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Human Subjects Division
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UW

UNIVERSITY OF WASHINGTON

Human Subjects Division
Box 359470
APPLICATION: Human Subjects Review

BOX FOR COMMITTEE USE ONLY
MASTER ☐ COMM. ☐ INVESTIGATOR ☐
APPLICATION NO. 49150-EA

I. PRINCIPAL INVESTIGATOR (Provide all the information requested. Change of PI requires a modification. All paper-based correspondence will be directed to this person. Please list the mailing address for paper-based correspondence. You may designate a contact person other than yourself in section II., below.)

Name Brian Hafner Title PhD Position Associate Professor
Home Institution (or source of paycheck) **UW Student? Home institution is UW.** University of Washington
Home UW Department (if applicable) Rehab Medicine Division Prosthetics & Orthotics
UW Position or appointment (choose the most appropriate one):
Faculty: [X] Regular Faculty Appointment [ ] Research Faculty Appointment [ ] Clinical Faculty Appointment
[ ] Visiting Faculty Appointment [ ] Dual Appointment with PNNL
[ ] Other (describe):
Student: [ ] Matriculated Undergraduate Student [ ] Graduate or Professional Student (matriculated or approved "On Leave") [ ] WWAMI Student
[ ] Resident or Fellow at the UW or Local VA [ ] UW Administration or Staff [ ] None
Campus Box # 356490 Other Address if not at UW
Telephone 206-685-4048 Fax 206-685-3244 e-mail bhafner@uw.edu

II. IRB CONTACT PERSON (Provide all the information requested. Change of Contact Person requires a modification. If this section is completed, all paper-based correspondence will be directed to this person.)

Name Cody McDonald Title CPO Position Prosthetics & Orthotics
Home Institution (or source of paycheck) University of Washington
Home UW Department (if applicable) Rehab Medicine Division Prosthetics & Orthotics
UW Position or appointment (choose the most appropriate one):
Faculty: [ ] Regular Faculty Appointment [ ] Research Faculty Appointment [ ] Clinical Faculty Appointment
[ ] Visiting Faculty Appointment [ ] Dual Appointment with PNNL
[ ] Other (describe):
Student: [ ] Matriculated Undergraduate Student [X] Graduate or Professional Student (matriculated or approved "On Leave") [ ] WWAMI Student
[ ] Resident or Fellow at the UW or Local VA [ ] UW Administration or Staff [ ] None
Campus Box # 356490 Other Address if not at UW
Telephone 206-221-6347 Fax 206-685-3244 e-mail codym@uw.edu

III. TITLE OF PROJECT: Evaluation of a Modified Running Prosthesis

IV. SIGNATURES: The undersigned acknowledge that: 1. this application is an accurate and complete description of the proposed research; 2. the research will be conducted in compliance with the recommendations of and only after approval has been received from the Institutional Review Board (IRB). The lead researcher is responsible for all aspects of this research, including: reporting any serious adverse events or problems to the IRB, requesting prior IRB approval for modifications, and requesting continuing review and approval.

A. Investigator: Brian Hafner, PhD ~~1/30/2015~~
TYPED NAME PLUS SIGNATURE **DATE**

B. Faculty sponsor (for student): Change requires a modification.
TYPED NAME PLUS SIGNATURE **DATE**

C. The Chair, Dean, or Director acknowledges the researcher is qualified to do the research, sufficient resources will be available, and (if no external funding review occurred) there was an internal review of scientific merit.
Peter Esselman, MD 2/2/15
TYPED NAME PLUS SIGNATURE **DATE**

Geri C Jaries FEB 19 2015 APPROVE ☒ DISAPPROVE ☐

IRB COMMITTEE SIGNATURE DATE

Subject to the following restrictions: _____

Period of approval is one year, from FEB 19 2015 through FEB 18 2016

☐ Subject numbers are approved as described in this IRB Application unless otherwise indicated above in "Subject to the following conditions" or in an accompanying letter.

VALID ONLY AS LONG AS APPROVED PROCEDURES ARE FOLLOWED

V. TYPE OF NEW SUBMISSION

[ ] **IRBshare**

MINIMAL RISK

[X] (The research meets the **definition of minimal risk** and falls into one or more expedited review categories. **You are done with this table.)**

[ ] **FULL COMMITTEE**

[ ] Full Committee (The research involves **greater than minimal risk** and requires review at a convened meeting of the IRB)

[ ] Full Committee (The research involves **no more than minimal risk** but does not fit into one of the expedited review categories)

[ ] **METHODS:**

Please mark the boxes to indicate the methods which best describe your study:

[ ] **Social-Behavioral Procedures/Considerations**

[ ]	Observational	[ ]	Population-Based Field Study
[ ]	Behavioral Interventions	[ ]	Surveys/Questionnaires
[ ]	Interview/Focus Groups	[ ]	Other – Describe:

