RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

A novel tele-neurorehabilitation program aimed at reducing fall risk in Parkinson's Disease patients

Site Principal Investigator: Mitra Afshari, MD, MPH
Address and Contact Information: 1725 W. Harrison Street, Suite 755
Chicago, IL 60612
(312) 563-2900

Sponsor(s): Department of Neurological Sciences– Section of Movement Disorders
Supported by: Departmental and the Consolidated Anti-Aging Foundation

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to gain a better understanding of whether videoconferencing-based home physical therapy (PT) and occupational therapy (OT) (i.e. "tele-neurorehabilitation") may be achievable and effective in improving how you walk and balance difficulty, and strength and physical endurance to reduce falls in people with Parkinson's disease (PD). Current availability of trained physical and occupational therapists with expertise in PD falls short of the need out in the community, so this study aims to demonstrate whether this type of therapy can be delivered directly into the patient's home using a tablet or smartphone.

If you agree to participate in this study, your participation may last up to 24 weeks. If you are participating in Arm 1 of the study, you will be asked to complete 2 in-person study visits, 4 at-home virtual visits, and 2 follow-up phone calls. If you are participating in Arm 2 of the study, you will be asked to complete 3 virtual home safety evaluations (HSEs) and 2 follow-up phone calls. The study doctor will determine which study arm you will be in.

During these visits, for Arm 1, you will be asked to complete questionnaires and follow the physical and occupational therapy regimens created for you. For Arm 2, you will be asked to have 3 virtual home safety evaluations with an occupation therapist. For a detailed list of study procedures, please see the "*What are the activities you will be doing if you participate in this study?*" section of this consent form.

There are risks to you for participating in this study. In this study, there is a risk of exercise-related physical injury. For a detailed list of risks you should know about, please see the "*What are the risks and discomforts of participating in this study?*" section of this consent form.

You may benefit from taking part in this study. By participating in this study, you will receive the Parkinson's Disease-specialized therapy and home safety evaluations that may otherwise not be available in your community. You may have improvement of how you walk, balance, mobility, postural stability, strength, and physical endurance, which all may reduce your risk for falls. However, because individuals respond differently to therapy, no one can know in advance if it will be helpful for you. We also hope that knowledge gained from this study may benefit others with PD in the future and improve the novel practice of "tele-neurorehabilitation."

You have the option to not participate in this study.

You will need to have a reliable caregiver to participate in this study with you. You or your caregiver will also need a tablet or smartphone (any brand) with Wi-Fi connectivity. If you do not own a tablet, you will be allowed to borrow one from the department that must be returned at the final in-person visit (Arm 1 only).

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?

You are being asked to participate in this study because you have a diagnosis of Parkinson'sDisease (PD) and your neurologist determined that you might benefit from physical therapy (PT) and/or occupational therapy (OT) to help prevent falls.

How many participants will take part in this study?

Approximately 40 total participants for Arm 1 and 30 total participants for Arm 2, for a total of 70 participants, are expected to take part in this study at Rush University Medical Center. This includes 20 participants and their caregivers (20) for Arm 1 and 15 participants and their caregivers (15) for Arm 2.

What are the activities you will be doing if you participate in this study?
This study will have two arms:

ARM 1: In the **TELEREHABILITATION ARM,** your participation will include one initial *in-person* PT/OT evaluation, four virtual PT/OT visits, and one final in-person or virtual PT/OT visit. You will also receive two follow-up phone calls. The mobile virtual platform for Arm 1 is comprised of a tablet on a height-adjustable rotating tablet floor stand with a gooseneck and wheels.

ARM 2: In the **VIRTUAL HOME SAFETY EVALUTIONS (HSE)-ONLY ARM,** you will receive ONLY the virtual HSEs and monitoring by an occupational therapist. There will be three virtual HSE visits with two follow-up phone calls. The mobile virtual platform for Arm 2 is comprised of your own tablet OR smartphone that will be guided through the home by your care partner only.

The study doctor will determine which study arm you will be in.

If you agree to be in this study, you and your caregiver will be asked to participate in the following activities:

For Arm 1, you will be greeted by the study doctor or coordinator at your regularly scheduled clinic visit with your primary Movement Disorders Neurologist to start the screening process. He/she will review the protocol, this consent form, and talk to you and your caregiver about how the in-person and virtual at-home visits will be performed, where they will be performed, and by whom. If they determine you and your caregiver are eligible for the study after talking to you and your Neurologist, you may enroll in the study after signing this form. If you wish to continue thinking about it and review these forms at home, the coordinator will follow-up with you and your caregiver over the phone.

