<<Insert University Logo>>

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: SPARX3
Study in Parkinson Disease of Exercise
Phase 3 Clinical Trial

SITE PRINCIPAL INVESTIGATOR:
<<PI FIRST LAST, CREDENTIALS>>
<<PI TITLE>>
<<PI ADDRESS 1
ADDRESS 2 (OPTIONAL)
CITY, STATE ZIP>>
Phone: <<PI PHONE>>

CO-INVESTIGATOR:
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SOURCE OF SUPPORT: NIH/NINDS

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KEY INFORMATION FOR SPARX3

Before joining our research study, SPARX3, we want to share key information about the study with you. We want to summarize five topics for you prior to reviewing the consent form.

1. This is a voluntary research study

   Participation in this study is voluntary and you do not need to participate in the study. If you choose to participate, a study team member will explain the study to you and will answer any questions you might have. You should take your time to make your decision.

   The purpose of this study is to compare the effects of 2 different levels of exercise intensity and to learn more about effects of aerobic exercise on people with Parkinson's disease (PD). This study will help us better understand what exercise guidelines should be used in the future.

2. Summary of Study Activities

   First, you will complete two screening visits to confirm that you meet the criteria to participate in the study. These visits consist of physical and memory/thinking assessments, a blood draw for exercise clearance, a questionnaire to screen for depression, and a brain scan (DaTscan) that helps confirm diagnosis of PD. These screening activities are explained in further detail below.

   If you are eligible to participate in this study, you will then complete a series of visits, which consist of more physical and memory/thinking assessments, questionnaires, blood draws, exercise tests, and brain scans. You will also be randomized (like flipping a coin) to one of two exercise groups. You will be asked to exercise, at a specific rate/intensity, 4 days per week for approximately 30 min, while we will closely monitor you. Your participation in this study, including study visits and the exercise sessions will last approximately 2 years (24-26 months). These research activities are explained in further detail below.

3. Risks and side effects related to SPARX3

   Overall, potential risks associated with participation in the study are unlikely and of low risk. One risk from this exercise intervention is that you may develop muscle soreness or strains. It is also possible that any existing musculoskeletal conditions you may have could be aggravated as a result of exercising. This is common with exercise for adults of any age. The most common side effects of DaTscan are headache, increased appetite, and dizziness. There is a rare risk of bleeding and local infection with blood drawing, an infrequent risk of bruising and fainting, and a likely risk of discomfort. These risks are explained in further detail below.

4. Reasonable expected benefits

   You may benefit from participating in the exercise program, such as physical fitness, weight loss, improvements in blood pressure, and improvements in blood cholesterol levels; however, there is no guarantee that this study will improve your symptoms related to PD.

5. Alternative procedures or treatment

   This study is not designed to treat or improve your symptoms related to PD. If you decide that you are not interested in participating in the study, you can continue with your care as decided by you and your movement disorder specialist. Your participation in this research study will have no effect on your current or future medical care at this hospital or with an affiliated health care provider.

Why is this research being done?
We are doing this study to learn more about physical exercise for people who have been diagnosed with Parkinson's Disease (PD) within the last 3 years and who are not currently managed with medications to help us better understand what exercise guidelines should be used in the future.

Who is being asked to participate in this study?
You are being asked to take part in this research study because you have been diagnosed with PD within the last 3 years, are between 40 and 80 years of age, are not currently being treated with drugs for your PD, and are not anticipated to need PD medication in the next 6 months.

What procedures will be performed for research purposes?
The following activities will be performed before beginning the exercise intervention and all data collected will be for research purposes only:

SCREENING VISITS
Before you begin the exercise study, you will complete screening assessments in order to confirm eligibility and make sure that this is an appropriate study for you. These assessments may be done in one or more visits. The following screening assessments will take place at ADD ADDRESS HERE.:

- A member of the study team will ask you basic demographic information, such as age, sex, date of birth, ethnicity, race, education level, marital status, handedness, and activity level. You will fill out a questionnaire that will be used to screen for depression. These will take about 15 minutes.
- We will conduct a physical/neurological exam (including clinical tests that assess how your nervous system functions to coordinate your ability to move) and will take and record vital signs, such as heart rate, temperature, blood pressure, height and weight. This will take approximately 35 minutes.
- We will collect information about medical history, surgeries, and information about conditions related to PD. We will also document medications, treatments, and the conditions for which you are being treated. These will be documented monthly and will take approximately 30 minutes.
- We will assess different cognitive abilities, such as memory, thinking, attention and concentration, and language. This will take approximately 10 minutes.
- We will draw approximately 3 tablespoons of blood from you to make sure that you do not have any medical conditions (e.g., liver disease, kidney disease) that would make it unsafe for you to exercise.