[ ] **Medical Procedures/Considerations**

[ ]	Bio-hazardous Substances	[ ]	Investigational/Approved Devices
[ ]	Controlled Substances	[ ]	Radiation Exposure
[ ]	Emergency Treatment	[ ]	Substance Abuse Treatment (with medication)
[ ]	Gene Transfer Study	[ ]	Surgical Procedures
[ ]	Stem Cell Research	[ ]	Genetic Testing
[ ]	Magnetic Resonance imaging (MRI)	[ ]	Complementary/Alternative Medicine
[ ]	Investigational/Approved Drugs and Biologics	[ ]	Other – Describe:

[ ] **DOES YOUR RESEARCH INVOLVE OR IS IT ASSOCIATED WITH ANY OF THE FOLLOWING:**

- [ ] Emergency Medicine
- [ ] Pregnant Women as a Target Population
- [ ] Genetics
- [ ] Stem Cells
- [ ] Neuroscience
- [ ] College of Arts and Sciences
- [ ] College of Education
- [ ] Dentistry
- [ ] Infectious Disease
- [ ] HIV/AIDS
- [ ] Psychiatry
- [ ] Rehabilitation Medicine
- [ ] Psycho-Social Drug Abuse Research
- [ ] Alaska Native/American Indian (ANAI)
- [ ] Public Health
- [ ] Global Health
- [ ] Health Services
- [ ] Quality of Care / Quality of Life
- [ ] Health Prevention / Health Education
- [ ] Nursing

VI. PRIMARY RESEARCH ROLES

Some research projects are conducted by a large team of individuals. Other projects can be performed by only one or two individuals. The IRB does not need to know the name of every member of your research team - instead, the IRB wants to know who is fulfilling

the following specific roles for your research. Note that the same individual may play multiple roles. If it is necessary to identify an individual by name, this will be specified below. Each section below must be completed.

1. Information for **individuals identified by name:**

The individuals below need to be identified by name. If these individuals change during the course of the research, a Modification approval from the IRB is needed before making the change.

Subject Contact Person (to answer questions, receive complaints or reports of side effects, etc.)

Check here if the same as: [ ] Lead Researcher [X] IRB Contact Person
If one of these boxes is checked, you do not need to complete the rest of this table.

Name _____ Title _____ Position _____

Home Institution (or source of paycheck)
UW Student? Home institution is UW. _____

Home UW Department (if applicable) _____ Division _____

UW Position or appointment (choose the most appropriate one):

Faculty: [ ] Regular Faculty Appointment [ ] Research Faculty Appointment [ ] Clinical Faculty Appointment
[ ] Visiting Faculty Appointment [ ] Dual Appointment with PNNL
[ ] Other (describe): _____

Student: [ ] Matriculated Undergraduate Student [ ] Graduate or Professional Student (matriculated or approved "On Leave") [ ] WWAMI Student

[ ] Resident or Fellow at the UW or Local VA [ ] UW Administration or Staff [ ] None

Campus Box # _____ Other Address if not at UW _____

Telephone _____ Fax _____ e-mail _____

Study Coordinator

Check here if the same as: [ ] Lead Researcher [X] IRB Contact Person [ ] Subject Contact Person
If one of these boxes is checked, you do not need to complete the rest of this table.

Name _____ Title _____ Position _____

Home Institution (or source of paycheck)
UW Student? Home institution is UW. _____

Home UW Department (if applicable) _____ Division _____

UW Position or appointment (choose the most appropriate one):

Faculty: [ ] Regular Faculty Appointment [ ] Research Faculty Appointment [ ] Clinical Faculty Appointment
[ ] Visiting Faculty Appointment [ ] Dual Appointment with PNNL
[ ] Other (describe): _____

Student: [ ] Matriculated Undergraduate Student [ ] Graduate or Professional Student (matriculated or approved "On Leave") [ ] WWAMI Student

[ ] Resident or Fellow at the UW or Local VA [ ] UW Administration or Staff [ ] None

Campus Box # _____ Other Address if not at UW _____

Telephone _____ Fax _____ e-mail _____

2. Information for **research staff who will perform procedures that involve risk to subjects:**

The individuals below do not need to be identified by name, rather, by qualifications. As long as the qualifications of the individuals and the procedures performed remain the same, a modification is not needed.

If an individual is **not** an agent of the UW, indicate his/her institution or organization. Should an individual not be associated with an institution or organization, state so. For all non-UW individuals, it will be necessary for this individual to receive IRB review. There are a number of mechanisms by which this may occur.

- If the non-UW individual is associated with Pacific Northwest National Laboratories, Puget Sound Blood Center, King County-Seattle Public Health, or Northwest Kidney Center: the UW has an institutional **Authorization Agreement** with these institutions by which it provides the IRB review (as long as any funding is administered through the UW).
- If the non-UW individual is associated with the Fred Hutchinson Cancer Research Center, Group Health, Seattle children's, Swedish Medical Center, or Benaroya Research Institute at Virginia Mason: the terms of the UW's **Cooperative IRB Agreement** with these institutions may or may not allow the UW IRB to do the review. The individual should contact their institution's IRB for guidance.

