You can help verify a new test for Freezing of Gait in Parkinson's disease!

Freezing of Gait (FOG) is hard to treat because it's hard to measure. We're fixing that. You can help!

Location and Time
- Emory Brain Health Center
- 1-2 ~3 hour study visits

Are you eligible?
- Diagnosis of Parkinson's disease
- Can walk ~30 feet unassisted
- No deep brain stimulation
- Willing to delay morning medication on study days

Compensation
- $100 e-giftcard per study visit

Scan me!!!

or: Web: redcap.link/fogtest
Voice: 404-712-7105
Email: bhc.motion.lab@emory.edu

EMORY UNIVERSITY SCHOOL OF MEDICINE
Department of Biomedical Informatics
Department of Neurology

THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH

EMORY IRB STUDY00007856
#FOGTEST

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 140 people who are being studied, at Emory and other sites.

Why is this study being done?
This study is being done for this purpose: to develop a new way to measure freezing of gait in people living with Parkinson's disease. You are being asked to be in this research study because you have Parkinson's disease and may experience freezing of gait.

Do you have to be in the study?
It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?
If you qualify and choose to join the study, you will participate for up to two weeks (up to 2 study visits, 3-4 hours each). If you do not experience freezing of gait, you will only be scheduled for one study visit. If you do experience freezing of gait, you will be invited for a follow up visit within 1-2 weeks of your first visit. The researchers will ask you to do the following during the laboratory study visit(s):

You will be asked to stop your medication for 12 hours prior to the visit so that the study team can first assess your Parkinson's symptoms in the "OFF" state. If you do not have safe and reliable transportation in the "OFF" state, then a taxi can be provided for you by the study.

After completing the "OFF" medication assessments, you will resume your medication and the rest of the assessments will be completed in the "ON" state. We will ask that you take 1.2 (120%) times your usual dose when resuming your medication at the study visits. You will need to provide this medication, and the study neurologist will help calculate the appropriate dosage.

The laboratory study visit(s) will consist of the following tests and procedures:

Balance and Gait Testing. During your laboratory visit(s), we will assess your balance and gait using wearable sensors. We will place small (watch-sized) sensors on your arms, legs and torso that will record your movements during the walking and balance tasks. During the gait and balance assessments, the study team will monitor you for safety and use a gait belt to prevent falls as needed. You will be asked to complete a number of walking trials of different lengths. Trained research staff will be present to ensure your safety while performing the walking and balance tests. You may take breaks as often as you would like. The balance and walking tests will be video-recorded for review by research staff.

Questionnaires & Surveys. During your laboratory visit(s), you will also complete several questionnaires about your activity levels, thinking ability, gender and sexual identity, and quality of life. Some of these questionnaires may make you uncomfortable or upset. You may choose not to complete any questionnaires that are upsetting to you.

Videos/photographs. During the assessment of Parkinson's symptoms, balance and gait testing in the laboratory you will be video recorded (with audio) or photographed. We will use the videos and photos to aid in data analysis, for educational materials, research presentations and publications. You will not be able to view the images before use, and you may be recognizable in the images.

All of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. This study is not intended to benefit you directly.

What are the risks or discomforts you should know about before deciding?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- Discomfort from lack of medication
- Falls
- Allergic response to straps
- loss of privacy
- breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
There will be no costs to you for participating in this study, other than costs related to loss of work. You will not be charged for any of the research activities. Transportation can be arranged if needed.

There is more information in the “Costs” section further below.

What Should You Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Take time to think about this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: Freezing of Gait – Clinical Outcomes Assessment: People with Parkinson's disease Cohort

IRB #: STUDY00007856

Principal Investigator: J. Lucas McKay, Ph.D., M.S.C.R.

Funding Source: This study is supported by the Michael J. Fox Foundation for Parkinson's Research.

Introduction
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:
- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

What is the purpose of this study?
The purpose of the study is to develop a new way to measure freezing of gait in people living with Parkinson's disease. You have been invited to be in this research study because you have Parkinson's disease and may experience freezing of gait. We will be developing a new clinical definition of freezing of gait, as well as a better way to quantify freezing of gait.

