Title: A Novel Strategy to Decrease Fall Incidence Post-Stroke

NCT: 02688777

Date: 10/20/20

Department of Veterans Affairs | VA RESEARCH CONSENT FORM

**Subject Name:** _____ **Date** _____

**Title of Study:** A Novel Strategy to Decrease Fall Incidence Post-Stroke

**Principal Investigator:** Dorian Rose, PhD, PT **VAMC:** North Florida/South Georgia Veterans Health System

UF Institutional Review Board
UNIVERSITY of FLORIDA

# *INFORMED CONSENT FORM*
***to Participate in Research***

## INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

## GENERAL INFORMATION ABOUT THIS STUDY

**1. Name of Participant ("Study Subject")**

_____

For PI Use:

Participant Social Security Number: _____

SSN should be written on this consent form by the research team prior to scanning into the VHA health record; if the subject does not have a VHA health record, this requirement is N/A.

**2. What is the Title of this research study?**

A Novel Strategy to Decrease Fall Incidence Post-Stroke

**3. Who can you call if you have questionsconcerns, or complaints about this research study?**

Principal Investigator: Dorian Rose, PhD, PT

Office: 352-376-1611; Ext. 105238 Cell: 352-275-1147

Other research staff:

Gainesville Site (Malcom Randall VAMC): Dorian Rose 352-376-1611; Ext. 105238; Jacksonville Site (Brooks Clinical Research Center): Kayla Blunt: 904-345-8969.

**4. Who is paying for this research study?**

The sponsor of this study is VA Rehabilitation Research and Development Service

**5. In general, what do you need to know about this Research Study?**

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board **(IRB) office at (352) 273-9600** or the North Florida/South Georgia Veteran's Health System Research Service Office at (352) 548-6069.

**a) In general, what is the purpose of the research, how long will you be involved?**

The purpose of this study is to determine the effectiveness of training backward walking on the prevention of falling, determine the timing of backward walking training in its ability to increase backward walking speed and determine the relationship between backwards walking speed and fall occurrence. You are being asked to be in this research study because you have had a stroke, meet the preliminary enrollment criteria, and have challenges in your walking and balance ability.

**b) What is involved with your participation, and what are the procedures to be followed in the research?** If you are deemed eligible for the study following the screening exam we will then complete a thorough evaluation, conducted by a physical therapist, to find out your comfortable forward walking speed, backward walking speed, the movement ability of your legs and to assess your balance. This evaluation will take place five times during your participation in this study

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regardless if you are in the Immediate Backwards Walking Group or the Delayed Backwards Walking Group. Each testing session will last approximately three hours. Once you have completed the first assessment session, you will be randomized (much like the flip of a coin) to either 1) an Immediate Backward Walking training group or a 2) Delayed Backward Walking Training group. If you are assigned to the Immediate Backward Walking training group you will begin the training within one week of your baseline assessment. If you are assigned to the Delayed Backward Walking Training group, you will begin training at the one-year mark of the onset of your stroke. You will be asked to attend 18-21 therapy sessions at the clinic. The training sessions will each last about an hour and a half.

**c) What are the likely risks or discomforts to you?**

The risks undertaken in the walking therapy programs of the study are no greater than those in everyday physical therapy clinics where persons who have had a stroke are challenged daily to exercise, train, practice and improve beyond their current abilities. This study involves exercise, which can be stressful to the body.

There is a risk of falling during walking activities, but guarding by research personnel will minimize the risk. If you were to fall during the walking activities you would immediately be assessed by research personnel to determine if injury occurred and would be provided medical attention as needed as described in Question #16 below.

This study may include risks that are unknown at this time.

**d) What are the likely benefits to you or to others from the research?** The possible benefits are that you may see improvements in how well you walk and/or in how fast, how long, or how often that you walk. Your balance may improve, you may fall less and you may become more confident in your balance and walking ability.

**e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?**

Your other choice is to decline participation in this study.

If you do not want to take part in this study, tell the Principal Investigator or her assistant and do not sign this Informed Consent Form.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

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## WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

**6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?**

Normal clinical care is medical or other treatment or services that you would receive even if you did not participate in this research study.

