PDGENE CONSENT FORM

TITLE:	Parkinson's Foundation: PD GENEration: Mapping the Future of Parkinson's Disease
ACRONYM:	PDGENE
PROTOCOL NO.:	PDGENE-01 WIRB® Protocol #20191209
SPONSOR:	Parkinson's Foundation
STUDY PRINCIPAL INVESTIGATOR:	Roy Alcalay, MD, MS
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Name Number(s)

PDGENE is being conducted by the Parkinson Study Group (PSG) under the sponsorship of the Parkinson's Foundation. The PSG is a multinational group of Parkinson's disease specialists.

1. INTRODUCTION/BACKGROUND:

You are being asked to participate in a research study, and this form outlines important information to help you decide whether to participate. You are encouraged to read this consent form carefully and to ask questions about anything that is not clear before making your decision. You may review this form electronically or print a copy to think about and discuss with family or friends. You may keep a copy and refer to it during the study.

You are being invited to take part in a research study which compares two different ways to communicate clinical genetic testing results for Parkinson's disease (PD). This study will evaluate satisfaction with the way we provide genetic testing and genetic counseling. It will also look at the impact of genetic testing for PD. The genetic tests used in this research are not approved by the U.S. Food and Drug Administration (FDA) and are considered investigational. Genetic counseling is the process that helps people understand genetic test results and familial risk for disease. This testing may provide more information about the possible roles of genes in the development of PD. Knowing your genetic test results may make you eligible to participate in additional research designed for your specific type of PD.

A group of PD specialists in the United States of America (USA) will run this study. We expect that about 600 participants will enroll in the pilot study (Phase 1) and expand to Phase 2 in which we hope to enroll 15,000 participants with PD at multiple Parkinson's Foundation and Parkinson Study Group centers.

2. KEY INFORMATION:

- Being in this research study is voluntary; you are completely free to choose whether or not to participate in this study.
- You are being asked to participate in this research study of genetic testing and genetic counseling because you have been diagnosed with PD, or probable PD.
- The purpose of this study is to determine how best to provide easily accessible genetic counseling by your site clinician (either in-person or by telephone) or by a centralized genetic counseling service by telephone and improve the communication of testing results to you.
- As part of this study, you will learn if you have PD-related mutations in the PD-associated genes, *GBA, LRRK2, SNCA, VPS35, PRKN, PINK-1, PARK7.*
- Your participation in this study will last for about 6 months, and may include up to 5 visits or activities (in-person, telephone calls, and online surveys).
- Activities or visits will include answering questions about your medical and family history, one blood draw or buccal sample (cheek swab) collection, genetic counseling, and completion of PD assessments and surveys.
- Your participation may be beneficial to others by providing information that is useful to our understanding of how we communicate testing results to people with PD.
- You do not have to participate in this study to receive treatment for your PD.

3. PURPOSE:

The study sponsor will provide PD genetic testing, as well as post-test genetic counseling, to eligible participants. This study seeks to evaluate differences between receiving genetic counseling through a site clinician at an in-person or telephone visit, or through a centralized genetic counseling service by a telephone call. It will also evaluate the impact of PD genetic testing on future actions.

4. WHAT DO I HAVE TO DO AS PART OF THIS STUDY?

If you decide to participate in this study, you will be asked to sign this consent form and undergo a Baseline Visit, which may be done either in-person at the clinic or through telemedicine, to make sure that you meet the criteria to be in the study. If the study team finds that you are eligible to participate, and you agree to undergo genetic testing for PD, you will be asked to complete two (2) follow-up activities after the Baseline Visit. The first follow-up activity involves genetic testing result disclosure and genetic counseling, either through the clinic (an in-person visit or telephone visit) or through the centralized genetic counseling service by telephone. The second follow-up activity will consist of you completing online survey questions approximately 30 days after your genetic counseling session and at the maximum of 118 days thereafter. This will conclude your study participation. Your participation in the study will last approximately 6 months.

