PDGENE-PF Informed Consent Form

(Online Research Participants)

Sponsor / Study Title:	**Parkinson's Foundation / "Parkinson's Foundation: PD GENEration"**
Protocol Number:	**PDGENE-01**
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.

What is the purpose of this study?

You are being invited to take part in the Parkinson's Foundation PD GENEration Genetic Registry study, which aims to collect and share Parkinson's disease genetic testing data from up to 500,000 study participants for research use. Participants will include people with Parkinson's disease (PD) and people at-risk for developing PD, and members of the general community that do not have PD. To investigate the genetic link to PD, we will ask participants to contribute their genetic test results and associated raw data and we will bank residual DNA for future research use. 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.

What will you be asked to do in this study?

If you decide to participate in this study, you will be asked to:

- Electronically sign this consent form
- 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
- 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
- Agree to undergo genetic testing for PD

How samples will be collected?

If you receive genetic testing through a clinical site, you will undergo a blood draw or a cheek swab collection. If you participate remotely (outside of a clinical site), the Parkinson's Foundation will send you a package to the mail address you provide which will include a buccal kit. As part of the study, you will collect a continuous sample of DNA from the cheek inside your mouth using a Q-tip or swab by following these steps:

- You will follow the instructions in the kit sent to your home.
- You will be asked if you have had anything to eat or drink, or if you have smoked or chewed gum within 30 minutes of the sample collection.
- The sample tube will already have your PDGENE ID on it.
- Begin by swabbing your cheek with the Q-tips or swabs provided, being careful not to touch your teeth.
- Swab 10 times with a back and forth motion. Carefully place the sample in the sterile container provided.
- Then repeat the same process on the other side with a second Q-tip or swab in the kit. A third Q-tip or swab will be included in the kit, in case the collection technique used to obtain the sample was incorrect. The sample obtained will be used for genetic testing.
- You will then send the sample you collected to Fulgent Genetics for genetic testing. The shipping label will contain the Fulgent Genetics address in the "Return to" and "Send to" portion of the label.

Are there any risks to being in this study?

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

Are there any benefits to being in this study?

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.

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.

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.

What choices do I have regarding the return of genetic testing results in the future?
You may select below whether you agree to being contacted about future genetic testing results.

Yes ☐ No ☐

I give my permission to be contacted in the future if research has found additional genetic variants related to PD. 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.

Yes No

☐ ☐

I give my permission to be contacted in the future if research has found additional genetic variants not related to PD that may have other 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.

BIOLOGICAL SAMPLE COLLECTION AND STORAGE:
This study involves storing leftover DNA from your genetic test for future PD research. The purpose of storing these samples is to make them available to PD scientists who are trying to develop new tests, treatments, and ways to prevent PD. We hope these samples will provide information that will help PD research or research for other health conditions. Samples will only be shared with researchers who have had their research approved by a review board.

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 the study team will be able to link your information with the unique identification code. Your samples will be stored indefinitely by the genetic testing company and may be transferred to another storage facility. These test results will not be uploaded to your Electronic Medical Record as samples are de-identified and will be used for research purposes only.

In addition, exome sequence 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. Successful research scientists and other organizations using the sample, other parts of 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.

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.

COSTS/PAYMENT:
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.

ALTERNATIVES TO PARTICIPATION:

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

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.

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.

WHOM TO CONTACT ABOUT THIS STUDY:

During the study, if you 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.

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, and/or concerns or complaints regarding this research study, 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.

Who should you contact if you have questions?

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

If you have any questions about your rights as a research subject, you may contact: Advarra IRB at 410.884.2900.

GENETIC TESTING
What genetic information will I learn as part of this project?
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 exome sequencing, a technique that reads the parts of the genes that code for proteins. This information will be analyzed by a clinically approved (CLIA) lab to look for changes,

or variants, within seven specific PD genes (*LRRK2, GBA, 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 variants in 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 variants. The presence of one of these variants 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 variants 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 variants 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 variants in the *GBA* gene. Individuals who carry two *GBA* variants have a condition called Gaucher disease, a metabolic condition with variable symptoms. Individuals with two *GBA* gene 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 *GBA* 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.

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.

Yes	No	
☐	☐	I give my permission for my data to be given to the Parkinson's Foundation data repository for genomic data sharing.

☐ By checking the box, you are confirming that you have reviewed and agree to participate in the Parkinson's Foundation: PD GENEration study and allow your data to be used by the Parkinson's Foundation, its contractors, and researchers.