Informed Consent Document

Project #NCT05410548

IRB Approval 3/28/2022

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Study: Can Comorbidity Screening and Referral by Prosthetists Enhance Post-Amputation Care?

Principal Investigator: J. Megan Sions, PhD, DPT

KEY INFORMATION

Important aspects of the study you should know about first:

- **Purpose:** The purpose of the study is to determine how clinical screening and referral by prosthetists for common health conditions affects results after lower limb loss.
- **Procedures**: If you choose to participate, you will be asked to complete a set of questionnaires and undergo a brief clinical evaluation with your prosthetist. You will be asked to re-complete these questionnaires 3 months later.
- **Duration:** The first evaluation will take about an hour and will occur at Independence Prosthetics-Orthotics, Inc. Three months later, the questionnaire packet will take about 30 minutes to complete at home.
- **Risks**: The main risk or discomfort from this research are falls during balance and mobility testing. But such testing is part of typical prosthetic care and therefore, participating in this study does not increase your risk. Some of the questionnaires may evoke feelings of sadness or stress, but you can skip any questions you would like to skip.
- **Benefits:** The main benefit to you from this research is that we may find things that, if addressed, may improve your treatment results.
- **Alternatives:** There are no known alternatives available to you other than not taking part in this study.
- **Costs and Compensation:** If you decide to participate there will be no additional cost to you and you could be compensated up to $60, provided as two $30 gift cards.
- **Participation:** Taking part or not in this research study is your decision. You can decide to participate and then change your mind at any point.

Please carefully read the entire document. You can ask any questions you may have before deciding If you want to participate.

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will be asked to do if you decide to take part, and the risks and benefits of being in the study. Please read the information below and ask us any questions you may have before you decide whether or not you want to participate.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the impact of medical screening and referral for certain health conditions, seen among people with lower limb loss. We will compare typical prosthetic care to prosthetic care plus medical screening. Medical screening is not usually part of standard prosthetic care. The impact of screening on prosthetic practice and patient results will be assessed.

The data collected in this study may be used as a part of Dr. Sions' PhD student's doctoral dissertation.

WHO IS BEING ASKED TO PARTICIPATE?

You will be one of approximately 70 participants in this study.

You are being asked to participate because…

- You can read and speak English, are between the ages of 18-85 years, and have an above-knee OR below-knee amputation of one leg. You do not have an amputation (greater than toe-level) on the other side.
- You have had a prosthesis for at least 1 year and are being seen as a patient at Independence Prosthetics-Orthotics, Inc.
- You are willing to have a clinician share findings from the examinations with your primary care provider.
- You will not be able to participate if you do not meet the above requirements.

PROCEDURES: WHAT WILL YOU BE ASKED TO DO?

As part of this study you will be asked to…….

- Complete a series of questionnaires (<30 minutes) covering your medical history, pain, mental health, physical health, function, and satisfaction with your care.
    - We will ask you to recomplete questionnaires at home 3 months later.
- Complete a one-time onsite evaluation with a prosthetist, which will take <30 minutes. This evaluation will occur at your prosthetist's office and may include assessment of your walking, balance, and mobility, as well as assessment of blood flow and sensation in your non-amputated side.
- All participants will receive a standard evaluation. Half of participants, selected at random (like a coin flip), will also receive additional testing.
- Your participation in this study will involve up to 1.5 hours in total. There will be up to a 1-hour evaluation session at the start of the study and a 30-minute follow-up completed 3-months later via computer.
- As is typical in practice, we will share some of the results of your evaluation, including how you performed on the walking, balance, and mobility tests, with you. Some results may be sent to your primary care provider following the evaluation or the follow-up evaluation.

WHAT ARE POSSIBLE RISKS AND DISCOMFORTS?

Possible risks of participating in this research study include ……

- You may experience sadness or stress, as some of the questionnaires ask about your mental health and your amputation. But, you may choose to skip any questions that you would prefer not to answer.
- You may lose your balance or become unsteady when undergoing testing of your walking, balance, and mobility, but your clinician will appropriately guard you during these tests to reduce your risk of experiencing a fall. Please note that this risk of falling would exist even if you choose not to participate in the study as such tests are common in prosthetic clinical practice.
- Other people who are in the clinic at the same time as you may see you participating in the study.

WHAT ARE POTENTIAL BENEFITS FROM THE STUDY?

- Participation in this study may result in your care team identifying concerning health conditions early, which allows you to receive early treatment and may improve your health long-term.
- Your participation in this study may ultimately improve care for persons following limb amputation.

NEW FINDINGS THAT COULD AFFECT YOUR PARTICIPATION

During the course of this study, we may learn new important information. This may include information that could cause you to change your mind about participating in the study. If any new important information becomes available while you are a participant, we will let you know.

CONFIDENTIALITY: WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

Your study data will be handled as confidentially as possible. If results of this study are published or presented, names and other personally identifiable information will not be used.

- To minimize the risks to confidentiality, we will de-identify all data collected during your evaluations, identifying you by a coded number.
- All paper records will be either with study personnel or securely locked away in files at Independence Prosthetics-Orthotics prior to transfer to the University of Delaware STAR Campus (540 S College Ave, Newark, DE). Locked paper files will be accessible only to research staff. Data from your paper records will be entered to a computerized database where you will be identified by your code number only. Your coded information will be indefinitely stored.
- There will be an electronic file linking your name and code number. This will be stored separately as a password-protected file on a server within the University of Delaware Department of Physical Therapy. This linking file will be destroyed 3 years after all participants are recruited.