- If the non-UW individual is associated with an institution or organization in which the UW **does not** have a Cooperative IRB Agreement, it will be necessary for the non-UW individual to provide their own IRB review. If the non-UW individual's institution or organization does not have their own IRB or does not use an IRB for review of their research and the non-UW individual's institution or organization has a Federalwide Assurance (FWA), the non-UW individual's institution or organization may enter into an **IRB Authorization Agreement** with the UW. This means that the UW will provide IRB review for the non-UW individual. The non-UW Individual's institution or organization may also wish to enter into an IRB Authorization Agreement even if they have their own IRB to prevent duplication of effort. However, entering into an IRB Authorization Agreement with a non-UW individual's institution or organization is at the discretion of the HSD.
- If the non-UW individual is not associated with an institution or organization or if the non-UW individual is associated with an institution or organization that does not have a FWA and does not routinely conduct research, an **Individual Investigator Agreement** may be entered into with the UW. The Individual Investigator Agreement extends the applicability of the UW's FWA to cover the non-UW individual, institution or organization. However, entering into an Individual Investigator Agreement with a non-UW individual, institution or organization is at the discretion of the HSD.

Please see SOP Authorization Agreements for information on how to obtain an Agreement for your research.

Study Procedures that involve risk to subjects

[ ] Phlebotomy (blood draw)

Who will perform this procedure?

[ ] Licensed Practitioner

Describe the qualifications for the Licensed Practitioner below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Study Nurse

Describe the qualifications for the Study Nurse below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Other:

Describe the qualifications for the Other Professional below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] MRI Scan

Who will perform this procedure?

[ ] Licensed Practitioner

Describe the qualifications for the Licensed Practitioner below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Study Nurse

Describe the qualifications for the Study Nurse below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Other:

Describe the qualifications for the Other Professional below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Surgical or Physically Invasive Procedure

Who will perform this procedure?

[ ] Licensed Practitioner

Describe the qualifications for the Licensed Practitioner below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Study Nurse

Describe the qualifications for the Study Nurse below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Other:

Describe the qualifications for the Other Professional below, including whether they are affiliated with the UW, any requirement for professional license or credential, and/or experience in performing this procedure:

[ ] Other Procedures Involving Risk to Subjects [name the procedure(s)]:

Examples: behavioral therapy; dietary counseling; assessments and/or interpretations of test reults that require specific expertise (e.g. physical exam; fitness assessment; cognitive state; suicidality; mental health; interpretation of imaging tests, genetic tests, cognitive tests, etc.)

For more than one "Other" procedures, copy and paste this portion of the table as many times as necessary.

Who will perform this procedure?

[ ] Licensed Practitioner

Describe the qualifications of the Licensed Practitioner below, including whether they are affiliated with the UW, what is their professional license, and their experience in performing this procedure:

[ ] Study Nurse

Describe the qualifications of the Study Nurse below, including whether they are affiliated with the UW, what is their professional license, and their experience in performing this procedure:

[ ] Other:

Describe the qualifications of the Other Professional below, including whether they are affiliated with the UW, what is their professional license, and their experience in performing this procedure:

3.a. **Non-UW Individuals, Institutions or Organizations.** It will be necessary for each non-UW individual, institution or organization listed below to receive IRB review of its involvement in this research. There are a number of mechanisms by which this may occur.

Please only list the non-UW individual, institution or organization below if you are:

- **The direct recipient of an award or if you will be providing funding to the non-UW individual, institution or organization through a mechanism such as a sub-contract; and**
- **If the non-UW individual, institution or organization will be acting on behalf of the UW research study to do any of the following: 1) Obtain consent from subjects, 2) Perform procedures involving subject interaction or observation, 3) Obtain identifiable data/specimens, 4) Have access to, or receive coded or identifiable data/specimens, 5) Intervene by manipulating the environment.**
- If the non-UW individual is associated with Pacific Northwest National Laboratories, Puget Sound Blood Center, King County-Seattle Public Health, or Northwest Kidney Center: the UW has an institutional Authorization Agreement with these institutions by which it provides the IRB review (as long as any funding is administered through the UW).
- If the non-UW individual is associated with the Fred Hutchinson Cancer Research Center, Group Health, Seattle children's, Swedish Medical Center, or Benaroya Research Institute at Virginia Mason: the terms of the UW's **Cooperative IRB Agreement** with these institutions may or may not allow the UW IRB to do the review. The individual should contact their institution's IRB for guidance.
- If the non-UW individual, institution or organization is one in which the UW **does not** have a Cooperative IRB Agreement, it will be necessary for the non-UW individual, institution or organization to provide their own IRB review. If the non-UW individual, institution or organization does not have their own IRB or does not use an IRB for review of their research, and the non-UW individual, institution or organization has a Federal Wide Assurance (FWA), the non-UW individual, institution or organization may enter into an **IRB Authorization Agreement** with the UW. This means that the UW will provide IRB review for the non-UW individual, institution or organization. The non-UW individual, institution or organization may also wish to enter into an IRB authorization Agreement even if they have their own IRB to prevent duplication of effort. However, entering into an IRB Authorization Agreement with a non-UW individual, institution or organization is at the discretion of the HSD.
- If the non-UW individual is not associated with an institution or organization that has a Federal Wide Assurance (FWA) or if the institution or organization listed below does not have a FWA and does not routinely conduct research, an **Individual Investigator Agreement** may be entered into with the UW. The Individual Investigator Agreement extends the applicability of the UW's FWA to cover the non-UW individual, institution or organization. However, entering into an Individual Investigator Agreement with a non-UW individual, institution or organization is at the discretion of the HSD.