Global Unique Identification Number (GUID)

You will be assigned a Global Unique Identifier (GUID) by the site staff as part of the National Institute of Neurological Disorders and Stroke's (NINDS) Parkinson's Disease Biomarkers Program (PDBP). This identification number is a computer-generated code that will be unique to you. The GUID allows researchers to share your de-identified data across research studies and study sites. We will collect 10 pieces of personal information about you (legal name at birth, legal family name at birth, additional legal name(s) at birth, day of birth, month of birth, year of birth, city or municipality of birth, gender of participant at birth, country of birth, and middle name, if applicable). NINDS issues our site access to a special computer program that performs a one-way encryption, often called a one-way hash code. The "one way" means that it is nearly impossible to recreate the original data. The encrypted hash codes do not have information to recreate your personal information (the information disappears). The GUID allows data to be associated to you without exposing or transferring personally identifiable information.

CTCC Unique ID

In addition, you will receive a 9-digit CTCC unique identification (ID) number. This number will be used to connect your research information to the other CTCC studies in which you may participate. Your site coordinator will help you get this unique number through a secure internet website by entering 9 pieces of information about you (last name at birth, first name at birth, gender at birth, day of birth, month of birth, year of birth, city of birth, country of birth, and mother's maiden name). After completion of this information, your study coordinator will provide you with a copy of the Unique ID number. Once you receive the 9-digit number, the 9 pieces of information you entered will be deleted from the database. You or your study coordinator will be able to obtain your unique number again should you misplace this information.

Pre-Screening Visit:

This visit may take approximately 1-1.5 hour(s). This visit will be conducted on the telephone. During this visit, we will:

- Ask you to watch a pre-consent video.
- Ask you some questions about your understanding of this study and we will answer any questions you may have.
- Ask you to select how you would like to participant in this study, either by an in-person visit or by a telemedicine visit. If you select the telemedicine visit, we will verify that you have the necessary technology to conduct this visit at your home. The telemedicine visit will be done using a secure video-conferencing system. Otherwise, you can select a site near you to participate in the study.
    - If you are eligible for the telemedicine visit, you will be sent an electronic consent form to your personal email address only, and we will review this consent form with you in detail. You will be instructed how to sign this consent electronically and will be able to print the consent form for future reference. If you prefer to be seen in-person, you will sign the informed consent at the site you select at the Baseline Visit.
    - Once the informed consent is signed, you will be scheduled for a Baseline Visit.
    - You will be sent a package from the study team that includes a buccal swab kit (to perform a cheek swab inside your mouth) and assessments you will need to complete.

Telemedicine Baseline Visit:

This visit will take about 1-2 hours. If you choose to participate via a Telemedicine Baseline Visit, we will conduct the following:

- Review consent signed electronically before any study procedures begin.
- Your identity will be verified by showing the site coordinator your photo ID.
- If you meet requirements, we will:
    - Review your medical and neurological history including demographics
    - Ask questions about your family's history and your general health.
    - Ask questions about your medical history, socioeconomic status, medications and collect your contact information (telephone, email, USPS mail address)
    - A buccal sample is continuous swab of the inside of your mouth cheek.

        - You will follow the instructions in the kit sent to your home.
        - You will be asked if you have had anything to eat, drink, if you have smoked or chewed gum within 30 minutes of the sample collection.
        - You will be observed by the site clinician or coordinator to assure proper technique is used to obtain the sample. They will also provide guidance in case you have questions.

- The sample tube will already have your PDGENE ID on it.
- Begin by swabbing your cheek with the swab(s) provided, being careful not to touch your teeth.
- Swab 10 times with a back and forth motion. You will carefully place the sample into the sterile container provided.
- Then repeat the same process on the other side with the second swab in the kit. A third swab will be included in the kit, in case improper collection technique was used to obtain the sample. 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 Fulgent Genetics address in the "Return to" and "Send to" portion of the label.
- A DNA sample and genetic data from the buccal sample will be stored at Fulgent Genetics.