The DaTscan will take place at the following location: ADD ADDRESS HERE.

- If you pass Screening Visit 1, you will have DaTscan brain imaging. The purpose of this is to see if you still qualify to participate in the study. In order to participate in the study your scan must show changes that are linked with PD. We are looking for low levels of a chemical in your brain called dopamine. Dopamine is involved with controlling movement. People with PD have less dopamine-containing nerve endings on this test and therefore too little dopamine.

  The imaging drug that will be used for this test is called DaTscan. This drug allows doctors to take pictures of the brain and nerve endings containing dopamine, using a SPECT (Single Positron Emission Computerized Tomography) scan machine. A SPECT scan is a routine medical imaging

test that uses radiation to take pictures of your body (like x-rays). DaTscan is FDA approved for imaging adults being evaluated for PD.

If your DaTscan indicates low levels of dopamine, you will be able to take part in the study. If your scan does not show low levels of dopamine, you are not eligible to continue in the study and will not complete any other study visits or procedures. A central reading facility at The Institute for Neurodegenerative Disorders and Molecular NeuroImaging in New Haven, Connecticut will help us to read the image and estimate the level of dopamine in your brain. Neither we nor you will be told the specific level of dopamine that was seen in the scan.

If you are participating in the Parkinson's Progression Markers Initiative (PPMI) 2.0 study and have already had a DaTscan completed within 8 weeks of your projected SPARX3 baseline visit, the PPMI2.0 scan results will be used in lieu of performing the DaTscan to determine eligibility.

DaTscan Brain Imaging Procedures:

At least one hour before the DaTscan imaging procedures, we will give you medication to take by mouth to protect your thyroid glands. This medication contains iodide. To avoid an allergic reaction to the iodide medication, please let the staff know if you have ever had a reaction to iodine. Once you have taken the iodide medication, we will insert an IV catheter (through a needle into a vein in your arm). We will use the catheter to inject you with DaTscan tracer, which will travel through your body. You may have to wait up to four hours for the tracer to reach your brain before we can start the scan. Women of childbearing potential will have a pregnancy test that must show a negative result prior to DaTscan tracer injection.

To begin the scan, you will lie on a narrow table and your head will be placed in the SPECT scan machine. The SPECT scan will take a "picture" of the radiation given off by the tracer. This picture of your brain will be taken for up to 1 hour. After the scan is completed, we will discuss with you any side effects that you may have had. You may ask to stop the scanning procedure at any time, and if so, may resume the DaTscan within 3 to 6 hours. The results would not be valid after this time period and you may have to reschedule the scan if you are not able to complete it within this time frame. Otherwise, you will not be able to participate in the study. Study staff will be able to see and hear you at all times during the scanning. You can speak to the staff at any time.

24-48 hours following the scan, you will need to drink more fluids and urinate frequently to remove the radioactive agent from your body.

- To understand how active you are, you will be asked to wear a small, light-weight device that will measure your activity level for one week. This will be given to you after you've completed the DaTscan. Specifically, this device will measure the intensity of your activity, walking pace and the distance you walk. We will give you the monitor at this visit, provide you with instructions on how to wear it, and give you a sheet to fill out over the course of the week. You will return this monitor to us at the end of the week. It will take about 10 minutes to go over the instructions.

We will contact you after the screening visits to tell you if you are eligible to come back for a baseline visit.