Please see SOP Authorization Agreements for information on how to obtain an Agreement for your research.

3b. Non-UW Individual, Organization or Location:

If there is more than one non-UW individual, organization, or location, copy and paste this table as many times as necessary.

Name of the non-UW Individual, Organization or Location:

Address of the non-UW Individual, Organization or Location:

Describe the activities that will be performed by/at the non-UW Individual, Organization or Location (if the specified activities will not be performed, please enter N/A):

Obtain consent from the subjects:

Perform procedures involving subject interaction or observation:

Obtain identifiable data/specimens?

Have access to, or receive coded or identifiable data/specimens:

Intervene by manipulating the environment:

VII. SECTION 1 - LIST EACH PROPOSED AND FUNDED GRANT OR CONTRACT RELEVANT TO THIS APPLICATION, AND ATTACH A COMPLETE COPY OF EACH GRANT OR CONTRACT. THIS SHOULD INCLUDE GRANTS THAT SUPPORT FACULTY TIME FOR DATA ANALYSIS AND MANUSCRIPT PREPARATION, (I.E. SALARY SUPPORT). IF NONE, CHECK HERE ☐. FOR CENTER OR PROGRAM PROJECT GRANTS LIST P.I. AND TITLE FOR EACH SEPARATE PROJECT OR CORE. ADD SHEETS IF NECESSARY.

For Center, Program, and Institutional Training Grants (e.g., NIH "P" awards and "T" awards): Attach only the following components of the application. The terms used here are from the standard NIH applications for these types of grants. If the grant is from another agency, provide the equivalent application sections.

- Cover page(s)
- Project/Performance Site Location
- Other Project Information
- Research Plan (for Center or Program grants)
- Research Training Program Plan (for Institutional Training grants)
- Biosketch (profile) for the principal investigator on the grant

For Department of Defense (DOD) funding, complete and attach the SUPPLEMENT: Department of Defense
For Department of Justice (DOJ) funding, complete and attach the SUPPLEMENT: Department of Justice

A. Type of proposal: ☒ Research ☐ Contract ☐ Fellowship ☐ Training grant ☐ Subcontract ☐ Other, specify

B. Name of principal investigator: **Brian J. Hafner, PhD**

C. Name of funding agency: **Royalty Research Fund**

D. Agency's number (if assigned): **A97186**

E. Title of proposal: **Endurance, energy expenditure, perceived function, and satisfaction of persons with transtibial limb loss using a running-specific prosthesis modified for walking**

F. Inclusive dates: from 03/01/15 through 04/30/16

G. Status: ☒ New ☐ Competing renewal ☐ Non-competing renewal

H. Submitted through UW Office of Sponsored Programs? ☒ Yes ☐ No, (attach explanation)

VIII. SUMMARY OF ACTIVITY. Answer in spaces provided (add numbered, referenced, single-sided sheets when necessary). Do not refer to an accompanying grant or contract proposal.

A. BACKGROUND AND PURPOSE OF RESEARCH. Provide relevant background information and explain **in lay language** why this research is important and what question(s) or hypotheses this activity is designed to answer.

Amputation of a limb is a life-altering event with profound physical, psychological, and social implications. To address their functional, vocational, and recreational needs, people with lower limb amputation (LLA) are often provided with a prosthesis or artificial leg. While use of a prosthesis can allow an individual to achieve a basic level of functional mobility, absence of an anatomical foot and ankle still impairs their physical performance. As a result, people with LLA regularly exhibit decreased walking speeds, diminished endurance, and restricted ability to participate in desired life situations.

Over the past three decades, increasingly sophisticated prosthetic foot designs have been developed by the prosthetics industry to replace amputated structures in the leg. Contemporary, energy storing feet (ESF) employ advanced materials and unique geometric designs to improve walking performance and endurance of their users. Although prosthetic limbs with ESF allow people with LLA the potential to return to an active lifestyle, even the most advanced ESF do not significantly reduce the increased energy demands required for walking when compared to conventional prosthetic feet.