    - Assess your PD symptoms, memory, thinking and mood
    - Ask questions to assess your understanding of genetic testing for PD and your knowledge of the genetics of PD
- At the end, we will randomize**(e.g., like flipping a coin; or drawing numbers from a hat)* how you will receive your test results and genetic counseling, either by a telephone call from the site clinician/genetic counselor or a telephone call from the centralized genetic counseling service.

Baseline In-Person Visit (at the Clinic):

This visit will take about 1-2 hours. If you choose to participant in-person during the Baseline Visit, we will conduct the following:

- Review the study, have you watch a pre-consent video, answer any questions you may have and ask you to sign this consent document if you wish to be a part of the study.
- If you meet all of the requirements of the study, the following will be done:
    - Review your medical and neurological history including demographics
    - Ask questions about your family's history and your general health.
    - Ask questions about your medical history, socioeconomic status, medications and collect your contact information (telephone, email, USPS mail address)
    - A blood sample (about 1/2 tablespoon) for genetic testing.
        - The sample will be labeled with your PDGENE ID, processed by the site team, and sent to Fulgent Genetics for genetic testing.
        - A DNA sample and genetic data from the blood sample will be stored at Fulgent Genetics.
    - Assess your PD symptoms, memory, thinking and mood
    - Ask questions to assess your understanding of genetic testing for PD and your knowledge of the genetics of PD
- At the end, we will randomize**(e.g., like flipping a coin; or drawing numbers from a hat)* how you will receive your test results and genetic counseling, either by a telephone call from the site clinician/genetic counselor or a telephone call from the centralized genetic counseling service.

Randomization will not occur at the University of California San Diego site as all participants will be counseled by central genetic counseling via telephone. For participants who prefer counseling in Spanish, all participants will be counseled by central genetic counseling via telephone. During Phase I (pilot), participants who are randomized to receive counseling at their site, but cannot schedule an appointment within 9 weeks of their initial visit, will be counseled by central genetic counseling via telephone.

Genetic Counseling Session:
This session will take about 30-60 minutes and will be within 3-12 weeks after the Baseline Visit. During this session, we will discuss the results and implications of your genetic testing. We will also confirm and discuss your family history information that you have previously provided. We will answer and address any questions or concerns you may have about the testing.

Post Counseling Surveys:
Within 3 months of the Baseline Visit, you will be sent a secured email with a link to complete online surveys. The surveys will assess your understanding, satisfaction and impact of the genetic testing. If you do not have an email address, we will send the paper surveys to you via United States Postal Service (USPS). These surveys will take about 15-30 minutes to complete. If you selected to contacted by email, the site coordinator will contact you to establish a "user account". You will receive a daily notifications until you establish an account. Daily notifications are part of the electronic system and cannot be changed. If you receive the surveys via USPS, we will ask you to return the completed surveys within a few days with the enclosed self-addressed envelope provided by the study staff. If no response is received within 90+ 28 days, the site coordinator will call and ask your permission to send an email that contains the 3 surveys which you may complete directly on the form. We will provide detailed instructions of how to complete and return the forms. If the forms are not returned within 14 days to the site coordinator, we will consider your study participation as complete.

No genetic results can be disclosed once study participation is complete. If you do not complete the genetic counseling session, you will be considered "lost to follow-up. If at a later time, you decide you would like to receive your genetic results, you will be allowed to re-enter the study by signing a new informed consent document and begin study procedures again which include another blood or buccal sample collection. You must agree to receive genetic counseling. However, if you do not complete the genetic counseling session, you will considered "lost to follow-up" and will not be given another opportunity to receive your genetic test results.

Premature Withdrawal:
If you decide that you wish to stop participating in the study, or are withdrawn from the study before completing the three surveys, we will ask that you complete surveys for an early (premature) withdrawal visit. Request for completion of the visit procedures and evaluations, whether or not the withdrawal is determined at a regularly scheduled study visit or at an unscheduled visit. During this session we will:

- Ask you questions about genetic testing and your knowledge of the results via an online surveys.
- If you are not able or refuse to return for a premature withdrawal session, we may want to ask you these questions via telephone call and send you the forms electronically by email.