For Arm 2, you may be contacted over the phone by the study coordinator after review of your chart from your most recent visit (video or in-person) by your regular neurologist to see if you are able to take part in the study.

For both arms, during the call, if you wish to enroll, the coordinator or study doctor will obtain formal consent by phone. You will send the consent forms signed by both you and your caregiver back to the study doctor/study coordinator. The study team will provide you with a self-addressed/pre-stamped envelope so you can easily return the consent forms to our office.

In-person study visits will be held at the Johnston R. Bowman Health Center 7th floor therapy gym at 710 S. Paulina Street, Chicago, IL 60612 or the 4th floor gym at the Outpatient Physical and Occupational Therapy Clinic at 1725 West Harrison Street, Suite 440, Chicago, Illinois 60612. Some study-related activities may occur at the Movement Disorders clinic at 1725 W. Harrison Street, Suite 755, Chicago, IL 60612. The virtual visits will originate at the two gyms, or if the therapists are forced to work remotely from their homes due to mandates caused by the 2020 coronavirus outbreak, they may conduct the virtual visits from their own homes. You and the person under your care will always be at your own home during the virtual visits.

Please see below the specific study visits of each study arm.

ARM 1: The Telerehabilitation Arm

This arm includes a total of 6 visits with physical and occupational therapists that are trained in treating walking and balance issues, and managing daily at-home tasks and home safety in PD. The 6 visits include:

- One initial in-person physical and occupational evaluation (180 minutes long)
- Four virtual at-home visits (each 60-90 minutes long) every 2 weeks via MyChart videoconferencing
- One final in-person (or virtual if necessary) physical and occupational evaluation (180 minutes long)

There will also be 2 follow-up phone calls: one phone call at 2 weeks and the other phone call at 14 weeks after the final in-person visit.

Baseline Visit (Visit 1)

Before any study-related tests and procedures can be done, you will be asked to read and sign this consent form. After you (and your caregiver) sign the consent forms, you will be asked to come to the study site for a Baseline Visit to determine if you meet the requirements to take part in this study. You will be asked to come to this visit in the "OFF"-medication state, but bring your PD medications to the appointment so you may continue the remainder of the evaluation and therapy in the "ON"-medication state. You will also be asked to bring your personal tablet (any brand). This visit will take about 3 hours to complete. The following procedures will be performed:

- You will be asked questions to see if you will be able to take part in this study.
- Information about your demographics (i.e., race, age, gender, etc.) will be collected.
- A member of the study staff will ask you several questions related to your complete medical history, including your history of PD, as well as what medications you are taking or have taken for your PD.
- You will be asked if you are currently experiencing any side effects.
- You will complete some questionnaires and interviews to assess how you walk, balance, and history of falls associated with your PD. The questionnaires will take about 1 hour to complete.
    - Some questionnaires may have been sent to you and your caregiver electronically. These will need to be completed before the Baseline Visit.
    - A Falls Diary will be given to you to record your falls. This will be sent electronically and needs to be completed within a week of your tele-visit.
- You will have a full assessment by an occupational therapist.
    - You will be asked to perform several tasks and activities so the therapist can properly evaluate you, your needs, and your goals.
- You will have a full assessment by a physical therapist.
    - You will be asked to perform several tasks and activities so the therapist can properly evaluate you, your needs, and your goals.
    - The therapist will help you create a Home Exercise Program (HEP) that you are encouraged to continue on your own at home with or without the supervision of your care partner. A HEP is an individualized set of activities which includes

walking, balance, muscle strengthening, and physical endurance activities appropriate to your abilities and available equipment/facilities. The HEP can be adjusted according to your progress at the end of each visit.