BASELINE VISIT

If after the two screening visits you meet all eligibility criteria and choose to continue participating, you will complete the following additional baseline assessments to determine your abilities prior to beginning the study intervention. You will be asked to come to ADD ADDRESS HERE., to complete the following assessments:

- We will draw approximately 3 tablespoons of blood from your arm, which will be used to evaluate levels of inflammation and markers relating to the function of nerve cells. Your biological samples will be sent to the Biospecimen Exchange for Neurological Disorders at Indiana University and the University of Florida. Only your unique subject identifier will be used to identify your information and biological sample. The biological samples may be provided to researchers at academic institutions, hospitals, and biotechnology/pharmaceutical companies. De-identified (all identifying information has been removed) clinical and genetic data may be provided to the researchers requesting biological samples. These researchers may perform analysis of the biological samples you have provided. As this is done for research purposes, you will not be given the results of these analyses. Your biological samples will be maintained in the laboratory indefinitely. These samples will be coded and not identified by your name.
- Evaluations of the symptom progression of your PD and how PD affects you and your life. We will record your functional status and assess the burden and extent of your Parkinsons Disease and will use this to track how your illness improves or worsens over the course of the study. We will also record your heart rate, blood pressure, temperature, height, and weight.
- We will write down of all of your medications, treatments, and conditions, and will track these, along with any changes in your health condition, each month you are in the study.
- We will assess different cognitive abilities, such as memory, thinking, attention and concentration, and language.
- You will be asked questions about the physical, mental, and social effects experienced by individuals living with neurological conditions.
- You will be asked to walk for 6 minutes at a comfortable speed and the distance walked will be measured. <<INCLUDE THE BELOW HIGHLIGHTED TEXT IF YOUR SITE WILL BE USING OPALS>> Before the walk test, we will place small (watch-sized) sensors (movement monitors) on your arms, legs, and waist that will record your movements during the walking. While walking, you will be provided a mask to wear for the duration of the assessment.
- You will complete an exercise test which will involve walking or running on a treadmill until exhaustion. You will breathe through a special mask or mouthpiece during this test. The exercise will be easy at first, but will gradually become more difficult until you can no longer continue. This test will take about 15 minutes.
- This visit will take approximately 3 hours.

EXERCISE INTERVENTION

Once you complete all of the assessments, you will be randomly assigned to one of the two exercise groups.

1) Moderate intensity: 60-65% of your maximum heart rate
2) High intensity: 80-85% of your maximum heart rate

Frequency: You will be asked to exercise 4 times per week
Type: You will complete all exercise sessions on a treadmill

Time: You will warm up for 5 minutes, spend 30 minutes at the specified heart rate range, followed by a 5-minute cool down.
Duration: You will be asked to continue the exercise intervention for a total of 18 months and encouraged to continue in the program without supervision from the exercise trainer.

At the beginning, you must exerciseunder the supervision of an exercise trainer. The trainer will tell you the heart rate you should reach during the first session, and will help guide you with increasing the amount of time on the treadmill and increasing your heart rate over time to either the 60-65% or the 80-85%, depending on the group you were assigned. The exercise trainer will teach you how to use the treadmill safely and will teach you how to use the heart rate monitor we give you. Supervision will take place until you have shown us that you can perform the exercise safely and correctly. You may request additional supervised exercise sessions at any time throughout the study. While completing supervised exercise sessions, there is a potential need for you to wear a mask.

Once the exercise trainer has determined you are able to perform the exercise safely and correctly, you may exercise without supervision at home or at an exercise facility of your choice. <<INCLUDE THE BELOW HIGHLIGHTED TEXT IF YOUR SITE HAS AN APPROVED EQUIPMENT TRANSFER AGREEMENT >> If you do not currently have access to a treadmill, we will work with you to arrange access. You may be required to sign a separate document depending on the type of arrangement chosen. You will exercise under the supervision of an exercise trainer, research assistant trained in exercise training, or exercise physiologist periodically over the duration of the studyWhile completing the supervised exercise sessions, there is a potential need for you to wear a mask.

During the exercise sessions you will be wearing a heart rate monitor and we will teach you how to monitor your heart rate and adjust your exercise to reach your target heart rate. Heart rate monitors must be worn for all exercise sessions. A study team member will download the data from your heart rate monitor at supervised visits.

Once each month, you will complete a questionnaire related to your health status. This will be completed with a study team member at one of your monthly supervised visits or may be completed via telephone by a study coordinator.

Every three months, you will receive a small device that measures how active you are (an activity monitor) which you will wear for one week. You will return the activity monitor the following week. This will take place at Screening, Month 3, Month 6, Month 9, Month 12, Month 15, and Month 18.

FOLLOW UP TESTING
At approximately the 3, 6, 9, 12, 18, and 24 month time points, you will be asked to return for follow-up assessments.

