The presence of one of these different types of genes does not necessarily mean you would develop one of these symptoms, although the test results could indicate whether you may have a greater chance of developing certain PD symptoms. In addition, it is possible that our understanding about carriers of certain types of genes could change as researchers learn more. The testing will focus on genes thought to be most significant in PD. It will not include all genes known to be associated with PD or different types of genes that are not clearly linked to PD at this time.

It should be noted that we may identify risks for other conditions not related to PD as part of testing. For example, with this genetic testing we will identify some individuals who carry two of the GBA1 gene. Individuals who carry two GBA1 variants have a condition called Gaucher disease, a metabolic condition with variable symptoms. Individuals with two GBA1 genes variants will receive information about Gaucher disease and will be referred to a Gaucher disease specialist in their area for further evaluation. Individuals who carry one GBA1 variant are carriers for Gaucher disease and have an increased risk of having a child with Gaucher disease. This information may be especially important to some individuals and/or their family members, including those who are planning to have children.

What is Genomic Data Sharing?
The Parkinson's Foundation, the study sponsor, requests that the data created as part of this study are shared with other researchers. This is known as genomic data sharing. Genetic information

(also known as genomic sequence data), medical record data (also known as phenotype data), and your DNA samples may be shared broadly in a coded form for future genetic research or analysis. We may give certain medical information about you (for example, diagnosis, age if you are under 85) to other scientists or companies not at the Parkinson's Foundation, including a health research (public or controlled access) or non-governmental database, but we will not give them your name, address, phone number, or any other directly identifiable information. If particular research projects require it, we may provide limited identifying information about you, e.g., zip code. Donating data may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

As part of this study, we will collect information about your health and your individual genes (genomic data). This information will be sent to the Parkinson's Foundation-controlled access data repository. Genomic studies look at genetic differences in the entire human genome (the complete set of human genes). Researchers look at these genetic differences to better understand certain health conditions and diseases.

The goal of collecting this information is to allow researchers to look for genetic connections that may increase the likelihood of getting a certain disease, the progression of a certain disease, or disease treatments. A random code will be assigned to your information before sending it to the data repository. Researchers will never get this code or the identifiers we removed.

There may be risks to your privacy and the privacy of your family members from storing your information in the repository. Although the Parkinson's Foundation takes measures to protect privacy, we do not know how likely it is that your identity could become re-connected with your genetic and health information. We believe the chance that this will happen is very small, but we cannot make guarantees. If your genetic information were re-identified, personal information about you, your health, and your risk of disease could become known to others. This could present unknown risks.

RISKS AND BENEFITS

Risks of Study Procedures:
This study involves collecting and storing personal, identifiable information about you, so there is a potential for invasion of privacy or breach in confidentiality. To minimize these risks, we will not store any directly identifiable information about you with your genetic data. Your information will be assigned a unique code number and stored in a secure manner. Information shared with researchers will only include the code number. Even by removing the identifying information, in some circumstances it may be possible to re-identify individuals, given the type and amount of data provided. Therefore, we cannot guarantee that your identity will never become known.

In addition, like any medical test, there is a small risk of laboratory error with the genetic tests performed as a part of a research study. There is also a risk that the test may not work and will need to be repeated. After repeat testing, there is a small chance the lab will still be unable to determine your mutation status. Therefore, it's possible that no results will be provided to you.

Receiving genetic test results may cause increased worry and anxiety among some individuals. It is possible that through this genetic testing you may learn unexpected information from your genetic test results. For example, you may learn that assumed family relationships are incorrect or inadvertently learn a family member's genetic test results. Your genetic testing results will have

implications for other family members and could impact relationships.

Some genetic information may help to predict future health problems for you and your family and this information might be of interest to your employers or insurers. 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. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long-term care insurance. GINA does not prohibit insurers from using information about an already-diagnosed disease such as Parkinson's disease. You are not required to disclose the genetic results to others, including employers or insurance companies.

The Confidentiality section of this document explains the precautions that will be taken to keep your genetic information confidential. However, absolute confidentiality cannot be guaranteed.

Side Effects of Study Procedures:
Risk From Tasso+ Blood Collection Device

- Minor bruising or residual marks may occur at the sample collection site.
- Fainting may occur with any blood sampling procedure. Use device while seated.

The Confidentiality section of this document explains the precautions that will be taken to keep your genetic information confidential. However, absolute confidentiality cannot be guaranteed.

Benefits of Study Procedures:
Your participation may provide more information about the possible roles of your genes in PD. Your participation may benefit others by providing information that is useful to our understanding of how we communicate testing results to people with Parkinson's disease. Your test results may help you determine if you are eligible for a clinical trial.