Commercially-available running-specific feet (RSF) like the Össur Cheetah (Össur, Reykjavik, Iceland) allow people with LLA to participate in athletic activities and sporting events. RSF provide significantly enhanced performance, compared to traditional ESF, by extending the length and increasing the stiffness of the prosthetic keel (forefoot). RSF also do not include a heel, as they are used only for running activities. Although transtibial runners with RSF exhibit endurance levels similar to non-amputees, the RSF design does not allow the biomechanical movements or provide the stability needed to use the foot for walking (over level or uneven terrain).

A Seattle-area prosthetist, Greg Davidson, currently provides many of his active LLA patients with a modified running-specific foot (mRSF). The mRSF combines the running keel (forefoot) of a RSF with the walking heel of a ESF. The mRSF can then be used for walking, running, and other routine daily activities. Mr. Davidson has fit and provided this prosthetic foot on over 100 of his patients. Preliminary feedback suggests that users experience improved overall function and high satisfaction with the device. However, empirical evidence is needed to support prescription of this prosthetic foot at other clinical facilities. The goal of this study is therefore to evaluate endurance, walking performance, mobility, and perceived exertion of transtibial prosthesis users (i.e., study participants) walking with a conventional ESF and the mRSF. Results will be compared to determine if the mRSF provides superior performance to the ESF, which is commonly prescribed to most active individuals with LLA.

Hypotheses:

1a. Participants with LLA will exhibit significantly increased endurance (as evidenced by an ability to walk significantly further in a timed walking test) wearing the mRSF compared to the ESF.

1b. Participants will report significantly reduced levels of exertion after performing a timed walking test in the mRSF, compared to the ESF.

2a. Participants will report significantly increased mobility, balance confidence, and health and significantly decreased fatigue when using the mRSF, compared to the ESF.

3a. Use of the mRSF will significantly reduce participants' net energy cost of walking (ECW) at slow, comfortable, and fast walking speeds, compared to the ESF.

B. RESEARCH PROCEDURES INVOLVED.

1. Provide a complete description of: a. the study design, and b. sequence and timing of all study procedures that will be performed, e.g., volume of blood, size of biopsy, drug administration, questionnaire, name of psychological test. Provide this information for each phase of the study (pilot, screening, intervention and follow-up). **Use lay language**. Attach study flow sheet, if available.

We will conduct a study to compare endurance, walking performance, mobility, and perceived exertion of participants with transtibial amputation wearing two different prostheses: (1) a prosthesis with a modified Running Specific Foot (mRSF), and (2) a prosthesis with a Energy Storing Foot (ESF). To maximize study resources, we will recruit participants who will be receiving from their prosthetist the mRSF prosthesis as part of their normal clinical care. We will fabricate a duplicate prosthesis with the ESF as part of this study to be used as a comparison.

Note: Both the mRSF and ESF included in this study are devices that people with LLA use daily in their normal lives outside of this study. These feet (and other components included in the prostheses created for this study) are class I devices and exempt from U.S. Food and Drug Administration premarket notification procedures.

We will conduct a randomized crossover study to compare endurance, energy expenditure, and reported health of participants with transtibial amputation wearing prostheses with the mRSF and ESF described above. Study participants will be randomly assigned to the first foot condition (i.e. ESF or mRSF). To standardize test conditions, the participant's prosthetist (Greg Davidson) will fabricate two comparable prostheses with identical (i.e. duplicated) prosthetic sockets, interfaces, and suspension mechanisms. The same socket cannot be used for both prostheses because of the unique, direct-lamination attachment of the mRSF to the socket. The duplicate socket will be fitted with common ESF, the Ossur Vari-flex foot. We have obtained written commitments from Ossur to donate prosthetic components and from Davidson Prosthetics to donate time and materials needed to fabricate the duplicate sockets and test prostheses. Participants will be asked to wear the same athletic shoes for all sessions in order to standardized footwear between tests.

Participants will be recruited from their local prosthetist's office (Davidson Prosthetics, Federal Way, WA). Davidson Prosthetics is the sole location for recruitment as this is the only provider of the mRSF in the Northwestern United States.

Participants will be asked to come to the University of Washington Assessment and Training Laboratory (ATL) for three test sessions. Participation in the study will require participants attend three visits over the course of about three months, totaling approximately 7.5 hours.

Session 1: At the first session, we will screen participants, explain the study to them, and obtain informed consent (**Appendix 1**). Participants who agree will then be administered a baseline survey and perform initial speed testing. The baseline survey will include non-identifiable, medical, and demographic questions we will use to characterize the study sample (**Appendix 2**). Participants will then be asked to walk on a treadmill for 6 minutes to determine their comfortable walking speed. The treadmill is equipped with full-length handrails that allow the participant to steady him/herself as needed. A researcher will be next to the subject at all times to assist the subject if he or she were to become distressed.