Participation in this study is not part of your normal clinical care.

**7. What will be done only because you are in this research study?**

If you are deemed eligible for the study following the screening exam we will then complete a thorough evaluation, conducted by a physical therapist, to find out your comfortable forward walking speed, backward walking speed, the movement ability of your legs and to assess your balance. We will use electromyography (EMG) to assess the activity of your leg muscles while you walk forwards and backwards. EMG involves placing small sensors on your legs to record the muscle activity as you walk. We will also place small reflective markers on your legs to record your movements as you walk. We will also have you walk across a mat that will record the pressure and timing of your feet as you walk. We will ask you some questions on how confident you are that you can perform various activities without losing your balance or falling. This evaluation will take place five times during your participation in this study regardless if you are in the Immediate Backwards Walking Group or the Delayed Backwards Walking Group: 1) an initial baseline assessment, 2) Six weeks following your baseline assessment, 3) Six-months following the onset of your stroke, 4) One-year following the onset of your stroke and 5) Six weeks after your one-year assessment. Each testing session will last approximately three hours. All tests will take place at the clinic. You should wear comfortable clothes for the tests and tennis shoes or lightweight shoes. Some of these tests will be familiar to you as they are routine tests used by therapists in rehabilitation clinics and with persons post-stroke. The walking and balance assessments may be videotaped. We will take periodic breaks during the testing to allow you to rest. If you should become tired at any point during the testing, we can take another break or schedule to complete the test on another day. We ask that you keep a record of any falls that you experience from the date you enter the study through your final evaluation. We will give you a supply of calendars and postcards. If you should fall, we ask that you note the date on the calendar and send us a postcard. We will then call you to follow-up on the fall

Subject Name: _____ Date _____

Title of Studv: A Novel Strategy to Decrease Fall Incidence Post-Stroke

Principal Investigator: Dorian Rose, PhD, PT VAMC: North Florida/South Georgia Veterans Health System

and learn more from you about what happened. Once you have completed the first assessment session, you will be randomized (much like the flip of a coin) to either 1) an Immediate Backward Walking training group or a 2) Delayed Backward Walking Training group. If you are assigned to the Immediate Backward Walking training group you will begin the training within oneweek of your baseline assessment. If you are assigned to the Delayed Backward Walking Training group, you will begin training at the one-year mark of the onset of your stroke. While on the treadmill, you will wear a vest like a parachute harness, which is then attached to a device to help you support your weight and keep you safe. The support device also makes sure that you cannot fall to the ground. The therapist working with you will help you take steps on the treadmill, trying to help your walking be smooth and coordinated.

You will also be asked to walk overground when you get off the treadmill. Your walking therapy may include walking indoors or outdoors, choosing an assistive device, examining for the need for leg braces, and suggesting ways to use the skills that you are learning on the treadmill at home and in your community.

You will be asked to attend 18-21 therapy sessions at the clinic. The training sessions will each last about an hour and a half. Times of your therapy will be coordinated with your trainer, who will be a licensed physical therapist. The therapist will monitor your heart rate and blood pressure during your training and will stop the therapy session should your heart rate or blood pressure exceed safe and acceptable limits. You will be asked to wear a heart rate monitor during the training. You may ask for as many rest breaks as you need during the treadmill program.

Should you be unable to keep an appointment, we ask that you notify your physical therapist. The therapist will reschedule your appointment for another day that week or add a session on to the end of the 6 week period. We ask that you complete 18-21 therapy sessions and all of the tests.

If you are in the Immediate Group we will keep in touch with you after your final exercise session by phone, letter, or email to schedule your additional assessment sessions over the next year and to inquire if you have had any falls.

If you are in the Delayed Group we will keep in touch with you after your initial assessment by phone, letter, or email to schedule your additional assessment sessions over the next year until you begin your exercise training and to inquire if you have had any falls.

Regardless of which Group you are in, it is important that you notify us if you are changing addresses or phone numbers so we can stay in touch.