- If chosen, you will be asked to wear a sensor during the evaluations that detect your movements.
- The study coordinator will help you and your care partner download the telecommunications software, the MyChart app (powered by Epic), onto your tablet and will make sure it works and show you how to use it for your virtual at-home visits.
    - You will also be given a rotating floor stand for your tablet to use at home during the virtual visits. This floor stand will need to be returned at the final in-person visit (Visit 6).
- You and your caregiver will be given a gait belt to be used during the virtual at-home therapy visits. You should wear the gait belt at all tele-visits for your safety.
    - A gait belt is an assistance safety device that can be used to help a patient sit, stand or walk around, as well as to transfer them from a bed to a wheelchair and vice versa. The gait belt is worn around the patient's waist, then held by the caregiver to steady the patient as they move around together. When used properly, a gait belt reduces the chance that a patient might accidentally fall.
    - Your caregiver will be trained on how to use the gait belt in the case you have a near fall or fall. The gait belt will need to be returned at the final in-person visit (Visit 6).

Prior to starting the at-home visits, the study physical and occupational therapists and study research coordinator will make a brief video visit to your home to view the location where your therapy will take place and make adjustments accordingly. This will allow the therapist to familiarize themselves with their working environment and is an additional safety measure to ensure your safety. If your home does not have an adequate space for therapy to take place, then the therapists may choose to exclude you from participating.

Virtual At-home Visits (Visits 2, 3, 4, and 5)

After the Baseline Visit, you will have your 4 scheduled virtual at-home visits every 2 weeks. Tele-OT visits will be done before the tele-PT visits but will occur within the same virtual at-home visit. These visits will last between 60-90 minutes. The following procedures will be performed:

- You will be asked if you are currently experiencing any side effects.
- You will be asked about what medications you are taking or have taken for your PD.
- You will be asked about any falls or near falls since the last visit.
    - You will be asked to provide your Falls Diary **(Visits 3 and 5 only)**.
- A virtual home safety assessment will be done by the therapists so they can educate you on areas where modifications could be made to reduce fall risk **(Visits 2, 4, and 5 only)**.
- You will have your OT assessment/session based on your specific goals that were set with your therapist.
- You will report to your physical therapist on how your HEP is going.
    - The study coordinator will also call you weekly to see how you are doing with your HEP.

- You will have your PT assessment/session based on your specific goals that were set with your therapist.
- You will be asked to complete a Telehealth Satisfaction Survey (TSS) at the end of the visit **(Visits 3 and 5 only)**

Final In-Person/Virtual Visit (Visit 6)

Two weeks after Visit 5, you will be asked to come to the study site for the Final In-Person Visit (see NOTE below). This visit will take about 3 hours to complete. The following procedures will be performed:

- You will be asked if you are currently experiencing any side effects.
- You will be asked about what medications you are taking or have taken for your PD.
- You will complete some questionnaires and interviews to assess how you walk, balance, and history of falls associated with your PD. The questionnaires will take about 1 hour to complete.
    - Some questionnaires may have been sent to you and your caregiver electronically. These will need to be completed before the Final In-Person Visit.
    - A Falls Diary will be given to you to record your falls. This will be sent electronically and needs to be completed within a week of your last tele-visit.
- You will have a full assessment by an occupational therapist.
    - You will be asked to perform several tasks and activities so the therapist can properly evaluate you, your needs, and your goals.
- You will have a full assessment by a physical therapist.
    - You will be asked to perform several tasks and activities so the therapist can properly evaluate you, your needs, and your goals.
- You will report to your physical therapist on how your HEP is going.
    - The study coordinator will also call you weekly to see how you are doing with your HEP.
- If chosen, you will be asked to wear a sensor during the evaluations that detect your movements.

NOTE: It may be necessary to convert the final in-person visit (Visit 6) into a virtual visit as institutional mandates may not allow for in-person research visits. If this is the case, the study activities of the final visit will be the same as Visit 5 with the addition of the final set of questionnaires.

Follow-Up Phone Calls

You will be contacted 2 weeks after Visit 6 for Phone Call 1 and 12 weeks after that for Phone Call 2. Each phone call will last up to 1 hour.

- You will be asked how you are doing and if you are currently experiencing any side effects.
- You will be asked about what medications you are taking or have taken for your PD.
- You will complete some questionnaires and interviews to assess how you walk, balance, and history of falls associated with your PD. These questionnaires will take about 15 minutes to complete.
- You will be asked about any falls or near falls since the last visit.
    - You will be asked to provide your Falls Diary.