MONTH 3
During this visit, we will assess the current status and progression of your Parkinson's disease. You will also be asked questions about current medications and your health status. You will be given an activity monitor at this visit to wear for one week to assess your overall activity level. This visit will take approximately 1 hour.

MONTH 6
At this visit, we will complete a physical/neurological exam including vital signs, will assess the

current status and progression of your Parkinson's disease and your need for dopaminergic medication. You will complete a memory/thinking assessment, a depression questionnaire, and will be asked questions about current medications your health status, and about how your PD has changed since beginning the study. You will be asked questions that monitor the physical, mental, and social effects experienced by individuals living with PD. You will also complete another blood draw. <<INCLUDE THE BELOW HIGHLIGHTED TEXT IF YOUR SITE WILL BE USING OPALS>> You will be asked to complete another exercise test and 6-minute walk test, while wearing movement monitors and a mask, like you completed at baseline. You will be given an activity monitor at this visit to wear for one week to assess your overall activity level. This visit will take approximately 3 hours.

MONTH 9
You will repeat all of the assessments at this visit that you completed during your Month 3 visit. This visit will take approximately 1 hour.

MONTH 12
You will repeat all of the assessments at this visit that you completed during your Month 6 visit. The assessments will take approximately 3 hours. You will also complete another DaTscan, just as you did at your screening visit. The DaTscan may take place on a different day than the Month 12 assessments, and will take between 3-7 hours, depending on how long it takes for the DaTscan tracer to reach your brain.

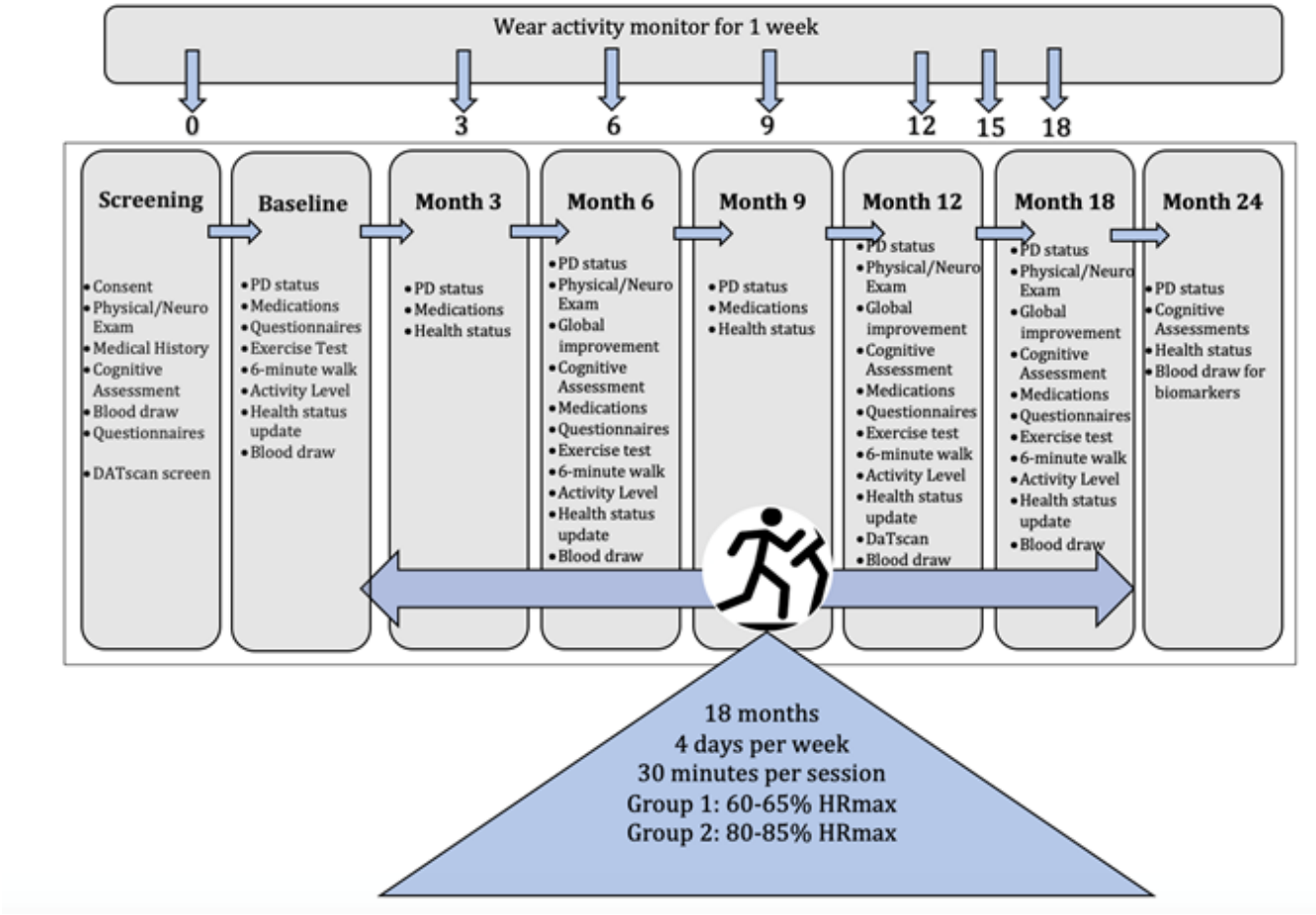
If you are enrolled in the Parkinson's Progression Markers Initiative (PPMI) 2.0 study and a DaTscan was performed within 3 weeks prior to the month 12 visit, the results of this scan will be used in lieu of performing the DaTscan.

