Participant Name:	Date:
Title of Study: Locomotor Response of Persons With Upper Limb Loss to Treadmill Perturbations	
Principal Investigator: Matthew Major, PhD	

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to choose whether or not to volunteer for a research study being funded by the Department of Veterans Affairs about recovery strategies used in response to trips. This initial information is to give you key information to help you decide whether to participate. We have included detailed information after this information. Ask the research team questions. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn about response strategies when recovering from a simulated trip. Your participation in this research will last about 2-3 hours.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There are no direct benefits to you for participating, however, the information gathered may improve the quality of life for persons with upper limb loss or difference. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There is a risk of falling during the experiment and a risk of loss of confidentiality. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Matthew Major, PhD of the Jesse Brown VAMC. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is (312)-503-5731.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to learn more about how individuals with upper limb loss or congenital limb difference maintain balance and we hope to inform possible therapeutic interventions to reduce the possibility of a fall. The mechanisms that underlie balance following a trip are not yet been fully understood. This study will collect information on strategies used to recover from a simulated trip by persons with upper limb loss or congenital limb difference and those without limb loss/difference to identify factors that may be responsible for balance and can be addressed through rehabilitation interventions.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 20 people will participate in this research study at Jesse Brown VAMC.

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HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 2 years. Your individual participation in the project will take 1 visit that will last between 2-3 hours.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you decide to take part in this study you will be asked to come to the study site, the Jesse Brown VAMC Motion Analysis Research Laboratory at 680 N Lake Shore Drive, Suite 1100, Chicago IL 60611 for one visit. Dr. Major or his staff will be present during the visit.

For participants with upper limb loss or difference:

During the visit, you will be asked about your current prosthesis type and use, side and cause of your limb loss or congenital limb difference, fall history, activity level, and assistive device use. We will take measurements of your height, weight, and length of your residual limb. You will also be asked to fill out the following surveys and are free to skip any questions that you prefer not to answer:

1. Socket Comfort Score (SCS) – The SCS is a simple rating of comfort on a scale of 0 to 10 where 0 is the most uncomfortable socket fit imaginable and 10 is the most comfortable socket fit.
2. Activities-Specific Balance Confidence Scale (ABC) – Collects information on perceived balance confidence when performing activities of daily living.
3. Functional Comorbidity Index (FCI) – Collects information on the presence of secondary comorbid conditions that may affect physical functioning.

For participants without upper limb loss or difference:

During your visit, you will be asked about fall history, activity level, and assistive device use. We will also take measurements of your height and weight. You will be asked to fill out the following surveys and are free to skip any questions that you prefer not to answer:

1. Activities-Specific Balance Confidence Scale (ABC) – Collects information on perceived balance confidence when performing activities of daily living.
2. Function Comorbidity Index (FCI) – Collects information on the presence of secondary comorbid conditions that may affect physical functioning.

For all participants:

Following collection of background information, we will measure the muscle strength of your legs using a handheld dynamometer and asking you to push against our hands. Then, we will apply small reflective markers to certain anatomical locations on your legs, pelvis, arms, and chest using hypoallergenic tape. Additionally, small sensors will be taped on your legs and arms to record your muscle activity.

You will then walk on a treadmill at two specific speeds for 5 minutes while wearing an overhead safety harness. You will then be given a seated break for 5 minutes. Following the break, you will again walk on the treadmill. The treadmill will suddenly stutter at

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some point while walking. Please react however you need to keep your balance after the stutter and continue walking until the treadmill comes to a stop. Please avoid using the handrail to keep your balance. There will be multiple walking trials during which a stutter will occur. You may rest at any time and for however long you need between trials. After completing the walking trials, you will complete a series of trials where the treadmill will start from a standing position and again please react however you need to keep your balance after the stutter and continue walking until the treadmill comes to a stop.

If you agree to participate in this study, photographs and video recordings will be made of you during your visit. These pictures and recordings are a part of the data record. You will be given the option of allowing us to use these photographs or video recordings in medical and scientific presentations and publications, however, no other personal information about you would be included in these presentations and publications.

Please indicate your willingness to allow the use of these photographs and/or video recordings to be used for educational purposes and to be disclosed in medical and scientific presentations and publications.

Yes ☐ No☐

You may ask questions at any time during the study visit. You may change your mind about staying in the study at any time during the study.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The likely risks and discomforts expected in this study are no more than you would experience when walking in the community, which includes the risk of falling. However, the treadmill stutter is meant to disturb your walking and not produce a fall. You will wear a safety harness while walking on the treadmill to protect against a fall.

There is the risk of potential loss of confidentiality. Information that identifies you will be used in this study and shared with the study sponsor and research staff. However, the research team will make every effort to protect your private health information and guard against any loss of privacy.