Participants will be given blinded control of the treadmill speed for the first 30 seconds of testing in order to select their preferred speed. Each participant's comfortable speed will be noted and used as a reference for the metabolic testing (see Session 2 and 3, described below). Slow and fast speeds will be self-selected using an identical method (blinded control of the treadmill adjustment). Participants will be asked to perform a 6 minute practice trial at their self-selected fast speed to ensure the participant is capable of sustaining the speed without undo stress. If a participant is unable to sustain the set speed for the entire 6 minutes, he/she may reduce speed as desired, and a weighted average of the start and end fast speeds will be used for treadmill testing in Sessions 2 and 3. We will also give participants a step activity monitor to wear on their prosthesis. The activity monitor is a small, unobtrusive sensor about the size of a pager that is worn on the prosthesis and measures steps taken by the participant while they are away from the lab. Participants will be shown how to attach the activity monitor to their prosthesis by study investigators. Session 1 is expected to take about 1.5 hours.

Session 2: The second session will be performed after participants use the randomly-assigned ESF or mRSF prosthesis for a period of 1 month. Upon arrival at the lab, study

staff will remove the activity monitor and ask the participant to complete a self-report survey (**Appendix 2**) to evaluate their perceived performance, health, and satisfaction with their prosthesis. The survey will be administered on a tablet computer (iPad) and includes the following standardized instruments selected to measure participants' mobility, fatigue, balance confidence, activity restrictions, and satisfaction:

- Prosthetic Limb Users Survey of Mobility - PLUS-M measures respondents' self-reported mobility with a prosthesis. The PLUS-M was developed by the investigators in a prior study to address methodological limitations present in existing mobility measures. We will administer the PLUS-M computer adaptive test (CAT) to achieve the greatest precision of measurement and ease respondents' burden (i.e., CAT requires participants answer fewer questions than would taking the entire survey).
- PROMIS - Fatigue - PROMIS-F measures symptoms and effects of fatigue on respondents' ability to execute daily activities over a 1-week recall period. We will also administer PROMIS-F by CAT.
- Activities Specific Balance Confidence Scale - ABC measures respondents' confidence in performing basic ambulatory activities. We will administer a version of the ABC recommended to ease administration and improve scoring. All 16 questions of the ABC will be administered (CAT not available).
- Trinity Amputation and Prosthesis Experience Scales - Revised - TAPES-R is a multidimensional health instrument that measures activity restrictions and satisfaction with a prosthesis. We will administer 19 TAPES-R questions (CAT not available).

We will next assess participants' walking performance and endurance using the 6-minute walk test (6MWT). The 6MWT is a sub-maximal test of aerobic capacity and endurance that exhibits good test-retest reliability in transtibial prosthesis users. The 6MWT will be conducted using a 100ft unobstructed indoor hallway, in accordance with recommended administration guidelines. During the 6MWT, participants will walk back and forth over a pressure-sensitive instrumented mat placed in the middle of the hallway. The mat will collect outcomes associated with walking such as step length, step width, walking speed. Upon conclusion of the 6MWT, participants will self-report their exertion using the Borg Rating of Perceived Exertion (RPE). The Borg RPE measures participants' perceived exertion after completing a standardized physical test. Note, participants will perform the 6MWT after evaluation of resting O2 consumption (see below) but before the treadmill testing so as to ensure baseline O2 consumption is not adversely affected by the 6MWT.

To assess the effects of the studied prosthetic feet on energy cost of walking, we will measure participants' real-time metabolic energy expenditure (i.e., O2 consumption) across three walking speeds (slow, comfortable, fast). The gold standard method for determining energy consumption is measurement of the amount of oxygen a person intakes (VO2) and carbon dioxide that a person expires (VCO2). We will measure VO2 and VCO2 using a portable Cosmed K4b2 monitor. The K4b2 monitor continuously samples the participant's expiration and inspiration using a mask that fits over their nose and mouth. Plastic tubes convey the gases to sensors that are located in a small, lightweight (1 lb) backpack system. Breath-by-breath measurements of the expired gases are stored in the system until they are uploaded by the researcher to a laptop after the experiment is completed.

Participants will be fitted with the K4b2 monitor upon conclusion of the self-report survey (described above). They will sit quietly for 5 minutes to achieve steady-state resting VO2 consumption rate (ml/min). Resting VO2 rate will be quantified as an average over the final minute of resting. Participants will then stand for 5 minutes to achieve a standing VO2 consumption rate (ml/min), again averaged over the final minute of standing.

Participants will remove the K4b2 monitor and conduct the 6MWT according to the protocol described above. After completing the Borg RPE, the participant will re-don the K4b2 monitor and sit quietly in order to return to their resting VO2 rate.

Participants will begin the treadmill testing once they have returned to their resting VO2 rate.

Participants will walk for 6 minutes on the treadmill at comfortable, slow, and fast walking speeds (as determined in Session 1). The order of the speeds will be randomized within-subjects to control for fatigue. This randomized order will be carried over into the third session so that participants are tested in the same order both times. Walking VO2 consumption rate (ml/min) will be averaged over the final 1 minute period of each activity. Participants will rest at least 5 minutes between each walking trial in order to return to their resting VO2 rate.