- You will report to your physical therapist on how your HEP is going.
    - The study coordinator will also call you weekly to see how you are doing with your HEP.
- Your OT and PT therapists will evaluate your progress and determine how well your therapy goals were met.
- You will be asked to complete a Telehealth Satisfaction Survey (TSS) at the end of the visit **(Phone Call 1 only)**.

After Phone Call 2, your participation in this study will be complete.

ARM 2: The Virtual Home Safety Evaluations (HSE)-Only Arm

This arm includes a total of 3 visits lasting 6 weeks with an occupational therapist that is trained in treating walking and balance issues, and managing daily at-home tasks and home safety in PD. The 3 visits include:

- Three virtual at-home visits (each 30 minutes long) every 2 weeks via MyChart videoconferencing
- You will be encouraged to perform the tasks necessary to meet the recommendations set out by the occupational therapist, however, the time you spend doing such is up to your own discretion.

There will also be 2 follow-up phone calls: one phone call at 4 weeks and the other phone call at 12 weeks after the final HSE visit.

Screening Visit

Before any study-related tests and procedures can be done, you will be contacted by a study coordinator to see if you would like to participate in the study. If you agree, your verbal consent will be obtained and you will be asked to read and sign this consent form. After you (and your caregiver) sign the consent forms, you will be asked to complete some questionnaires related to the study. This call will take about 1 hour to complete. The following procedures will be performed:

- You will be asked questions to see if you will be able to take part in this study.
- Information about your demographics (i.e., race, age, gender, etc.) will be collected.
- A member of the study staff will ask you several questions related to your complete medical history, including your history of PD, as well as what medications you are taking or have taken for your PD.
- You will be asked if you are currently experiencing any side effects.
- You will complete a questionnaire to assess how you walk, balance, and history of falls associated with your PD. These questionnaires will take about 15 minutes to complete.
    - The questionnaire will be sent to you and your caregiver electronically. This will need to be completed before the first virtual visit.
    - A Falls Diary will be given to you to record your falls. This will be sent electronically and needs to be completed within a week of your tele-visit.
- The study coordinator will help you and your care partner download the telecommunications software, the MyChart app (powered by Epic), onto the tablet or smartphone and will make sure it works and show you how to use it for your virtual at-home visits.

Virtual At-home Visits (Visits 1, 2, and 3)

After the Screening Visit, you will have your 3 scheduled virtual at-home visits. The study team will tell you when you will have your first virtual visit. Visit 2 will take place 4 weeks after Visit 1 and Visit 3 will take place 2 weeks after Visit 2. These visits will last about 30 minutes. The following procedures will be performed:

- You will be asked if you are currently experiencing any side effects.
- You will be asked about what medications you are taking or have taken for your PD.
- You will complete a questionnaire to assess how you walk, balance, and history of falls associated with your PD. These questionnaires will take about 15 minutes to complete.
- You will be asked about any falls or near falls since the last visit.
    - You will be asked to complete your Falls Diary every 2 weeks.
- A virtual home safety assessment will be done by the occupational therapist so they can educate you on areas where modifications could be made to reduce fall risk.
- The study coordinator will also call you weekly to see how you are doing with your HEP.
- You will be asked to complete a Telehealth Satisfaction Survey (TSS) at the end of the visit **(Visit 3 only)**.

Follow-Up Phone Calls

You will be contacted 4 weeks after Visit 3 for Phone Call 1 and 12 weeks after that for Phone Call 2. Each phone call will last up to 1 hour.

- You will be asked how you are doing and if you are currently experiencing any side effects.
- You will be asked about what medications you are taking or have taken for your PD.
- You will complete a questionnaire to assess how you walk, balance, and history of falls associated with your PD. These questionnaires will take about 15 minutes to complete.
- You will be asked about any falls or near falls since the last visit.
    - You will be asked to provide your Falls Diary.
- The study coordinator will also call you weekly to see how you are doing with your HEP.

After Phone Call 2, your participation in this study will be complete.

Will your information be used for research in the future?

Information collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information are shared. Since identifying information will be removed, you will not be asked for additional consent.

Will you be contacted about participating in future research?

If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What are the risks and discomforts of participating in this study?