Please note that a therapist who is not involved in the exercise intervention program is conducting all of the tests. It is very important that you do not tell the therapist or reveal to the therapist in any way what your group assignment is for the study.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

We would like to videotape some of your rehabilitation intervention sessions so we can examine more closely how we can best assist you to walk on the treadmill and to provide feedback to our therapists regarding how they are assisting you. We would also like to videotape some of your assessments so we can more closely examine your performance and so we can provide feedback to the therapists regarding their completion of the assessments. The final page of this form contains a Consent to be Videotaped. Your decision to be or not be videotaped will not affect your participation in this study. If you decline to be videotaped you can still participate in this study. If you agree to be videotaped you will have the option to choose to be videotaped just for research purposes, for research and educational purposes or for research, education and presentation purposes. If you are videotaped, videorecordings will be stored in a locked cabinet within a locked office only accessible to study personnel. Videorecordings will be retained in accordance with VA records retention policy.

We will also review some parts of your medical record to obtain information about your stroke and your general health.

The Principal Investigator listed in question 3 of this form and the research team conducting the research procedures described above will monitor how you do during the research. If you have any questions about the research procedures now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

**8. How long will you be in this research study?**

Your participation should last a total of up to 14 months, but the window for you to complete all assessments can be extended up to 24 months.. This includes five assessment sessions over this period and the 18-21 exercise sessions which will be scheduled for 3 times each week for 6 weeks.

**9. How many people are expected to take part in this research study?**

We anticipate up to 152 people taking part in the research study.

## WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

**10. What are the possible discomforts and risks from taking part in this research study?**

The risks undertaken in the walking therapy programs of the study are no greater than those in everyday physical therapy clinics where persons who have had a stroke are challenged daily to exercise, train, practice and improve beyond their current abilities. This study involves exercise, which can be stressful to the body. Exercise temporarily increases blood pressure and can temporarily increase the risk of heart attack or stroke.

You may experience some fatigue while you are being tested or during the therapy sessions. Should you become tired, you will be allowed to rest.

You may experience temporary muscle soreness as you increase the use of trunk and limbs during the walking intervention.

Safety in therapy is mandatory. Research personnel will walk beside you during all aspects of the exercise intervention and all aspects of the assessment that assess your gait.

There is a risk of falling during walking activities, but guarding by research personnel will minimize the risk. If you were to fall during the walking activities you would immediately be assessed by research personnel to determine if injury occurred and would be provided medical attention as needed as described in Question #16 below.

Subject Name: _____ Date _____

Title of Study: A Novel Strategy to Decrease Fall Incidence Post-Stroke

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Stroke patients, including those in this study, are at risk for another stroke, coronary heart disease related event and cardiac related death, regardless of intervention.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this consent form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of any new information that may become available and might affect your decision to remain in this study. This includes, but is not limited to, information that may affect your safety, well-being or medical care.

If you wish to discuss the risks or discomforts described above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 of this form.

**11a. What are the potential benefits to you for taking part in this research study?**

The possible benefits are that you may see improvements in how well you walk and/or in how fast, how long, or how often that you walk. Your balance may improve, you may fall less and you may become more confident in your balance and walking ability.

**11b. How could others possibly benefit from this study?**

The things that we learn in this study may help us improve the rehabilitation of other patients with stroke.

**11c. How could the researchers benefit from this study?**

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3may benefit if the results of this study are presented at scientific meetings or in scientific journals.

**12. What other choices do you have if you do not want to be in this study?**

Your other choice is to decline participation in this study. If you do not want to take part in this study, tell the Principal Investigator or her assistant and do not sign this Informed Consent Form.

**13a. Can you withdraw from this study?**

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

**13b. If you withdraw, can information about you still be used and/or collected?**

If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study.

**13c. Can the Principal Investigator withdraw you from this study?**

You may be withdrawn from the study without your consent for the following reasons:

- The Principal Investigator decides that continuing in the study would be harmful to you or the study procedures have a bad effect on you.
- A change in your health and physical functioning making it difficult for you to comply with the protocol.
- Funding for the study stops or another similar administrative reason
- You do not follow the instructions given to you by the investigator

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## WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

**14. If you choose to take part in this research study, will it cost you anything?**

There will be no costs to you for any procedure, treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not being done only for this study (e.g., normal hospital and prescription expenses which are not part of the research study) will be charged to you or your insurance. These costs may not be charged if you are a veteran and you are being treated at the North Florida/South Georgia Veterans Health System (NF/SG VHS), however some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study."