Session 2 will require about 3.0 hours to complete. Upon conclusion of Session 2, participants will transition to the second prosthesis (ESF or mRSF, depending upon randomization) and will be asked to use it exclusively for 1 month before returning for Session 3.

Session 3: The third session will be identical to the Session 2, but will be conducted with participants using the alternate prosthesis (e.g., ESF if they were previously tested in the mRSF).

2. Would subjects undergo these or similar procedures (medical, psychological, educational, etc.) if they were not taking part in this research? ☒ No ☐ Yes If "Yes," describe how the study procedures differ from what subjects would otherwise undergo.

The study procedures include outcome measures (survey measures, 6MWT, or Borg RPE) that a prosthetist might perform in a clinic to evaluate a patient's performance with a new prosthesis. However, the Cosmed K4b2 portable metabolic analysis system and treadmill walking are unlikely to occur in normal prosthetic clinical practice. These procedures are more likely to be conducted as part of a physical therapy treatment plan and would not be considered unusual procedures at a physical therapy clinical visit.

3. Check all of the boxes below that apply to your research:

Drug administration

☐ Administration of a drug (either FDA-approved or investigational) for research purposes to a subject-patient during general or regional anesthesia.

☐ Administration of a drug (either FDA-approved or investigational) for research purposes to a subject-patient during the 1.5 hours preceding general or regional anesthesia.

Blood lines

☐ Inserting an intravenous (central or peripheral) or intra-arterial line for research purposes in a subject-patient **during** general or regional anesthesia.

Sample collection

☐ Obtaining samples of blood, urine, or cerebrospinal fluid for research purposes while a subject-patient is under general or regional anesthesia.

☐ Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery, while the subject-patient is under general or regional anesthesia.

Radio-isotopes

☐ Administration of a radio-isotope for research purposes during the 3 hours prior to anesthesia or while a subject-patient is under general or regional anesthesia.

If you checked this box, you are responsible for informing **in advance** all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.

Experimental devices

☐ Implantation of an experimental device while a subject-patient is under general or regional anesthesia.

Other experimental manipulations or procedures

☐ Other manipulations or procedures performed solely for research purposes while a subject-patient is under general or regional anesthesia (e.g., experimental liver dialysis, experimental brain stimulation)

None of the above

☒ None of the above apply to my research

4. If you checked any box in question #3 except "none of the above", answer the following questions:

   a. Provide the name and institutional affiliation of the physician anesthesiologist who is a member of your research team or who will serve as a safety consultant about the interactions between your research procedures and the general or regional anesthesia of the subject-patients. If your procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member.

   N/A

   b. If you have not yet consulted with an appropriately qualified person about this issue, describe in detail your plans to do so. The IRB will not approve your application without this consultation. If UW Department of Anesthesiology approval has been obtained, please provide the Department's letter of support.

   N/A

5. Required application supplements. Complete and attach the indicated SUPPLEMENT, as appropriate

   a. **SUPPLEMENT: Drugs, Biologics, Botanicals** – for research involving the use of any of the following:
      - Drugs regulated by the FDA (prescription, over-the-counter, approved, or investigational)
      - Biologics regulated by the FDA (prescription, over-the-counter, approved, or investigational)
      - Botanicals
      - Dietary Supplements

   b. **SUPPLEMENT: Devices** – for research involving the use of any medical device (approved or investigational; including software used with a medical device, and including mobile medical applications).

      See attached (**Appendix 3**).

   c. **SUPPLEMENT: Genetic Research** – submit this supplement when your research involves genetics. **Genetic research** is defined as research involving the analysis of any of the following: DNA; RNA; chromosomes; mitochondria; any or all parts of the human genome; or biomarkers such as proteins or metabolites which may be implicated in, associated with, or cosegregated with a disorder, syndrome, condition, or predisposition to disease or behavior. Usually genetic research involves the collection and/or use of human biological specimens such as blood, skin, or other tissues, nail clippings, or hair. Genetic research may also include the construction of pedigrees ("maps" of the distribution of a particular trait or condition among related individuals) or family medical histories.

   d. **SUPPLEMENT: Department of Defense** – for research involving any component of the federal Department of Defense (DOD). "Involvement" means funding; collaboration or cooperative arrangements; use of facilities, resources, or personnel; use of military or civilian members of the DOD (or their records/specimens) as subjects.

   e. **SUPPLEMENT: Department of Justice** – for research involving the federal Department of Justice (DOJ) or any of its components (such as the National Institute of Justice, or any facilities/personnel of the Bureau of Prisons). "Involvement" means funding; collaboration or cooperative arrangements; use of facilities, resources, or personnel; use of records or specimens from DOJ employees or from prisoners in any Bureau of Prisons facility.

   f. **SUPPLEMENT: GWAS dbGaP** – for research that will involve submitting data to the federal Database of Genotyped and Phenotyped (dbGaP) information.

   g. For research involving the **Department of Energy (DOE)**, researchers should consult the **CHECKLIST Department of Energy** to ensure that they have addressed all DOE requirements. However, the Checklist does not need to be completed and submitted unless the researcher believes it would be a useful attachment.