If you are participating in Arm 1, you will be at home during the tele-PT and tele-OT visits and performing the aforementioned therapy as guided by the physical and occupational therapists, so the main risk of participating in this study is exercise-related physical injury both in the in-person and tele-PT/OT sessions. The potential side effects or risks associated with the tele-PT/OT visits include:

Likely

- Fatigue and mild soreness from exercising

Less Likely

- Falls
- Aggravation of previous pain
- Pain from possible injury or strain to a muscle or joint during exercise

Rare but serious

- Exercise-induced heart attack
- Respiratory distress or failure
- Fracture from a fall
- Head trauma from a fall

We are trying to minimize the above risks by having the first visit be in-person to truly assess your fall risk and capabilities as they come into play for the tele-PT/OT visits. We will be asking you to assess your perceived level of exertion during some exercises in your home to gauge how hard your body is working, and we will slow the session down or have you take a break if it seems like your body is working too hard. We will also be asking your caregiver to supervise you during the sessions and even provide some verbal guidance if needed.

If you are participating in Arm 2, your caregiver will be assigned the duty of guiding the mobile platform (tablet or smart phone by hand) through the home for the virtual HSEs study visits in order to minimize your fall risk, however, you may during this process also experience physical injury. Should your caregiver experience injury, however, you are at risk of the stress or discomfort that may be associated with that.

Questionnaires

Questions asked for the purpose of this study may make you feel uneasy and uncomfortable. You do not have to answer any questions you do not wish to, and you may stop at any time. You may refuse to answer any questions that make you feel uncomfortable or upset.

Loss of Confidentiality

There is a risk that information about you may become known to people outside this study. However, the telecommunication software Epic Canto and MyChart app is securely-encrypted and has been previously used without any reported security breaches.

There may be other risks that may happen that we cannot predict.

What if there is new information that may affect your decision to participate in this study?
During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps.

The researchers also have the right to stop your participation in this study without your consent if:

- Your home environment is deemed unsafe for therapy despite modifications;
- You experience one fall during any study visit that leads to serious injury;
- You have more than one fall during a tele-visit;
- You have more than 4 falls per month while you are in the study. This includes falls during study visits and outside of study visits;
- You have a serious exercise-induced cardiac or pulmonary event during or within 24 hours from any of the study visits;
- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?
This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Mitra Afshari, her study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Mitra Afshari and her study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes:

- All information in a medical record
- Certain health information relating to your Parkinson's disease

Dr. Mitra Afshari and her study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and

review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- To the Researchers;
- Monitoring agencies such as the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Mitra Afshari is not required to release to your study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed above.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Mitra Afshari at 1725 W. Harrison Street, Suite 755, Chicago, IL 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

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.

If you disclose actual or suspected abuse, neglect, or exploitation of a child, or disabled or

elderly adult, the researcher or any member of the study staff must, and will, report this to Child Protective Services (such as the Department of Family and Human Services), Adult Protective Services, and/or the nearest law enforcement agency.

What are the costs to participate in this study?

All physical and occupational therapy sessions will be covered by the study. However, you will need to provide your own personal tablet or smartphone to use during the study. If you do not own a tablet or smartphone and you are in Arm 1, you will be allowed to borrow one from the department that must be returned at the final in-person visit. If you are in Arm 2 and do not own a tablet or smartphone, you will not be able to participate in the study.

Will you be paid for your participation in this study?

You will not be paid for being in this study. However, you and your caregiver will be provided with a light meal on the days that you come for in-clinic study visits (if necessary). A parking voucher to help cover the cost of parking at the medical center for the in-clinic visits will also be provided. Only one parking voucher will be provided to cover you and your caregiver's parking costs.

What if you are injured as a result of your participation in this study?

If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Mitra Afshari at telephone number (312) 563-2900. This number is available 24 hours a day.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. The study staff will assist you in obtaining pre-authorization from your insurance company. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

What other information should you know about?

Investigator Dual-Role

If your doctor is also the person responsible for this study, please note that she is interested in both your clinical care and the conduct of this study. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Dr. Mitra Afshari at (312) 563-2900.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Mitra Afshari in writing at the address on the first page. Dr. Mitra Afshari may still use your information that was collected prior to your written notice.

Subject consented into: ☐ **Arm 1** ☐ **Arm 2**

SIGNATURE BY THE PARTICIPANT:
By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form. You will be given a signed copy of this consent.

Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE BY WITNESS:
I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant and the person signing the form has done so voluntarily.

Name of Witness

Signature of Witness	Date of Signature

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature