NewGait: A Low-Cost Rehabilitation System to Improve Post-Stroke Gait (Biomechanical Adaptations)

NCT06269367

Date of IRB Approval: 11/21/2024

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: NewGait: A Low-Cost Rehabilitation System to Improve Post-Stroke Gait (Biomechanical Adaptations)

Company or agency sponsoring the study: The study is by the department of health and human services, National Institute of Health. University of Michigan researchers have partnered with Elite Athlete Products in this small business technology transfer (STTR) phase 1 grant and have received a subcontract from them.

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Principal Investigator: Chandramouli Krishnan P.T. Ph.D., Department of Physical Medicine and Rehabilitation, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include muscle fatigue. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by providing further scientific insight. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be about 2-3 hours each visit for up to 4 visits.

You can decide not to be in this study.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: Post-stroke gait recovery is a significant rehabilitation challenge. Several gait therapies (e.g., treadmill training, split-belt training, robotic training) have been established; however, recovery after these interventions is modest at best, and results vary from significant to minimal improvement. Therefore, there is a critical need for rigorous science-based approaches to effectively address post-stroke gait deficits. This study will test the biomechanical effects and clinical utility and useability of NewGait system and compare it with other similar devices.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Individuals who have had a stroke can participate in this study. The inclusion/exclusion criteria of this study are:

Inclusion Criteria

1. Aged between 40 to 75 years
2. Unilateral cortical or subcortical stroke
3. Chronic stroke (≥ 6 months) At least 6 months following their stroke
4. Able to walk independently with/without assistive devices for 5-10 mins (~150m)
5. No significant cognitive deficits as determined by the Mini Mental State Examination (MMSE) score (score ≥ 22)

Exclusion Criteria

You will not be eligible for the study if any of the following criteria apply:

1. Cerebellar stroke
2. Traumatic brain injury
3. History of unstable heart condition, uncontrolled diabetes or hypertension
4. History of a recent lower-extremity trauma or fracture
5. History of significant orthopedic or neurological conditions that could limit walking ability (e.g., multiple sclerosis, total knee replacement)
6. History of significant spatial neglect
7. Joint contractures or significant spasticity in your lower limbs
8. History of a recent Botulinum Toxin (Botox) injection to the lower-extremity muscles (≤ 3 months)
9. Pregnant or actively planning to become pregnant (self-reported)
10. Inability to communicate or unable to consent

3.2 How many people are expected to take part in this study?
30 subjects are expected to participate in this study. All subjects will be tested at the University of Michigan.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
Prior to acceptance into the study you will be asked to give your informed consent. There are two parts in this study: (1) Participating in the screening/orientation session and (2) participating in the laboratory experimental sessions. You are being consented for the following:

1. Consent to participate in laboratory experimental sessions
2. Consent to be contacted for future/other ongoing studies (optional)
3. Consent to being photographed or videotaped (optional)

As a subject in this study, you will be asked to undergo:

Part 1) Screening/Orientation session

The screening/orientation visit is performed to further ensure that you are eligible for the study, to provide you an orientation to the study procedures, and to obtain information on your clinical characteristics (e.g., age, height, weight, stroke duration, etc.).

- During the screening/orientation session, we will first orient you to the study procedures.
- We will ask questions that relate to your eligibility.
- We may also measure your muscle strength of various joints by having you perform maximal contractions.
- We may have you walk on a treadmill to test your ability to walk and to perform a biomechanical evaluation.
- We may also measure your movement ability using standardized test procedures.
- These tests include 10 meter walk test, 6-minute walk test. During these tests you may be asked to walk a set distance at your comfortable walking speed. We may review your medical records information to ensure eligibility.

It is possible that based on the results of the screening/orientation visit you will not be eligible to continue with the research. If eligible, we can perform the laboratory experiments on the same day as the screening depending on your availability and wishes.

Part 2) Laboratory Experiment Sessions

You may be required to visit the laboratory up to 4 times for testing depending on your availability. We may do multiple experimental conditions on the same day or different days, depending on your ability and availability. Each visit is expected to last about 2-3 hours. During these sessions you may be tested on the following procedures:

<u>Overground Walking:</u>

- We will then place sensors on your legs that can measure how you walk and your muscle activation patterns.
- We may also place some markers that can track your movement patterns during walking using a camera/motion capture system.
- You will then walk overground for a few times at your comfortable and fast walking speeds to measure your walking ability.
- This procedure could take approximately 15 minutes. It will be repeated 3 times.