What will you be asked to do?
The study will take place in the Brain Health Center Motion Analysis Laboratory, at 12 Executive Park Drive, Atlanta, Georgia, 30329, Room 517.

Prior to each study visit, you will be asked to postpone your Parkinson's medication intake on the morning of the study visit (i.e. last dose of medication for Parkinson's disease the night before your assessment visits). Each study visit consists of the following items:

1. ***Tests without medication (approx. 45 min)***
    a. Clinician-Reported Outcome (ClinRO) test for Freezing of Gait & Patient Meaningfulness survey: During this test, you will be asked to perform a number of walking tasks, such as stepping, turning, or walking through a doorway. You will be asked to perform these tasks separately, but also simultaneously with an attention task where you will be asked to concentrate on a test at the same time as walking. After completing each task you will be asked a few questions about your experience with the task. To assess the reliability of the clinical scoring, the test will be evaluated by two researchers. Furthermore, your movements will be recorded using five lightweight motion sensors (one on each shin, one on each foot and one on your lower back), as well as through a video recording from upto two perspectives (front view and possibly side view). It is important to note that your face will be visible in these videos, and you will be recognizable. This is necessary because

Freezing of Gait often involves the whole body, including involuntary movements of the head/face. These video recordings are required to verify the scores given by two researchers and will only be analysed by the researchers involved in this study. Moreover, these images will only be shared with other participating centres after your face has been made unrecognizable by means of blurring the video recording.

b. MDS-UPDRS-III: The MDS-Unified Parkinson's Disease rating scale is a clinical test to assess the severity of your motor symptoms.

2. Medication intake & questionnaires (approx. 1 hour)

After completion of the ClinRO and MDS-UPDRS-III, you will be able to take your regular dose of dopaminergic medication. While we wait for it to take effect, we will ask you to complete several questionnaires:

a. Patient Reported Outcome (PRO) questionnaire: This questionnaire was newly developed to determine the severity and impact of Freezing of Gait on your quality of life.
b. Questionnaires gauging your mental health (e.g. Parkinson Anxiety Scale and Geriatric Depression Scale).
c. Questionnaires concerning symptoms you may experience (e.g. New Freezing of Gait Questionnaire, Characterizing Freezing of Gait questionnaire, Falls Efficacy Scale-International, Parkinson's Disease Questionnaire-8, REM sleep Behavior Disorder screening questionnaire and MDS-UPDRS parts 1, 2 and4).
d. Demographics: your age, sex at birth, height, weight, education, employment, marital status, living arrangements, ethnicity, gender identity and sexual orientation.
e. General health and Parkinson's disease specifics: disease duration, medication intake, number of falls and fall related injuries in the past 6 months, smoking status, alcohol consumption and cognitive assessment.

3. Tests with medication (approx. 45 min)

a. Clinician-Reported Outcome (ClinRO) test & Patient Meaningfulness survey
b. MDS-UPDRS-III

Wearing the sensor at home. Upon completion of the first study visit, we will ask you to wear a motion sensor for 7 days consecutively (see Figure 1). This is a small sensor that will be attached to your lower back and that will allow us to measure your physical activity such as walking movements when you are not in the clinic/research facility. Please make sure to follow the below guidelines:

1. Wear the sensor continuously during the 7-day period, i.e. also while sleeping and showering.
2. You may shower with the sensor as it is waterproof, but please do not take a bath or go swimming during the 7-day period.
3. Continue your daily activities as usual and do not change your routine, with the exception of bathing or swimming as described in point 2.
4. After the 7-day period, you may remove the sensor and return it to the researcher.

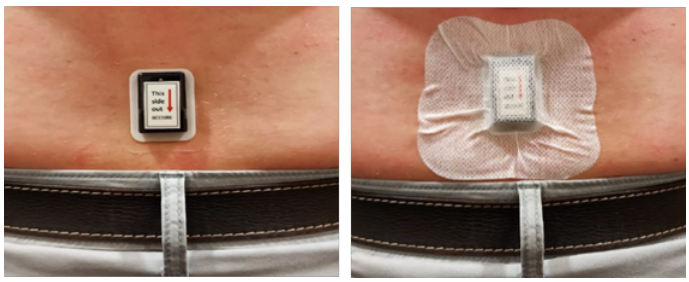

Figure 1. Axivity motion sensor placed on the lower back to be worn for 7 consecutive days.