The surveys may contain questions that seem personal or embarrassing. The questions may upset you. You may refuse to answer any of these questions. If the questions make you very upset, we will help you to find a counselor.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize photographs and video recordings to be made of you by the research team while you are participating in this study.

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WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There may be no direct benefits to you from your taking part in this research study. However, the information we get from this study might ultimately improve quality of life for prosthesis users.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected by locking all paper documents in a filing cabinet that is located in a locked VA laboratory. Access to paper documents and electronic research data will be limited to Dr. Matthew Major and his designated study team and will be stored on a secure VA computer. Data will be stored with a code, without your name or identifiers. For security, the data and the master list linking your name and the code will be stored separately.

Identifiers might be removed from the identifiable private information 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.

We will make every effort to keep the information collected for this study confidential.

People who will know you are a research subject include members of the research team. Otherwise, no information about you, or provided by you during the research, will be disclosed to others without your written permission, except there are times when we might have to show your records to other people. For example,

- if necessary, to protect your rights or welfare (for example, if you are injured and need emergency care); or
- when the JBVAMC Institutional Review Board or the JBVAMC Research and Development Committee monitors the research or consent process; or
- when the Office for Human Research Protections (OHRP), the Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), or other governmental regulatory agencies monitor the research, or if required by law.

Health Information Portability and Accountability Act (HIPAA)

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI): 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. Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

The research team working on the study will collect information about you. Your individually identifiable health information is information about you that contains your health information and

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information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. 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 Your individually identifiable health information used for this VA study includes the information marked below:

☐ Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings

☐ Specific information concerning:

☐ alcohol abuse ☐ drug abuse ☐ sickle cell anemia

☐ HIV

☒ Demographic Information such as name, age, race

☐ Billing or Financial Records

☒ Photographs, Digital Images, Video, or Audio Recordings

☒ Questionnaire, Survey, and/or Subject Diary

☒ Other as described: limb loss characteristics (amputation level, cause) and age.

DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may have access to your information in the performance of their VA/VHA job duties

Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information. Your information will be disclosed to **Other Federal agencies required to monitor or oversee research (such as** Office of Human Research Protections (OHRP) and the Government Accountability (GAO).

Access to your Individually Identifiable Health Information created or obtained in the course of this research: While this study is being conducted, you will have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Revocation: You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Principal Investigator for this study at the following address: Matthew J. Major, PhD, 680 N Lake Shore Drive, Suite 1100, Chicago, IL, 60611.

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If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator. The research team will not collect information about you after you revoke the authorization.
If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.

Expiration: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will expire at the end of this research study

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WHAT WILL I BE PAID FOR MY PARTICIPATION IN THE STUDY?

You will be paid $75.00 for this study. Validated parking is available for the parking garage located at 321 E. Erie Street (1 block west of the Jesse Brown VAMC Motion Analysis Research Laboratory). You will be paid in cash at the completion of the study visit and payment will not be prorated.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

Every reasonable effort to prevent any possible injury from this study will be taken. In the event the study results in any physical, mental or emotional injuries to you, VA will provide necessary medical treatment (not just emergency care) at no cost to you. This does not apply to treatment for injuries that result from if you do not follow the study procedures.

Additional compensation, beyond paying for treatment, has not been set aside. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with Federal Tort Claims Act. For additional information concerning claims for damages, you may contact VA District Counsel at (708) 202-2216. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

If you believe that you may have suffered a research related injury (physical, mental or emotional injury or injury caused by loss of confidentiality or privacy), contact:

DURING THE DAY: Dr Matthew Major at (312) 503-5731 and

AFTER HOURS: Dr. Matthew Major at (847) 287-7678.

Emergency and ongoing medical treatment will be provided as needed.

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DO I HAVE TO TAKE PART IN THE STUDY?

It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

You can decide to leave the research study at any time and this can be done by informing Dr. Matthew Major of your desire to withdraw.

If you choose to withdraw from the study, the study team may continue to review the data already collected for the study but cannot collect further information, except from public records.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The researchers also have the right to stop your participation in this study without your consent if they believe it is in your best interest. A possible reason for removal is visible signs of illness during the study visit.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

You may contact Dr. Matthew Major at (312) 503-5731 or Rebecca Stine at (312) 503-5726 with any concerns or complaints as to this research study.

If you want to talk to someone who is not involved in this research about your rights as a JBVAMC patient you should contact the Patient Advocate Office at the Jesse Brown VA Medical Center at (312) 569-7959.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Jesse Brown VAMC Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Jesse Brown VAMC IRB at 312-569-6166 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

One of the research study personnel has explained the study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

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Principal Investigator: Matthew Major, PhD

I agree to participate in this research study as has been explained in this document.

_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date