MONTH 18
You will repeat all of the assessments at this visit that you completed during your Month 6 visit. At the end of the 18 months, you will not be required to continue exercising according to the study protocol. However, we believe the exercise prescriptions for this study are beneficial for you and we suggest that you continue with your exercise routine to the best of your ability. We will contact you monthly to ask you about your health status over the phone. You will then come back about 6 months after this unsupervised time period for additional follow up assessments. This visit will take approximately 3 hours.

MONTH 24
Your final study visit will take place at about the 24-month time point. During this visit, we will assess the current status and progression of your Parkinson's disease and will assess your need for dopaminergic medication. You will be asked questions about your medications and health status. You will answer a questionnaire that monitors the physical, mental, and social effects experienced by individuals living with PD. You will complete another blood draw. This visit will take approximately 1 hour and 30 minutes.

SYMPTOMATIC TREATMENT VISIT (IF NEEDED)
During the course of the study, you and your neurologist may decide that it is best for you to begin medication for your PD. If this is the case, an additional visit will be scheduled to assess the current status and progression of your Parkinson's disease and your need for dopaminergic medication. This visit will take approximately 1 hour.

Below is a schematic with an overview of the study procedures.



What happens if I need to be placed on Parkinson's medication during the course of the study?
During the course of the study, you and your neurologist may decide that it is best for you to begin medication for your PD. If you begin medication, you will still be a participant in the study and will continue with the exercise program. Before you begin medication, we will try to schedule an additional study visit so that we can assess the current status of your Parkinson's disease.

For any follow up visits that take place after you have begun taking Parkinson's medication, we will ask you to not take those medications for 12 hours before the start of the study visit. We will perform some assessments while you are off medication, then will allow you to resume taking your dopaminergic medication as usual and will finish the study visit while you are on your medication as normal.

Your neurologist may be a study investigator. If your neurologist is a study investigator, he or she will be unaware of the group to which you will be assigned and the decision to begin medications will not be influenced by study participation.

What are the possible risks, side effects, and discomforts of this research study?
<u>Breach of Confidentiality</u>

Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that research information, and additional information beyond that collected for research purposes, may be captured and used by others not associated with this study.

We will protect the privacy and confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records once your personal information is disclosed to others outside of <<ENTER SITE-SPECIFIC INFORMATION HERE>>.

A possible risk from your participation in the study involves loss of privacy as a result of providing biological samples for research. This could affect future insurability, employability, or reproduction plans, or have a negative impact on family relationships and/or result in paternity suits or stigmatization.

In addition, there is a Federal law, called the Genetic Information Nondiscrimination Act (GINA), that generally makes it illegal for health insurance companies and group health plans to use genetic information in making decisions regarding your eligibility or premiums. GINA also makes it illegal for employers with 15 or more employees to use your genetic information when making decisions regarding hiring, promoting, firing, or setting the terms of employment. This new Federal law does not protect you against genetic discrimination by companies that sell life, disability, or long-term care insurance.