If Freezing of Gait is not one of your symptoms, we will ask you to return the motion sensor via a prepaid postal envelope, after which the study ends for you.

If Freezing of Gait is one of your symptoms, we will ask you to return after 7-14 days for a second session to determine reliability in a test-retest scenario. This second test session will occur exactly the same way as the first session, where

you will attend having postponed taking your Parkinson's medication. We ask you to return the motion sensor during this session. Lastly, we will ask whether you are still prepared/interested to participate in an online interview session (session3), in which we will ask you to describe your experiences with Freezing of Gait and other Parkinson's symptoms you may experience in detail so that we can understand how important freezing of gait is to you at present.

Optional interview session. If you decide to take part in the **optional interview session**, you will be asked to complete a pre-interview survey, after which you will be invited for an online videoconference via the platform Zoom. The pre-interview survey will ask questions to help determine your experiences with Freezing of Gait and other Parkinson's disease symptoms, and to what extent these changes are bothersome or important to you. A link to the survey will be emailed to you and you will be asked to complete this survey before your interview. The interviewers use this information to pre-map your symptoms as a basis for the interview. During the interview, you will be asked about what symptoms are most important or bothersome to you. A personal symptom map will be created to portray your personal symptoms, which will be created by the interviewer with your input. Next, you will be asked to hierarchically order symptoms by how important each symptom is to you, and then to discuss specifically what about each symptom is important. You will be able to make changes and correct as needed. This interview will take approximately 90 minutes to complete and will be performed while you are on your Parkinson's medication. The information collected during the interview will be combined with the other information we collect from you in the study. Once you have completed the 1:1 interview, you will have the option of receiving your personal symptom map via email, which you will indicate yes or no to at the end of the consent form. If you have questions once you receive your map via email, you may contact the study team to discuss your personal symptom map in more detail with your interviewer.

Who owns your study data and samples?

If you join this study, you will be donating data. You will not be paid if your data are used to make a new product. If you leave the study, the data that were already collected may still be used for this study.

What are the possible risks and discomforts?

The most common risks and discomforts expected in this study are:

Discomfort. You may experience some discomfort due to an increase in Parkinson's symptoms from going off of your anti-Parkinson's medications. These discomforts will be familiar to you if you have ever delayed a dose of medication, for example because your doctor asked you to or because you forgot. Almost everyone experiences some discomfort, although it will vary significantly from person to person. This discomfort will resolve by the end of the visit and your symptoms will return to their typical on-state level after you have taken your medication.

Falls. While you are off your Parkinson's medication, you may experience your symptoms more and be at risk for falls. You may be at an increased risk of falling while performing the gait and balance tasks during the laboratory test session. We will minimize this risk by having a team member with you at all times, who is experienced in working with people who have gait difficulties. Additionally, a gait belt may be placed around your waist to aid in catching you if you lose your balance. We consider the risk of falls very, very small, probably less than 1 out of 1000 patients will experience a fall.

Rare but possible risks include:

Skin irritation. It is very rare, but skin irritation from straps used to secure the wearable sensors is possible. We consider the risk of skin irritation very, very small; probably less than 1 out of 1000 patients will experience this.

Breach of privacy/confidentiality. Although every attempt is made to keep subject information private, there is a chance of a breach of confidentiality. We will store the study data and images in a protected location to which only the researchers have access, and store the data without personal identifiers. We consider the risk of breach of privacy/confidentiality very, very small; probably less than 1 out of 10,000 patients will experience this.

Psychological or emotional discomfort. You may feel uncomfortable with study activities or assessments. The study team will make every effort to make your participation comfortable, such as providing breaks as needed. You may discontinue your participation in the study at any time, for any reason, including psychological or emotional discomfort. We consider the risk of psychological or emotional discomfort very, very small; probably less than 1 out of 1000 patients will experience this.