CONFIDENTIALITY
Records of your participation in this study will be held confidential except when sharing the information required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.

By signing this consent form, you consent to the collection, access, use and disclosure of your information as described above.

NEW FINDINGS
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Future Research Studies:
Identifiers will be removed from your identifiable private information or identifiable biospecimens collected during this study and could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

ALTERNATIVE TO PARTICIPATION
This research study is for research purposes only. The only alternative is to not participate in this study.

What happens if you do not wish to participate in this study?
Your participation in this study is completely voluntary. You can decide not to participate or you can end your participation in the study at any time by submitting a request to be withdrawn to the Parkinson's Foundation. Such a decision will not result in any penalties or loss of benefits to which you are otherwise entitled. In the event that you do end your participation in this study, the information you have already provided will be kept confidential and will remain part of any research already conducted.

COMPENSATION FOR PARTICIPATION AND COST
Will you be paid to participate in this study?
You will not be paid to participate in this study.

Are there any costs to being in this study?
There will be no cost to you for participating in this study. You will not be paid for your participation in the study and there is no cost incurred by you to participate. The costs of any medical follow-up that may be recommended as a result of the genetic testing will not be covered by the study.

In the event that additional genetic variants are detected from research in the future, you may be re-contacted by telephone, USPS or email. Before you are given the test results, we will provide you with more information so that you can determine if you still want to receive these results. This discussion will include:

- More information about the type of genetic variants that may be reported to you
- How the research findings will be confirmed in a clinically approved (CLIA) laboratory before they are returned to you
- Implications that this information may have for your health
- Implications that this information may have for your family members

At that time, you will have the option to change your mind and receive no additional findings.

If we do not contact you in the future, it does not necessarily mean that you do not have genetic variants related to Parkinson's disease or variants that could impact your health. Rather, it means that there may not be additional genetic results available through this study.

FUTURE CONTACT
You may be contacted for future outreach, education, research, either directly by telephone, USPS, email or your clinician. We may ask you to provide a new sample or additional medical information, to participate in other research studies, or allow us to use your samples and/or data for other studies. If additional study processes are needed in order to participate in other research opportunities or return additional test results to you, you may be asked to provide additional consent. You will have the option at that time to decide whether to become involved in additional research.

There is the possibility that you could be recontacted about additional genetic findings, including newly reported variants, from the sample you provided. There is another category of additional genetic or secondary findings that could also be returned to you. More details regarding this option are in Part 2 of this consent form.

It is very important for you to keep us updated on how to reach you for future contacts. If your contact information changes, please contact the study team to provide these details. It is your responsibility to inform the team of these changes to ensure you can receive future updates.

Whom to Contact About This Study:

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study,

Please contact the Investigator at the telephone number listed on the first page of this consent document.

For more information or questions about this research, you may send an email to genetics@parkinson.org.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call toll free:
  877-992-4724
- or by email:
  adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00048622.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives and partners of Parkinson's Foundation.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share your health data will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF CONSENT

STATEMENT of authorization:

I have read this form, and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

PD GENERATION STUDY CONSENT

Participant Printed Name:_____

I give my permission for my data to be given to the Parkinson's Foundation data repository for genomic data sharing.

I confirm that I have reviewed and agree to participate in the Parkinson's Foundation: PD GENEration study and allow my data to be used by the Parkinson's Foundation, its contractors, and researchers.

LEGALLY AUTHORIZED REPRESENTATIVE

Yes ☐ No ☐

Will a legally authorized representative (LAR) be consenting on behalf of this participant?

If Yes, please indicate full name of LAR:_____

If Yes, please indicate your relationship to:

☐ 1. Health care representative/Power of Attorney

☐ 2. Spouse

☐ 3. Adult children

☐ 4. Parent(s)

☐ 5. Adult sibling(s)

☐ 6. Grandparent(s)

☐ 7. Adult grandchild(s)

☐ 8. The nearest other relative in the next degree of kinship not listed in items 3-7

☐ 9. The individual's religious superior, if the individual is a member of a religious order

Signature of Participant/Legal Representative:_____

Date:_____

Printed Name of the Person Conducting the Consent Discussion: _____

Signature of the Person Conducting the Consent Discussion: _____

Date: _____

PDGENE-PF Informed Consent Form- PART 2

INTRODUCTION TO OPTIONAL ADDITIONAL GENETIC FINDINGS

This section is about the possibility of receiving, in the future, additional genetic findings from the sample you provided. This information, specifically health-related genetic information, would be **in addition to** the genetic information relating to seven specific Parkinson's genes called *LRRK2, GBA1, SNCA, PRKN, PARK7, PINK1, and VPS35* that you will receive as a PDGENE-PF study participant. Sometimes these additional types of results are referred to as "secondary findings", meaning a result not related to the main interest of the study.

