Indiana University Informed Consent Statement for Widespread Recruitment Database for Parkinson's Disease

INTRODUCTION

You are being asked to participate in the Widespread Recruitment Database (WRD) for Parkinson's disease. Please read this form carefully to make an informed decision about whether you would like to be included in this recruitment database.

If you have any questions while reading this form, please do not agree to the terms of the consent or authorization, but instead provide your contact information. The research team at Indiana University (IU) will then contact you to discuss any questions that you may have. You can also contact the study staff directly at 888-830-6299 or wrd@iu.edu.

You are being invited to enroll in WRD because you:

- Are undergoing, or have completed genetic testing through the Fox Insight Genetic Substudy (FIGS) and would like to discuss your testing report with a genetic counselor
- Have previously completed genetic testing through a commercial company (such as 23andMe) or clinical testing
- Have previously participated in genetic testing for the Widespread Recruitment Initiative, as part of the Parkinson's Progression Markers Initiative (PPMI) study
- Would like to join our registry, so our team can keep you informed of future opportunities to contribute to Parkinson's disease (PD) research

STUDY PURPOSE

PD research has been gaining momentum over the past decades, which includes a focused interest into the role that genetics plays in Parkinson's disease. This has been accelerating researcher's understanding of the disease, as well as allowing the development of targeted new therapies to slow or stop the progression of PD. Research studies are ongoing that are enrolling individuals who have inherited mutations genes related to Parkinson's disease and knowledge of an individual's mutation status can be valuable information for PD researchers.

The WRD intends to identify and educate individuals who may be eligible to participate in new research opportunities. This can be achieved in the following ways:

Some individuals may have already completed genetic testing for PD through entities outside of the IU team (such as through commercial testing with 23andMe). Participants with pre-existing genetic testing reports will be asked to securely provide these to our team for review. The WRD has an established team of licensed genetic counselors who are available to review previous genetic testing reports with participants by phone and answer any questions they have.

The WRD also seeks to build a registry of volunteers who are interested in contributing to PD research. This includes individuals with and without previous genetic testing. One goal of the WRD team will be to communicate current and future PD research opportunities to registry participants. Therefore, it is possible that several research initiatives will be discussed with a participant. It is also possible that participants may be contacted in the future as new collaborations with PD research studies are formed.

PROCEDURE FOR THE STUDY

If you are interested in participating in the WRD, you must read and agree to the terms of this Informed Consent form (IC) and Authorization by signing your name electronically on both forms. Paper copies of these forms are available as needed and can be provided by contacting our study team. After agreeing to the terms of this form, you will be asked to provide your contact information (mailing address, e-mail address and telephone number). You will then be asked to complete a series of screening questions.

Participants without previous genetic testing:

For individuals who do not have previous genetic testing results for PD, we will request that you complete a series of screening questions. After your survey is completed and submitted to our team, you will receive an automated notification that our team has received your survey. Depending on your survey responses, you may receive notifications or contact from our team members to notify you of research opportunities for which you qualify. If additional questionnaires or study processes are requested in order to participate in these opportunities, our team will provide materials for additional consent.

Participants with previous genetic testing:

For those who have undergone previous genetic testing for PD (such as mutations in the *LRRK2*, *GBA*, *SNCA*, *Parkin* genes, etc), you will be asked to provide a copy of your test report through a secure upload or transfer to our team.

If your previous testing was completed through the Parkinson's Progression Markers Initiative (PPMI) study, you agree to share your previous genetic testing results as well as other collected demographic information with the WRD study. The WRD team will include this data in the WRD recruitment database.

For all participants seeking genetic counseling:

For individuals who have previous genetic testing results , a genetic counselor is available to you to talk to you should you have any questions. A genetic counselor is a health professional who has training in both medical genetics and counseling. A genetic counselor from Indiana University will review your test results with you and provide genetic counseling regarding your test results by telephone. The genetic counselor will discuss the implications of your results with you and obtain a family history.

It is possible that genetic testing may show that you carry one or more PD mutations. Carrying one or more PD mutation is associated with an increased risk for Parkinson's disease; however, it is possible that the degree of risk for Parkinson's disease may be uncertain or may change as more information is learned about Parkinson's disease. Carrying a PD mutation also has implications to other relatives, including offspring.

If reviewing testing results for the *GBA* gene, it is possible that genetic testing will identify some individuals who carry mutations in both copies of the *GBA* gene (one copy inherited from your father and the other copy inherited from your mother). Particular pairs of mutations in *GBA* can

cause a recessively inherited condition called Gaucher disease. Individuals who carry two mutations may have variable symptoms of Gaucher disease, while others may be asymptomatic. Individuals found to have two mutations will be counseled about Gaucher disease and will be referred to a Gaucher disease specialist in their area for further evaluation. Individuals who carry one *GBA* mutation are carriers for Gaucher disease. Carriers of a *GBA* mutation have an increased risk to have a child with Gaucher disease and this information may be important to some individuals and/or their family members, including those who are planning to have children.

Post genetic counseling:

After genetic counseling has been completed, participants will be mailed a genetic counseling summary letter, which may include other materials outlining other research opportunities that you are eligible to pursue. In some situations, you may be asked to self-refer and will be provided with contact details explaining how to enroll in another study. We may also ask your permission for the team at Indiana University to securely forward your contact information, genetic testing results and Parkinson's disease status to a research site, so their team may contact you directly.

In addition to the written materials you receive, you may also be asked to complete an online survey to assess the session and/or other aspects of the testing or study process. .

BENEFITS FROM PARTICIPATING IN THIS STUDY

Depending on your participation status, you may provide more information about the possible role of genes in Parkinson's disease. You may benefit from receiving information about clinical trials related to Parkinson's disease.

RISKS FOR PARTICIPATING IN THIS STUDY

While participating in this study, there is a potential risk of loss of confidentiality. Information that you provide will be stored on a locked computer server. There is a slight risk that someone could break the security of this computer system, find information about your family history, causing a loss of confidentiality. However, safeguards are in place to reduce the risk of this happening. There may be other privacy risks that we have not foreseen.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the study sponsors, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP), who may need to access your medical and/or research records.

COSTS OF PARTICIPATING IN THIS STUDY

You will not be paid for your participation in this recruitment database. Genetic counseling will be available, as needed, and provided at no cost

PROTECTION OF GENETIC INFORMATION

Since some genetic variations can help to predict future health problems for you and your relatives, this information might be of interest to health care providers, life insurance companies, and others. However, Federal and State laws provide some protections against discrimination based on genetic information. For example, a federal law known as the Genetic Information Nondiscrimination Act (GINA) 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 prevent companies that sell life insurance, disability insurance, or long-term care insurance from using genetic information as a reason to deny coverage or set premiums. Please note, our team does <u>not</u> provide participant information to entities outside the scope of our research.

VOLUNTARY PARTICIPATION

Participation in this research project is completely voluntary. You may decide to stop your participation in this study at any time by contacting the WRD study staff by telephone or e-mail. You do not have to participate in this study, and your medical care or involvement in other research will not change as a result of your decision to participate or not to participate. If you decide to withdraw from the study, any research data that has been obtained will remain part of any research already conducted. If you would like to withdraw from a research study or clinical trial to which you have been referred, you must submit this request directly to the research study or clinical trial study staff.

PEOPLE TO CONTACT

If you have any questions about this study, or in the event of an emergency, you may contact the study coordinator at (888) 830-6299. The Principal Investigator, Dr. Tatiana Foroud can be reached at (317) 274-2218 between 8:00 AM and 5:00 PM, Monday through Friday. If you cannot reach the researcher during regular business hours (i.e. 8:00AM-4:00PM), please call the Indiana University Human Subjects Office at (317) 278-3458 or (800) 696-2949. For questions about your rights as a research participant or to discuss problems, complaints or concerns about this research study, or to obtain information, or offer input, contact the Indiana University Human Subjects Office at (317) 278-3458 or (800) 696-2949.

SUBJECT'S CONSENT

I have reviewed the information above and had the opportunity to ask questions regarding this consent form. I willingly agree to participate in this research study. I may withdraw from this study at any time without fear of changing the investigator's interest or the quality of medical care that I may seek or receive in the future from the doctors participating in this study. I have received (or will receive) a copy of this form for my records and future reference.

Printed name of Individual

Signature of Individual **Date**

Printed name of Person Receiving Consent

Signature of Person Receiving Consent **Date**

Citations:

1.) *Special Considerations for Genome Research,* National Human Genome Research Institute, https://www.genome.gov/27559024/informed-consent-special-considerations-for-genome-research/#_Return_of_results, June 16 2016