Risks specific to the optional interview session.

- You may become fatigued during the 1:1 interview. If you become tired, you may take a break or stop the interview at any point.
- It is possible that you may feel uncomfortable answering questions on the survey or during the interview that ask about your personal thoughts and behaviours. You may choose not to answer questions or stop the interview at any point.

Will you benefit from the study?

There is no direct benefit from being in this study.

Will you be paid for your time and effort?

Compensation will be provided via electronic gift card. You will get $100 for each completed study visit, for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. We will also send you home with a small body worn sensor. You will get $25 if you wear the sensor as directed and return it as requested.

If Freezing of Gait is one of your symptoms, you will get $225 total if you complete both study visits and return the motion sensor at the second study visit.

If Freezing of Gait is not one of your symptoms, you will get $125 total if you complete one study visit and return the motion sensor via a prepaid postal envelope.

What are your other options?

Since this is not a treatment study, the alternative is not to participate.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

Information and videos/photos about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, Emory, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your information and videos/photos.

Medical Record
If you have been an Emory patient before, then you already have an Emory medical record. If you have never been an Emory patient, you do not have one. An Emory medical record will be made for you if an Emory Atlanta provider or facility gives you any services or procedures for this study.

No information from this study will go into your medical record.

In Case of Injury
If you get ill or injured from this research, contact the person listed in the contact section of this form.

Emory will help you get immediate medical care. However, Emory and the Michael J Fox Foundation for Parkinson's Research do not have programs (or do not plan) to pay for this medical care or compensate you if you are hurt from being in this study.

The costs for any treatment or hospital care you receive from a study-related injury not covered by a health insurer may be billed to you if you do not have insurance. You will be responsible for deductibles, co- payments, and co-insurance. There are no plans to pay you or give you other compensation for the injury. You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

Costs
There will be no costs to you for participating in this study, other than costs related to loss of work. You will not be charged for any of the research activities. Transportation can be arranged if needed.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

If you withdraw, you will be compensated for any study visits they have completed. You will be asked to provide a reason for withdrawal, but this will be at your discretion.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will get your protected health information (PHI) from health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA). Because the health care entities are covered by HIPAA, we must have your authorization to get your PHI from them. However, once we get your PHI from the health care entities, it changes from PHI to individually

identifiable information (IIHI) and is no longer covered by HIPAA. We will put your IIHI in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

No Provision of Treatment
There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or disclosed for the research study includes:

- Medical information about you including your medical history and present/past medications.

Purposes for Which Your IIHI Will be Used/Disclosed:

- To conduct this research study
- To ensure compliance with state and federal regulations and provide oversight of the study
- To determine your health, vital status or contact information should you be unreachable during the study

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests, including subpoenas or court orders, that require us to disclose your IIHI.

Authorization to Use IIHI is Required to Participate:
By signing this form, you give us permission to use and disclose your IIHI for this research study.

People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff
- The funder of the research, its agents, study monitors and contractors including laboratories if applicable
- Institutional Review Boards (people who provide ethical review of research)
- Other Emory offices and persons who watch over the safety, effectiveness and conduct of the research
- Other researchers and centers that are a part of this study
- Government agencies that regulate the research as applicable to this study (e.g. regulatory agencies within and outside the United States such as the Office for Human Research Protections)
- Emory may use and disclose your IIHI to run normal business operations.
- The Principal Investigator and research staff will disclose your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.

In certain cases where a researcher moves to a different institution, your IIHI may be disclosed to that new institution and their oversight offices. The IIHI will be disclosed in a secure manner and under a legal agreement signed by both institutions to ensure it continues to be used under the terms of this consent and authorization.

Expiration of Your Authorization
Your HIPAA authorization will expire once no more PHI is needed from your medical records for this study.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at bhc.motion.lab@emory.edu.