Withdraw of Consent:
If you wish to withdraw your consent for this study, we ask that you do this in writing to the study doctor who is conducting this study. Because of the permissions included in this study, we would like to verify in writing what part or all of the study from which you are withdrawing. For example, you may wish to stop with the follow-up surveys but would still like your stored DNA sample to be used for future research.

Unscheduled Visit
An unscheduled visit may need to occur if we need to collect a second blood or buccal swab sample from you due to problems that may occur (e.g. clotted sample, broken tube, unlabeled tube, sample contamination, or laboratory equipment malfunction). This visit should take 10-15 minutes. This visit may be done via telemedicine (for the buccal swab sample) or in -person (for the blood sample).

5. GENETIC TESTING

What genetic information will I learn as part of this project?

DNA is the genetic material in our body and segments of DNA make up 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 then 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*), and a report will be issued with these specific results.

Your site 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. Although the presence of one of these variants would not necessarily mean you would develop one of these symptoms, test results could indicate whether you may have a higher chance for developing certain PD symptoms. In addition, it is possible that our understanding of carrying 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 be provided 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 to have 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 additional information from this testing might I learn in the future?

Exome sequencing produces a large amount of genetic data. Apart from the genes related to PD listed above, we will not be evaluating this information or providing interpretation of additional genes or variants as part of this project, at this time. However, these data will be stored and may be shared with other researchers. Thus, in the future there may be additional genetic information discovered such as:

1) Genetic variants directly related to PD
2) Genetic variants that are unrelated to PD, but may have implications for your health or the health of your family members. Some of these findings could have serious health implications that may require medical follow-up or treatment.

In the event that additional genetic variants are detected from research in the future, you may be re-contacted by telephone or USPS. Before you are given 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 decision and not receive the 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. If we do not contact you within 7 years, it is unlikely you will be contacted in the future.

What choices do I have regarding return of genetic testing results in the future?
You may select below if you are agreeable 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:
PDGENE involves collecting blood or buccal swab samples to be used for current study analysis and stored 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 that 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 blood or buccal swab 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 sent to Fulgent Genetics for genetic testing and sample storage. Your samples will be stored indefinitely and may be transferred to another storage facility. You will not be able to access your stored samples or request they be used for clinical purposes outside of this study scope. 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 a file will be transferred to the University of Rochester Clinical Trials Coordination Center (CTCC), Clinical and Data Management Core 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.

6. NUMBER OF SUBJECTS:

There are multiple sites participating in this study with about 600 participants for the Phase I (pilot), and up to 15,000 participants for Phase 2. We will enroll approximately XXX participants at **[SITE NAME].**

7. RISKS AND DISCOMFORTS:

Taking part in this study has risks. Some of these risks we know about and there is also a possibility of risks that we have not foreseen.

Some of the questions you will be answering are personal and may make you feel uncomfortable or upset. Please tell the site clinician or study staff if you feel uncomfortable or upset while answering questions. You do not have to answer any questions that you do not want to. You may get frustrated or feel tired when completing some of the study activities.

There is a risk of loss of confidentiality of your information, however, there are safeguards in place to reduce the chance of this happening. Please ask the site clinician or study staff if you would like to know more about how your information will be protected while you are in this study.

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, there may be no results to provide back 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 could 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 can help 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.

8. BENEFITS:

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 testing results may help you determine if you are eligible for a clinical trial.

9. FUTURE CONTACT:

You may be contacted for future research, either directly by telephone, USPS or through your site. We may ask you to provide a new sample or additional medical information, 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.

10. COSTS/PAYMENT:

You will not be paid for your participation in the study and there is no cost incurred by you to participate. The cost of genetic testing and counseling will be paid by the study. Parking expenses (with receipts) associated with your visit(s) will be reimbursed. The costs of any medical follow-up that could be recommended as a result of the genetic testing will not be covered by the study.

11. REIMBURSEMENT FOR PARKING, (IF APPLICABLE)

You may be reimbursed for reasonable out of pocket parking expenses for any completed on-site visit(s) after submission of receipts to the study team. You will only be reimbursed for actual expenses up to a maximum amount of $30.00. Such reimbursed expenses are not taxable.