- The findings of this research may be presented or published. If this happens, no information that gives your name or other identifiable details will be shared.
- Images of your limbs and/or prosthesis will only be taken with your consent. Photos and/or videotaping will be from the waist-down, with any identifiable markings or tattoos blurred. Researchers and professionals might view these images during presentations or in publications. Images will be stored indefinitely. Consent for images is not required for participation; this is optional. See below for more details.

We will keep your study data confidential and only those with permission in the research team will have access to information that identifies you. We may have to report certain information for legal or ethical reasons, such as child abuse, or intent to hurt yourself or others. If required, your records may be inspected by authorized personnel in the following groups and agencies: (1) the University of Delaware Institutional Review Board, which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans, and (2) any funding sources.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

USE OF DATA COLLECTED FROM YOU IN FUTURE RESEARCH:

- Your de-identified and coded information collected as part of the research may be provided to research journals. Data may be shared through research data sharing sites, but no identifiable information will be shared.
- Identifiers about you may be removed from the identifiable private information and after such 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.

HIPAA AUTHORIZATION

State and federal privacy laws protect your Protected Health Information (PHI). These laws say that, in most cases, your health care provider can release your PHI for the purpose of conducting research only if you give permission by signing an Authorization.

If you agree to participate in the research study, the research team will need to collect and use your PHI. To allow your health care provider to share your PHI with the research team, your approval is required. Signing this Authorization is completely voluntary. However, if you do not sign this Authorization, then you may not participate in the research study.

Who May Disclose and Who may Use and/or Receive my PHI?

By signing this document, you are hereby permitting your physicians and medical care providers to disclose the PHI described in this Authorization to the research team involved in this project.

Once your PHI is shared with these persons, you understand that the PHI may no longer be protected by federal or state privacy laws.

What PHI Will Be Disclosed and Used, and for What Purpose?

The following PHI may be disclosed to, collected by, used by, and shared with those listed above for the following purpose:

- To confirm your medical diagnoses, medications, amputation-specific and prosthetic-specific details.
- To understand the effect of your medical treatment.

Requested PHI may include:

- Surgical reports regarding amputation, revision surgery and other procedures, and follow-up care.
- Medical history/treatment.
- Prosthetic care records; prosthetic care service utilization.

This Authorization will expire at the conclusion of the research study. You may cancel this Authorization at any time before, during, or after your participation in this study by giving a written request with your signature on it to the Principal Investigator at megsions@udel.edu. If you cancel this Authorization, your PHI obtained before that date may still be used for this research study.

I hereby authorize the disclosure and use of my Protected Health Information.

_____ _____

Signature of Patient Date

_____ Relationship to person signing: self

Printed Name of Person Signing

COSTS AND COMPENSATION

- There are no financial costs associated with participating in this study.
- You may receive up to $60 in gift cards for participation in this study.

- You will receive $30 after completing the onsite evaluation.
- You will receive an additional $30 after completing the 3-month follow-up questionnaire packet.

WHAT IF YOU ARE INJURED DURING PARTICIPATION IN THE STUDY?

If you are injured during your participation in the study, you will be sent to the appropriate medical provider. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of a third-party payer (for example, your health insurance). By signing this document, you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide later not to participate, or if you decide to stop taking part in the research, there will be no penalty or loss of benefits to which you are otherwise entitled.

Your decision to stop participation, or not to participate, will not influence current or future relationships with the University of Delaware and/or Independence Prosthetics-Orthotics, Inc.

The principal investigator of the study may stop your participation in the study if at any time it is determined that your safety or that of a research team member's is at risk.

FINANCIAL INTERESTS OF THE RESEARCHERS

This research study is a joint collaboration between the University of Delaware and Independence Prosthetics-Orthotics, Inc. Independence provides financial support for some of the study staff, who are pursuing research training. This relationship has been disclosed to the University of Delaware and is being managed to avoid potential conflict of interest.

INSTITUTIONAL REVIEW BOARD

This research study has been reviewed and approved by the University of Delaware Institutional Review Board (UD IRB), which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. If you have any questions or concerns about your rights as a research participant, you may contact the UD IRB at hsrb-research@udel.edu or (302) 831-2137.

CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues related to this research study you may contact the Principal Investigator, Dr. Megan Sions at (302) 831-7231 or at megsions@udel.edu. Please contact Dr. Sions if you experience an injury as a result of participating in this study.

CONSENT TO PARTICIPATE IN THE RESEARCH STUDY:

I have read and understood the information in this form and I agree to participate in the study. I am 18 years of age or older. I have been given the opportunity to ask any questions I had and those questions have been answered to my satisfaction. I understand that I will be given a copy of this form for my records.

_____	_____	_____
Printed Name of Participant (PRINTED NAME)	Signature of Participant (SIGNATURE)	Date
_____	_____	_____
Person Obtaining Consent (PRINTED NAME)	Person Obtaining Consent (SIGNATURE)	Date

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OPTIONAL CONSENT TO BE CONTACTED FOR FUTURE STUDIES:

Do we have your permission to contact you regarding participation in future studies? If you agree to being contacted in the future, we will keep your contact information. Please **write your initials** next to your preferred choice.

_____ YES _____ NO

OPTIONAL CONSENT FOR USE OF DE-IDENTIFIED VIDEO RECORDINGS/PHOTOGRAPHS

I voluntarily give my permission to the researchers in this study to use videos and photographs of me, from the waist down, collected as part of this research study for publications, presentations, and/or educational purposes. I understand that no identifying information beyond that contained in the photograph or video recording will be provided to educational/scientific audiences. Identifying features, such as markings or tattoos, will be blurred.

_____	__ _____	_____
(Printed Name of Participant)	(Signature)	(Date)