Treadmill Walking:

- You will then be asked to walk on a treadmill. If needed, a harness may be placed firmly around your waist. The harness is attached to a cable and pulley system that is capable of supporting your entire body weight while you are in a standing position. There is a handrail on the treadmill that you can use to steady yourself if needed.
- Use of the harness and handrails will ensure you are comfortable and secure at all times. You will then walk over the treadmill for a few minutes after which, you will put one of the assistive devices on.
- The experiment will require you to walk on the treadmill. We will be recording the movements of your body and legs and the device using a computer program. You will walk on the treadmill several times with some rest in between trials.
- We may also measure muscle activation and may have you perform maximal contractions to standardize your muscle activation.
- At some points, you will wear the device that will be tested on that day, and at other points, we will remove the device to see how your walking changes. We may also remove the device and have you wear other devices included in this study to compare the devices.
- You may receive feedback of your performance during walking. This feedback may include variables like muscle activation, joint angles, or the force you exert on the ground, and may be provided in such a way that it improves your engagement during the experiment.
- Your level of exertion (i.e., effort exerted during walking) will be recorded by asking you questions orally during testing.
- This procedure could take approximately an hour.
- Following treadmill walking, you will then repeat the overground walking.
- At the end of the session (multiple sessions may happen on the same day or different days), we may administer a survey discussing how it felt to walk with the device. We may also conduct a brief interview to understand and receive feedback about your experience with the devices. We may also audio-record this discussion to document your input.
- After completing each testing session, we may schedule you for your next visit. All visits, besides when you come in for screening and consenting, will be relatively the same. The order in which we use the assistive device (NewGait, TripleFlex, TheraTogs, TheraSuit, or other similar devices) during each session will be randomized. Completion of a maximum of up to 4 visits will end your participation in this study. However, your data will be stored for further analysis and future research purposes as data generated from this study may serve as normative data. Because technology is advancing, current data can be reanalyzed using sophisticated algorithms as and when new techniques emerge. However, we will take adequate measures to ensure that your privacy is protected (please see Section 9.0).

At the end of this consent form, you will be given the option of allowing us to take photographs and/or make audio or videotape recordings of you, which may be used in medical or scientific publications and presentations. We may publish and present photographs, audio recordings, and videos of you, which may include your face, depending on your decision. No other personal information about you will be included in the presentation. Consenting for taking photographs or video is optional and you have the option to indicate your choice by signing your name at the end of the consent form. You will also be asked whether or not you want to be contacted for future studies that will happen in our lab or elsewhere. In case, you would like to be contacted please provide your consent by signing your name the appropriate location.

Your participation in this study will last for up to 4 visits, with each visit lasting about 2-3 hours. However, the number of sessions may increase if the data collection was not complete due to any unforeseeable circumstances (e.g., the experiment must be stopped due to a fire alarm, tornado warning, or equipment malfunction).

4.3 When will my participation in the study be over?
Completion of the required study visits will end your participation in this study. However, your data will be stored for further analysis and future research purposes as data generated from this study may serve as normative data. Because technology is advancing, current data can be reanalyzed using sophisticated algorithms as and when new techniques emerge. However, we will take adequate measures to ensure that your privacy is protected (please see Section 9.0).

4.4 What will happen with my information and/or biospecimens used in this study?
With appropriate permissions, your biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies. Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The researchers have taken steps to try to minimize these risks, typically noted along with each bullet point. Please ask the researchers if you have any questions.

Surface EMG Related:

- *Allergic Reaction (infrequent):* Subjects may experience allergic reactions from the application of electrode paste and adhesive tapes necessary for surface EMG recordings. We will use hypoallergenic tapes to minimize allergic reactions. If redness or excessive itching occurs, the area will be monitored closely by study staff and testing will be ended at their discretion or in accordance with the subject's wishes.