At that point, we will stop collecting your IIHI. We may use or disclose the IIHI already collected so we can follow the law, protect your safety, make sure that the study was done properly and the data is correct. If you revoke your authorization, you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to the research records for this study because the study does not include treatment that is billed to insurers or government benefit programs. Your information collected for this study may be disclosed to others without your permission. The researchers, funders, and people and companies working on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact Dr. J. Lucas McKay at 404-712-7105.

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at **https://tinyurl.com/ycewgkke.** 

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 140 people who are being studied, at Emory and other sites.

Why is this study being done?
This study is being done for this purpose: to develop a new way to measure freezing of gait in people living with Parkinson's disease. You are being asked to be in this research study because you are a companion to a person with Parkinson's disease.

Do you have to be in the study?
It is your choice to join this research study. You do not have to be in it. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?
If you qualify and choose to join the study, you will participate in a single study visit (3-4 hours) as a companion to a person with Parkinson's disease participating in the study.

The researchers will ask you to do the following during the laboratory study visit:
You will be asked to provide demographic information about yourself and to assist your companion with Parkinson's disease in answering questions.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. This study is not intended to benefit you directly.

What are the risks or discomforts you should know about before deciding?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- loss of privacy
- breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to participate.

Costs
There will be no costs to you for participating in this study, other than costs related to loss of work. You will not be charged for any of the research activities. Transportation can be arranged if needed.

There is more information in the "Costs" section further below.

What Should You Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Take time to think about this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: Freezing of Gait – Clinical Outcomes Assessment: Companion Cohort

IRB #: STUDY00007856

Principal Investigator: J. Lucas McKay, Ph.D., M.S.C.R.

Funding Source: This study is supported by the Michael J. Fox Foundation for Parkinson's Research.

Introduction
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:
- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

What is the purpose of this study?
The purpose of the study is to develop a new way to measure freezing of gait in people living with Parkinson's disease. You have been invited to be in this research study because you are a companion to a person with Parkinson's disease.

What will you be asked to do?
- If you qualify and choose to join the study, you will participate in a single study visit (3-4 hours) as a companion to a person with Parkinson's disease participating in the study.
- We will first record a few demographic characteristics, specifically age, sex, relationship to the patient and the duration of your relationship with the patient.
- Next, you will be asked to complete the companion version of the Patient Reported Outcome (PRO) questionnaire. This questionnaire was newly developed to determine the severity and impact of Freezing of Gait on the quality of life of the patient you are supporting.
- Overall, this session will take max. 30 minutes.

Who owns your study data and samples?
If you join this study, you will be donating data. You will not be paid if your data are used to make a new product. If you leave the study, the data that were already collected may still be used for this study.

What are the possible risks and discomforts?
Rare but possible risks include:
Breach of privacy/confidentiality. Although every attempt is made to keep subject information private, there is a chance of a breach of confidentiality. We will store the study data and images in a protected location to which only the

researchers have access, and store the data without personal identifiers. We consider the risk of breach of privacy/confidentiality very, very small; probably less than 1 out of 10,000 participants will experience this.

Will you benefit from the study?

There is no direct benefit from being in this study.

Will you be paid for your time and effort?

You will get a $25 electronic gift card for completing the questionnaires.

What are your other options?

Since this is not a treatment study, the alternative is not to participate.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

Information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, Emory, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your information.

Costs

There will be no costs to you for participating in this study, other than costs related to loss of work. You will not be charged for any of the research activities. Transportation can be arranged if needed.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

If you withdraw, you will be compensated for any study visits they have completed. You will be asked to provide a reason for withdrawal, but this will be at your discretion.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

People Who will Use/Disclose Your Information:

The following people and groups will use and disclose your information in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your information to conduct the study.
- Emory may use and disclose your information to run normal business operations.
- The Principal Investigator and research staff will share your information with other people and groups to help conduct the study or to provide oversight for the study.
- Michael J Fox Foundation for Parkinson's Research is the Sponsor of the study. The funder may use and disclose your information to make sure the research is done correctly and to collect and analyze the results of the research. The funder may disclose your information to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your information to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including: Office for Human Research Protections
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your information may be shared with that new institution and their oversight offices. Information will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact Dr. J. Lucas McKay at 404-712-7105.

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**