12. COMPENSATION FOR INJURY:

If you are directly injured by clinical procedures solely required to participate in the study, the study doctor will refer you for treatment. If you receive medical care for the injury, you may need to pay for treatment of your injuries. You will be reimbursed for reasonable and necessary medical expenses for such treatment. The **[NAME OF INSTITUTION]** may seek payment for treating study related injuries from your health insurer or the study sponsor. You may not be reimbursed for care covered and paid for by a third party like your health insurance provider, or costs such as required co-payments or deductibles related to that coverage. No other funds have been set aside to pay for such things as lost wages or expenses due to a current underlying illness or condition.

If your research injury is paid for by Parkinson's Foundation, we will collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. This information will be used only in accordance with the law. If you are a Medicare beneficiary, information about the study you are in, and any payments made related to your injury, will be reported to the Centers for Medicare & Medicaid Services (CMS), in accordance with CMS requirements. This information will not be used for any other purpose.

13. CONFIDENTIALITY OF RECORDS, PERMISSION FOR RELEASE OF INFORMATION and HIPAA Authorization:

We will make every effort to keep the information collected from you private. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be protected in published reports from the study and in databases in which results may be stored.

If you have never received a copy of the Notice of Privacy Practices from **[NAME OF INSTITUTION],** please ask the site clinician for one.

Your research records may be inspected and/or copied for quality assurance and data analysis, including:

- the site clinician and his/her research associates;
- the Indiana University Genetic Counseling Core;
- the CTCC Data Clinical and Data Management Core;
- the study sponsor: The Parkinson's Foundation
- the Clinical Trials Coordination Center;
- and (as allowed by law) state or federal agencies, specifically, the Office for Human Research Protections (OHRP), the IRB, and the FDA, who may need to access your medical and/or research records.

Your genetic test results or other research results from this study may be included in your medical record.

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 website at any time.

14. ALTERNATIVES:

This is not a treatment study so your alternative is to not participate in the research.

15. VOLUNTARY PARTICIPATION:

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 withdraw to the study doctor. Such a decision will not result in a penalty 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.

16. CONTACT PERSONS:

For more information concerning this research, if you have questions, concerns, or complaints, or if you believe that you have suffered a research related injury, please contact: **[SITE NAME AND PHONE NUMBER OF CONTACT PERSON FOR STUDY INFORMATION].**

If you have questions, concerns, or complaints or questions about the rights of research participants, you may call the Institutional Review Board at (800) 562-4789**.**

17. GENOMIC Data Sharing

The Parkinson's Foundation, the study sponsor, requests that we share the data created as part of this study with other researchers. This is known as Genomic Data Sharing. Genetic information (also known as genomic sequence data) the medical record data (also known as phenotype data), and your blood sample 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, blood pressure, age if less than 85) to other scientists or companies not at the **[SITE NAME]**, including to a *(public or controlled access)* government or non-government health research 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 would 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 relatives 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.

18. CONSENT TO PARTICIPATE IN STUDY:

If you have any questions about the study, please ask to speak to the site coordinator before signing. You may also ask to speak with a clinician or genetic counselor prior to signing.

If something should happen to you and you are not able to receive your test results due to death or incapacitation, we can arrange to provide this information to a person you designate below. The study results may be provided in person or over the phone.

Yes ☐ No ☐ I wish to have a designee receive my genetic testing results.

Designee if I cannot receive test results due to death or incapacitation:

_____	_____	_____
Designee Name	Telephone Number or Email	Date

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. If needed, I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a copy of this form for my records and future reference.

_____	_____	_____
Participant Signature	Participant Printed Name	Date

In my judgment, the subject has demonstrated comprehension of the information.

_____	_____	_____
Signature of Person Receiving Consent	Printed Name and Title of Person Receiving Consent	Date

****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?

The study doctor and the study staff. [They may also share the research information with [enter SMO company name], an agent for the study doctor. delete if the site does not have an SMO]

Who might get this information?

The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2060.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

_____ _____

Signature of Subject **Date**