Version Date: 03.11.2022	R&D Stamp: VA R&D	COMIRB Approval Stamp/Date:

Subject Name: _____ **Date:** _____

Title of Study: Dual-tasking for Individuals with Lower Limb Amputation: Exploring the Relationship to Falls and Instrumental Activities of Daily Living

Principal Investigator: Laura Swink, PhD, OTR/L **VAMC**: 554

VA Investigator: Laura Swink, PhD, OTR/L **COMIRB#** 21-3425

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about the relationship of dual-tasking (doing two activities at the same time) and the risk of falling for Veterans who have had a lower limb amputation.

You are being asked to be in this research study because you have had a lower limb amputation and experienced a recent fall or near-fall.

Other people in this study

Up to 60 people from your area will participate in the study.

Up to 60 people around the country will be in the study.

What happens if I join this study?

If you join the study, you will be asked to complete questionnaires, physical function assessments, and a walking assessment that includes doing another activity such as counting backwards while you walk. When completing the questionnaires, you are free to not answer any question that you prefer not to answer. This study visit will take approximately 1 hour and 45 minutes to complete.

This research study is expected to take approximately 1 year. Your individual participation in the project will take 1 day.

What are the possible discomforts or risks?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

There is a risk of wounds or skin breakdown on your residual limb or on your intact foot. To minimize this risk, you will be asked about your limb status during the physical assessments.

There is also a risk of falling. The study team will work with the clinic prosthetists and physical therapists to minimize fall risk.

There is a risk that people outside of the research team will see your research information. We will do all we can to protect your information, but it cannot be guaranteed.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the relationship of dual-tasking (doing two activities at the same time) and the risk of falling for Veterans who have had a lower limb amputation.

This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Who is paying for this study?

This research is being sponsored for by the Veterans Administration Career Development grant.

Will I be paid for being in the study?

You will be paid $50.00 for the visit in this study. The total amount possible to be paid to you is $50.00 if you complete the visit. If you leave the study early or if we have to take you out of the study, you will be paid only for the visit you have completed.

It is important to know that payments from participation in a study are taxable income.

Your SSN will be collected and used to report this taxable income to the IRS.

Will I have to pay for anything?

There will be no cost to you for participation in this study. 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 medical care and services provided by the VA that are not part of this study. If you decide to participate in this study, you cannot be charged nor your insurance billed, for research-related interventions or procedures that are required by the protocol.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled. If you withdraw from the study,

for data already collected prior to withdrawal the investigator may continue to review the data already collected for the study but cannot collect further information.

What happens if I am injured or hurt during the study?

Every reasonable safety measure will be used to protect your well-being. The VA Eastern Colorado Health Care System (ECHCS) will provide necessary medical care and treatment for any injury that is a result of participation in this study for veterans, in accordance with applicable federal regulations (38 CFR 17.85). Compensation for such an injury may be permitted by applicable federal laws and/or regulations. The VA is not required to provide treatment for injuries in research studies if the injuries are caused by your non-compliance with study procedures.

You should inform your care provider(s) if you decide to participate in this research study. If you have questions about an injury related to the research, call Dr. Laura Swink at 315.373.9168.

Who do I call if I have questions?

The researcher carrying out this study at the VA is Dr. Laura Swink. You may ask any questions you have now. If you have any questions, concerns, or complaints later you may call Dr. Swink at 315.373.9168. You will be given a copy of this form to keep.

If you have questions regarding your rights as a research subject, concerns or complaints about this research study, please call the Colorado Multiple Institutional Review Board (COMIRB) office at 303.724.1055. This is the Board that is responsible for overseeing the safety of human participants in this study. If you want to verify that this study is approved or if you would like to obtain information or offer input, please contact the VA Research Office at 720.857.5092

How will my private information be protected?

Taking part in this study will involve collecting private information about you. We will keep all research records that contain your identifiable health information confidential to the extent allowed by law. Records about you will be kept in a locked filing cabinet in a locked room and on password protected computer accessible only by authorized study team members.

Identifiers might be removed from the identifiable private information or data that are collected. After that removal, the information 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.

Access to health records
While this study is being conducted, you will have access to your research related health records.

Health Information Portability and Accountability Act (HIPAA)

Who will see my research information?

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include:

- Federal agencies such as the Food and Drug Administration (FDA), the General Accountability Office (GAO), the Office of the Inspector General, Office for Human Research Protections (OHRP), and the VA Office of Research Oversight (ORO) that protect research subjects like you, may also copy portions of records about you.
- People at the Colorado Multiple Institution Review Board
- The investigator and research team for this study
- The sponsor, the Veterans Administration (group paying for the study), study monitors or agents for the sponsor
- Officials at the institution where the research is being conducted, and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- Our local VA Research and Development Committee
- UCDenver and its Clinical Trials Management System
- UCDenver CCTSI REDCap

I understand that by signing this consent form, a copy of limited data about me, restricted to ***all*** research data that is collected as part of this specific VA research study will be stored in the REDCap database (or Data Storage System) at the University of Colorado Denver's (UCD's) Colorado Clinical and Translational Sciences Institute (CCTSI). This data will be used solely for the purposes defined in this consent form and for this specific study. Data collected about me for this study placed on the CCTSI REDCap Database will not be accessed or used for any other study or purposes and will only be accessed by VA-credentialed personnel. The CCTSI REDCap Database is a highly secure, nationally-utilized data management system, and it is housed within the highly-secure environment at the University of Colorado Denver.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Swink and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment, or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

Agreement to be in this study

I have read this form or it has been read to me. A member of the research team has explained the study to me. I have been told about the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this form below, I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I will receive a copy of this consent after I sign it. A copy of this consent form will be placed in my medical record.

Subject's Signature: _____ Date: _____

Print name: _____

Consent form explained by: _____ Date: _____

Print name: _____.

Print name: _____

Witness of Signature ☐

Witness of consent process ☐