Physical Risks

The main side effect from this exercise intervention is that you may develop muscle soreness or strains. Additionally, it is possible that any existing musculoskeletal conditions you may have could be aggravated as a result of exercising. This is common with exercise for adults of any age. The occurrence of such events will be minimized by gradually increasing the exercise intensity and duration to the target levels during the first 8 weeks of training.

While on the treadmill, you may lose your balance or stumble (less than 1 in 100). Trained personnel will assist you early in the training sessions and will instruct you on how to use the handrails on the treadmill to assist with balance when necessary, as well as other safety precautions to use while exercising. When you are exercising on your own, we will ask that you never exercise when you feel lightheaded or dizzy or when your Parkinson's symptoms are worse than usual.

You may experience a rash or irritation from the heart rate monitors and/or activity monitors.

There are cardiac risks associated with participating in exercise testing and training. During exercise you may experience a serious (affecting your heart) event. An example of a cardiac event would be a heart attack or another medical condition that causes damage to your heart or cardiovascular system. The risk of exercise testing is low, with approximately 6 cardiac events per 10,000 tests. The risk of this happening to you is rare, because it occurs in less than 1% of people (less than 1 out 100 people). During exercise you may experience an increase in heart rate, an increase in blood pressure, shortness of breath, general fatigue, and in some cases muscle soreness. The risk of this happening to you is likely because these occur in more than 25% of people (more than 25 out of 100 people). In the event that you experience a serious medical condition during your assessment of physical function, the session will be stopped and appropriate emergency medical care will be provided. This may include

providing emergency care until appropriate medical personnel arrive. If you experience a serious medical event while completing unsupervised exercise, seek emergency treatment.

Risk Associated with DaTscan

You may experience a metallic or bitter taste in your mouth from the iodine used during this procedure. If you are allergic to iodine, you might get itching, a rash, bloating, severe blood pressure changes (shock), and death if given iodine, therefore, those who are allergic to iodine are excluded from this study. The most common side effects of DaTscan are headache, increased appetite, and dizziness. In clinical trials, headache, nausea, vertigo, dry mouth, or dizziness of mild to moderate severity were reported. Hypersensitivity reactions, generally consisting of redness of the skin and an unpleasant sensation of the skin that provokes the urge to scratch, have been reported following DaTscan administration. The effect of DaTscan on a developing baby still in the womb (embryo or fetus), or on a breastfeeding infant, is unknown and may be harmful. Because of these unknown risks, women may not take part in this study if they are pregnant, trying to become pregnant, or breastfeeding.

<<SITE SPECIFIC RADIATION LANGUAGE**>>or use paragraph below:**

Participation in this study will involve exposure to radiation associated with the administration of the DaTscan. Each DaTscan injection (5 mCi; a "mCi" is a unit of radioactivity dosage) will result in a whole body radiation dose of about 4 mSv (a mSv is a unit of radiation dose). For comparison, radiation workers are limited, by Federal regulation, to receiving a maximum, annual whole body radiation dose of 50 mSv. In the event that technical issues arise that prevent the completion of the planned scanning activities following the administration of the DaTscan, you may be asked to return on another day to complete the scanning study activities. This will require a second administration of the DaTscan. The maximum exposure to radiation associated with the administration of DaTscan for all scanning study activities (including the possibility of a repeat administration at both scanning timepoints) would be the exposure associated with four (4) DaTscan administrations (5 mCi each, total exposure 16 mSv). For comparison, radiation workers are limited, by Federal regulation, to receiving a maximum, annual whole body radiation dose of 50 mSv. There is no minimum amount of radiation exposure that is recognized as being totally free of the risk of causing genetic mutations (abnormal cells) or cancer. However, the risk associated with the radiation exposure received from participation in this study is considered to be low in comparison to everyday risks.

Risk Associated with Blood Draws

There is a rare risk of bleeding and local infection (less than 1%, less than 1 out of 100 people) with blood drawing, an infrequent risk of bruising and fainting, and a likely risk of discomfort. To minimize risk of infection, the needles used for this procedure are single use, pre-sterilized, individually packaged. Pressure will be applied post-venipuncture to decrease the risk of bleeding and bruising.

Psychological Risk

You may experience non-physical risks such as boredom, frustration, stress, and time constraints when completing the questionnaires. The risk of this happening to you is likely because this occurs in more than 25% of people (more than 25 out of 100 people). You do not have to answer upsetting questions and may choose to discontinue participation at any time. If we unexpectedly discover a condition that requires further attention beyond our abilities, we will inform you and make the appropriate referrals to ensure the problem is addressed.