Please read this form carefully. If you have questions, there is a list of people you can ask at the end of this form. We will give you a copy of this form.

WHAT WILL BE TESTED?

If you decide you want to receive additional results, a clinically certified laboratory will look for additional genetic changes (variants) that may be related to Parkinson's disease (PD) or other conditions that could impact your health in a major way. The list of genes or variants that the laboratory could find may change over time based on new discoveries. This may result in another outreach by our team in the future for more discussion.

If we do not contact you in the future, you could still have genetic variants related to Parkinson's disease or other health conditions. Not all variants that could cause disease are known and not all gene variants that could cause disease will be detected. Only about 2-4% of the time are these additional findings found in people. In other words, most people will not have an additional finding to report.

Parkinson's Disease-related Conditions

If you give us permission, the study will let you know if they find other gene variants in a limited set of genes that **may be related** to Parkinson's disease, rare or atypical forms of Parkinson's disease, or overlapping neurologic conditions. Some of these conditions may feature symptoms such as problems with dystonia (uncontrolled muscle movement), dementia (problems in thinking and memory) or changes in personality, and possibly other symptoms not typically found in Parkinson's disease. The results of this genetic testing could lead to a change in your current diagnosis and/or medical care. They might also suggest you are more likely to develop additional symptoms you were not expecting or have a faster progression of symptoms. It will be important for your neurologist to explore the meaning of the results with you, if abnormal.

For these additional genetic variants, we will only look at a limited set of genes, and we will only contact you if we find something.

Non-Parkinson's Disease-related Conditions

If you give us permission, the laboratory will look at your DNA to find gene changes (variants) that are **not related** to Parkinson's disease but could be important to you and your family's health. They would look for variants in a limited set of health-related genes associated with specific inherited breast or colon cancer syndromes or inherited heart conditions. Some of the cancer genes can involve variants that cause other cancers as well. There may be things you can do to prevent or treat these conditions. If abnormal, it will be important for your doctor to explore the meaning of the results with you.

For these additional genetic variants, we will only look at a limited set of genes, and we will only contact you if we find something.

HOW WILL I LEARN ABOUT THESE ADDITIONAL FINDINGS?
You will not be required to do anything in order to receive these findings except check "yes" and verify your contact information is up to date. **We cannot predict the timing of when these additional results might become available.** If additional findings are detected in your sample as part of future research, you will first be contacted using your provided contact details (phone, email, and address). Before you are given the additional test results, we will confirm that you still wish to receive them. At that time, you have the option to change your mind and receive no additional findings. A genetic counselor will be available to answer any questions you may have regarding learning about these findings to help you determine if you still want to receive these results. If you confirm that you would like to receive the additional results, you will be scheduled to speak to your physician or a genetic counselor who will explain the results and provide additional clinical follow-up as needed.

WHAT ARE THE LIMITS OF THESE ADDITIONAL GENETIC RESULTS?
The results you get will not tell you everything about your genetics/DNA. This is especially important to remember about health-related results. Even if we do not find a health-related variant, you could still have one not looked for. You will only be contacted about these additional findings if there is something significant to report.

If you receive abnormal results, it may not be easy to predict or know the impact of this on you or your family's health. Some gene variants may be more likely to cause disease than others. There may be some uncertainty.

Because these genetic results from PDGENE-PF are clinical research results, there is a slight chance your PDGENE-PF results could be incorrect. Do not make major medical changes or decisions based only on the additional genetic results obtained under the PDGENE-PF research study. It is strongly recommended that you meet with your doctor to discuss any abnormal additional genetic findings that are found.

WHAT CHOICES DO I HAVE REGARDING RETURN OF ADDITIONAL GENETIC FINDINGS?
Below are the choices you have about being contacted about additional genetic testing results. You can choose to receive these types of results. You can also choose not to receive any additional results. Please select Yes or No for each category of additional results

Parkinson's Disease-related and Non-Parkinson's Diease-related results

Yes	No	
☐	☐	I give my permission to be contacted if the clinical laboratory has found additional genetic variants that may be related to Parkinson's disease or my clinical symptoms or that may have other major implications for my health or for my family's health. I understand that I will be given more information about these research findings before results are given to me and I will have the option to decline to receive these results after I receive additional information.

STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to receive these optional additional genetic findings. All of my questions were answered to my satisfaction. I will receive a signed copy of this form for my records. I am not giving up any of my legal rights by signing this form.

Signature of Participant/Legal Representative:_____

Date:_____

Printed Name of the Person Conducting the Consent Discussion: _____

Signature of the Person Conducting the Consent Discussion: _____

Date: _____