**15. Will you be paid for taking part in this study?**

You will be paid $25 for each assessment and exercise session. Payment will occur halfway through study participation and then once you have completed participation in the study. It may take up to three weeks to receive payment once the appropriate forms have been submitted.

Your compensation for participation in this research study will come from the VA Finance Office, who will issue payment to you by direct deposit to your bank account. If it is not possible for you to receive payment by direct deposit, payment will be issued to you on a pre-paid debit card. If a pre-paid debit card is issued, you will be required to maintain this card throughout the study as all study payments will be deposited to the card. The study team will provide you with additional information regarding electronic funds transfers. You may be responsible for paying income taxes on any payments provided by the study. Any payment made to you on a VA-funded study, regardless of amount, has to be reported to the Internal Revenue Service (IRS) because the payment system cannot distinguish payment from reimbursement for expenses. If you have any outstanding debts to the government (such as back taxes, child support arrears, or defaulted school loans), the government can garnish this payment to offset your outstanding debt.

## 16. What if you are injured because of the study?

If you experience an injury or illness as a result of your participation in this VA approved research study, all medical treatment considered necessary by your physician (emergency as well as medical treatment beyond emergency) will be provided by the VA. There will be no cost to you, unless you fail to follow the directions of the study procedures. Care will be provided at a VA medical facility unless the VA medical facility is not capable of providing the care. If this occurs, you will be treated by a private facility or physician and the VA will pay the private facility or physician for the reasonable cost of your care. In some cases the VA may approve private care for a non-veteran.

If you do not follow study procedures, you may be treated by the VA on the basis of your veteran's eligibility. If you are not a veteran and have not followed study procedures the VA can only provide limited care at your expense.

No additional money has been set aside for pain, suffering or any money losses you may suffer during your treatment. You have not waived any legal rights by signing this form.

In the event of a research-related injury, have questions about any discomforts that you experience while participating in this study or if you experience an adverse reaction, please immediately contact the Principal Investigator listed in question 3 of this form during the day and 352-275-1147 after business hours. If you seek emergency hospitalization in a private hospital because you are unable to come to the VA, have a family or friend contact your study doctor so that the VA can coordinate care with the private hospital.

## 17. How will your privacy and the confidentiality of your research records be protected?

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Certain federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), or the VA Office of the Inspector General

**Subject Name:** _____ **Date** _____

**Title of Studv:** A Novel Strategy to Decrease Fall Incidence Post-Stroke

**Principal Investigator:** Dorian Rose, PhD, PT **VAMC:** North Florida/South Georgia Veterans Health System

(OIG), that oversee human subject research may also have the legal right to review your records. Otherwise your research records will not be released without your permission unless required by law or a court order.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

Department of Veterans Affairs

**VA RESEARCH CONSENT FORM**

**Subject Name:** _____ **Date** _____

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## SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how privacy will be protected:

_____ _____

Signature of Person Obtaining Consent Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your privacy will be protected. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Person Consenting Date

Department of Veterans Affairs

**VA RESEARCH CONSENT FORM**

**Subject Name:** _____ **Date** _____

**Title of Studv:** A Novel Strategy to Decrease Fall Incidence Post-Stroke

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## Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

_____ photographed _____ video recorded _____ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, _____, or [his/her] successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under [his/her] direction to students, researchers, doctors, or other professionals and persons. Please indicate under what conditions Dr. _____ has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

The following will be retained in accordance with VA records retention policy (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

As described in the Informed Consent Form, and for the purposes of **education at the Malcom Randall VAMC or the University of Florida Health Science Center.** The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

As described in the Informed Consent Form; for the purposes of **education at the Malcom Randall VAMC, the University of Florida Health Science Center or for presentations at scientific meetings outside the Malcom Randall VAMC or University.** The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

_____ _____

Signature Date