Walking Related:

- *Spasms (Infrequent):* If subjects suffer from spasticity, the initial movement while walking with resistance may trigger muscle spasms. This will gradually settle down with time. The resistance will be adjusted if this occurs to ease the spasms.

- *Skin irritation (Infrequent):* Subjects may experience some skin irritation from the cuffs due to bracing attached to the limbs. If subjects experience irritation, adequate padding (coban or foam pads) will be provided between their skin and the cuffs to reduce the amount of irritation.

- *Tripping/Fall (Infrequent):* Subjects may trip if walking with resistance/assistance, especially if the subject has weak muscles. To minimize risk, subjects will be able to hold handrails, which increases stability while walking. We will also provide them with an option of wearing a body weight-supporting harness to improve the feeling of safety during some activities. However, in our experience, many people do not prefer wearing a harness, as the harness may produce some amount of discomfort while walking (a feeling of tight compression). Subjects may also experience tripping or falling during functional evaluation. However, these risks are no more than what they would encounter in their day-to-day activities. For safety purposes, the subject will always be under the close supervision of a researcher while undergoing functional evaluation.

- *Muscle or joint pain (Infrequent):* During or following the experiment, subjects may feel temporary or persistent muscle aching or joint pain, or general fatigue. Any discomfort may be improved by adjusting the resistance, providing appropriate rest breaks at any time during the experiment, or using an over-the-counter pain reliever.

- *Risk of fatigue (Likely):* There is a risk that subjects can become fatigued from walking with resistance for prolonged periods of time. Subjects will be allowed to rest and can also choose to end the test at their own will at any time. As with any research study, there may be additional risks that are unknown or unexpected. As described above, these risks will be minimized by allowing subjects to rest as needed and withdraw from the study voluntarily at any time. A research assistant will stand near subjects during the tests and will actively observe the subject for any distress. All devices will be built to eliminate risks of irritation or severe discomfort.

- *Muscle Fatigue or Soreness (Infrequent):* During measurement of muscle strength, subjects may experience temporary muscle fatigue and soreness. Although this soreness may persist for a period of several days following testing, this level of soreness is not greater than they would experience following a regular exercise session.

- Loss of privacy (Rare): A loss of privacy may occur from participating in this study. The seriousness of a breach of this information is minimal. All data and medical information collected from participants will be considered privileged and held in confidence; participants will be assigned confidential codes and no identifying personal data will be stored with study data. RedCap™ (Research Data Capture) system may be utilized for the storage of patient

demographic information, clinical assessment scores, and all processed data via encrypted university computers. The raw/unprocessed data will be coded with a unique patient identifier and stored offline on a password-protected laboratory computer.

- Unforeseeable Risks (Rare): As with any research study, there may be additional risks that are unknown or unexpected.

Additionally, there may be a risk of loss of confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Participation in this study is voluntary. The alternative is to not participate.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the

study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No, You can decide to leave the session at any point without any consequences to you.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher’s telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan’s medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
You will receive $50 for testing for each session in which you participate. You will receive the payment upon the completion of study participation.

8.3 Who could profit or financially benefit from the study results?

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

- In any publications that result from this research report, neither your name, nor any information from which you may be identified will be published without your consent.
- Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you.
- Personal identifiers will be removed from the data before we share any of this information with anyone else.
- Only the research investigators of this study will have access to the list that connects identifying information with your information. This will be kept in a locked cabinet in the PI's office or lab.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

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

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. 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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.

- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Chandramouli Krishnan, PT, PhD
Mailing Address: 325 E Eisenhower Parkway, Room 3013 (3rd Floor), Ann Arbor, MI - 48108
Telephone (Cell): 319.321.0117

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
- Other (specify):_____

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent to video/audio recording/photography solely for purposes of this research

This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you [CAN STILL/CANNOT] take part in the study.

_____ Yes, I agree to be video/audio recorded/photographed.

_____ No, I do not agree to be video/audio recorded/photographed.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent to be contacted for future/other ongoing studies

I understand that I may be eligible for other ongoing or future studies in the lab. I would like to be contacted for any other ongoing or future studies.

_____ Yes, I agree to be contacted for future research.

_____ No, I do not agree to be contacted for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____