What are the possible benefits from taking part in this study?
The benefits of participating in an exercise program have been shown to include improvements in physical fitness, weight loss, improvements in blood pressure, and improvements in blood cholesterol levels. However, there is no guarantee that any or all of these changes will occur as a result of your participation in this study. The information learned from this study may benefit individuals with PD in the future.

Can I participate in other research studies and/or take part in other forms of exercise while enrolled in this study?

- We ask that you do not enroll in other studies which have an intervention, such as studies that require you to take a drug or change your usual routines, as well as studies that require a DaTscan™ SPECT imaging procedure as part of the study activities, with the exception of the PPMI2.0 study.
- You can continue to engage in your usual physical activities. We ask that you do not engage in additional endurance exercise other than that prescribed in this study.

If I agree to take part in this research study, will I be told of any new risks that may be found during the study?
You will be promptly notified if, during the conduct of this research study, any previously unknown risks about the exercise intervention or testing activities are found.

What do I need to know about reproductive health and/or sexual activity if I am in this study?
If you are currently breastfeeding, are pregnant, or plan to become pregnant within the next 12 months, you are not eligible to participate in this study, since the effect of DaTscan on a developing baby still in the womb (embryo or fetus), or on a breastfeeding infant, is unknown and may be harmful. If you change your mind about becoming pregnant, you should tell us immediately. If you are menopausal and have not had a menstrual period for the past 24 months or more, you will not need to have a pregnancy test. Also, you will not need to have a pregnancy test if you have had surgical removal of your uterus and/or ovaries (hysterectomy). All other female subjects must have a negative pregnancy test before participating in the DATscan portion of the study. If you are a woman who can become pregnant, you will have a pregnancy test as part of the routine laboratory tests at your screening visit and at your 12 month visit. If you do become pregnant over the course of the study, you will be asked to obtain medical clearance from your physician to continue with the exercise program.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?
Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purposes of this research study. However, if one of the assessments reveals a potential health problem that requires further evaluation, you will need to be cleared by your own health care provider if you want to take part in the study, and you or your insurance company will be billed in the standard manner.

Who will pay if I am injured as a result of taking part in this study?

<INSERT LOCAL COMPENSATION FOR INJURY LANGUAGE HERE>

Will I be paid if I take part in this research study?
You will be paid up to $300 for completing all activities related to the research study. You will be paid by the local research team. The payment schedule will be as follows:

- Informed Consent & Screening Visit1 -- $30
- Screening Visit 2 -- $30
- Baseline Assessments -- $30
- 3 Month Assessments -- $30
- 6 Month Assessments -- $30
- 9 Month Assessments -- $30
- 12 Month Assessments -- $30
- 18 Month Assessments -- $30
- 24 Month Assessments -- $30
- Symptomatic Treatment Visit (if needed) -- $30

All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 28% of the payment be sent by the institution to the IRS for 'backup withholding'; thus, you would only receive 72% of the expected payment.

ADD SITE SPECIFIC INFORMATION ABOUT METHOD OF PAYMENT HERE

Who will know about my participation in this research study?
Any information about you obtained from this research will be kept as confidential (private) as possible. Any information you provide that could identify who you are (e.g., your name, your date of birth, etc.) will be stored in a locked file cabinet, on password-protected computers, or in a password-protected secure and encrypted multi-site database system. Other information we collect will be de-identified, meaning that we will replace your personal information with a number code. The key linking code numbers with individual names will be maintained in a password-protected file. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

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

To help us protect your privacy, a Certificate of Confidentiality has been issued from the National Institutes of Health for this study. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this

research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of *[list what will be reported, such as child abuse and neglect, or harm to self or others].*

Will this research study involve the use or disclosure of my identifiable medical information?
Your participation in this study requires us to collect some personal information from you. Any information you provide that could identify who you are (e.g., your name, your date of birth, etc.) will be stored in a locked file cabinet, on password-protected computers, or in a password-protected secure and encrypted multi-site database system. Other information we collect will be de-identified, meaning that we will replace your personal information with a number code. The key linking code numbers with individual names will be maintained in a password-protected file.

<If your site requires that a research record be created in the subject's name to, for example, schedule and log visits, please state that here and confirm that no test results will be stored in those records.>

In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study:

- Authorized representatives of the study sponsor, the University of Pittsburgh Office of Research Protections, investigators from the University of Pittsburgh, and/or an independent research monitor may review your identifiable research information for the purpose of conducting and monitoring of this research study.
- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- Information collected from this study may be shared with other investigators involved with the PD-GENE study and the PPMI2.0 study if you are currently or become a research subject in either of those particular studies. Investigators from both the PD-GENE study and PPMI2.0 study will also share data with our investigators. The information that will be shared will be de-identified, i.e. coded and the information linking the code with your identity will be stored in a separate secure location.
- In accordance with NINDS requirements, the final research data and documentation from this clinical trial will be sent to the NINDS Office of Clinical Research repository. Data will be stripped of potential identifiers precluding linkages to individual participants and disclosure of individual subjects.
- Biological samples will be stored at the Biospecimen Exchange for Neurological Disorders at Indiana University. The data, samples, and genetic data generated from samples may be shared with other researchers and with federal repositories, in a de-identified manner (without identifiers). These research data/samples may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the <<YOUR UNIVERSITY NAME>> for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the<<YOUR UNIVERSITY NAME>>, or their agents may realize.
- Authorized representatives of the <<YOUR UNIVERSITY NAME>> or other affiliated health care

providers may have access to identifiable information related to your participation in this research study for the purpose of (a) reviewing eligibility criteria associated with research participation; (b) scheduling appointments associated with research participation; and/or (c) for internal hospital operations (i.e. quality assurance).

- In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by state (or provincial) law, the appropriate agencies.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

<<SITE SPECIFIC INFORMATION**>>or use paragraph below:**

The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for a minimum of 7 years and for as long (indefinite) as it may take to complete this research study. Raw de-identified data will be stored indefinitely and may be used in future related studies. Only the research team will have access to the server and database files.

Is my participation in this research study voluntary?

Your participation in this research study is completely voluntary and you may withdraw your consent for participation, at any time.

If you do withdraw from the study, then you may request that your demographic and clinical data and any unused sample be destroyed. However, data and samples that have already been distributed to approved researchers will not be retrieved, and any information recorded during your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your doctor is involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor. Your decision not to participate or to withdraw your consent for participation in this research study will have no effect on your current or future relationship or medical care with this institution or with affiliated health care provider.

If I agree to take part in this research study, can I be removed from the study without my consent?

It is possible that you may be removed from the research study by the researchers. You may be removed from the study, for example, if it is determined that you no longer meet the eligibility criteria to participate or if you become non-compliant with the follow-up activities.

<<INSERT LOCAL HIPAA LANGUAGE OR USE THE FOLLOWING>>

HIPAA Authorization for Disclosure of Protected Health Information (PHI)

As part of this research study, we are requesting your authorization or permission to review your medical records to determine whether you meet the conditions for participation in this study. This authorization is valid for an indefinite period of time. We will access the medical record and collect only eligibility information at enrollment. After enrollment, should you initiate medications for Parkinson's disease or be hospitalized for any reason, we will review your medical record and collect this information as well.

No research-derived information will be placed in your medical record.

This identifiable medical record information will be made available to members of the research team for an indefinite period of time.

Your medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the National Institutes of Health and the University of Pittsburgh Office of Research Protections, for the purpose of monitoring the study. Authorized representatives of <<INSERT UNIVERSITY NAME>> or affiliated health care providers may also have access to this information to provide services and addressing billing and operational issues.

We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside <<INSERT UNIVERSITY NAME>>.

You can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up that point will continue to be used by the research team.

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VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

Any questions I have about my rights as a research participant or the research use of my medical information will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

<IF YOUR SITE WILL BE VIDEO TAPING ASSESSMENTS, INCLUDE THE BELOW TEXT>
The researcher may video record me to aid with study assessments. The researcher will not share these recordings with anyone outside of the immediate study team.
I agree _____or I disagree _____

<<SITE ADVOCATE INFORMATION (OPTIONAL)>>

By signing this form, I consent to participate in this research study and provide my authorization to share my medical records with the research team.

_____
Participant's Name

_____ _____
Participant's Signature Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____
Printed Name of Person Obtaining Consent Role in Research Study

_____ _____
Signature of Person Obtaining Consent Date