C. DECEPTION: If any deception or withholding of complete information is required for this activity, explain why this is necessary and attach a protocol explaining if, how, when, and by whom subjects will be debriefed.

No deception is required for this study.

D. SUBJECTS

The IRB reviews the number of subjects you plan to study in the context of risks and benefits. If your research is approved for a specific number of subjects, the data from any "extra" subjects cannot be described as having been obtained with IRB approval.

See the HSD website for the definition of "human subject" http://www.washington.edu/research/hsd/docs/1253. Before answering the questions below, be sure that you are familiar with the definition.

1. **Subject groups/categories and numbers.** Complete this table by listing:

   - Your groups or categories of subjects. "Group" should be defined as appropriate for your research.
     - "Units" within a group. For most research, a group will consist of individuals, such as children aged 8-12, or individuals with high blood pressure. However, this will not be true for all research. Examples of groups with "units" that are not individuals:
       - Dyads such as Alzheimer's-patient-and-caregiver, with one group of the dyads assigned to one intervention (e.g., behavioral modification) and another group of the dyads assigned to a comparison intervention(e.g., drug treatment).
       - Families. For example, a study of mental health interventions for homeless families might have one group of 30 families assigned to one intervention and another group of 30 families assigned to a different intervention.
       - Other. For example, the "units" in autism research might be an autistic individual and all his/her living blood relatives. The units in an academic excellence study might be a student-parents-teacher unit.
     - Types of groups. There are many ways in which subjects might be grouped. Examples:
       - By intervention. Example: research comparing two different drugs for high blood pressure.
       - By subject population. Example: research comparing the incidence of domestic violence in families living in urban settings versus families living in rural settings.
       - If you have only one group, fill in only one line in the table. Add more lines if needed.
   - The age range of each group.
   - The upper limit/number of **completed** subjects you need for each group. ***Completed*** *means that all research procedures involving the subjects or the obtaining of specimens/records/data have been completed as far as is possible for each subject, including any follow-up (such as follow-up access to medical records.) In some cases, such as an online survey, it is not possible to predict the number of subjects who will complete the research. If you cannot predict or describe the maximum number of subjects you need in each group, check the appropriate box and provide your rationale in the space provided below the table.*

Group name/description	**Age range of subjects**	**Maximum desired number of individuals (or other group unit, such as families) who will complete the research.***	**Cannot provide a number.****
People with lower limb loss	>18	24	☐**
			☐**
			☐**
			☐**

***This is the number of subjects (individuals, dyads, families, etc., as appropriate) in each group that will be considered for approval by the IRB.**

****If you cannot predict or describe the maximum number of subjects you need in each group:**
Provide your rationale and description of research scope here. *Include any information or estimates you might have about the number of subjects, so that the IRB has a sense of the scope of your research. For example, your research might be a small pilot study of all patients presenting with a rare disease at UW Medicine in the next year. Or, it might involve a survey posted on Craig's List for two weeks that could result in thousands of responses.*

N/A

NOTE: In your periodic Status Report, you will be asked to complete the table below with your subject numbers. While developing your research protocol, please plan ahead so that you will have an accurate record of the subject numbers above.

This is for illustration only. Do not complete this table.

Group Name / Description	# Completions				# Ongoing (subjects still involved)	# Withdrawals, drops, lost		
	Total approved by IRB	A At time of last Status Report	B Since last Status Report	A + B Total to date		C At time of last Status Report	D Since last Status Report	C + D Total to date

2. Explain how you will achieve equitable subject representation in the following categories. If not applicable, justify exclusions.

   a. Age (minors, elderly):

   We will not be recruiting minor participants for this pilot study. At present, the mRSF is not regularly provided to children, so we will not be recruiting participants under the age of 18 for this study.

   b. Gender:

   We will not exclude participation based on gender. Both males and females are welcome to participate in this study.

   c. Ethnic and racial minority populations:

   We will not exclude participation based on ethnicity or race.

3. What characteristics (inclusion criteria) must subjects have to be in this study? (Answer for each subject group, if different.)

   Inclusion criteria include: 18 or more years of age, non-dysvascular unilateral transtibial amputation, prosthetic user for >1 year, are scheduled to receive a prosthesis with a mRSF, able to walk continuously for at least 6 minutes with or without an assistive device, able to read and write English.

4. What characteristics (exclusion criteria) would exclude subjects who are otherwise eligible from this study? (Answer for each subject group, if different.)

   Exclusion criteria include any health condition that would limit use of a prosthesis (e.g., skin breakdown), ability to safely walk for at least 6 minutes (e.g., heart disease), or participation (current or planned over the study period) in another research study that may affect the fit or function of his/her prosthesis.

5. Describe the subject recruitment strategies you will use for each group of subjects. (You should obtain letters of cooperation from agencies, institutions, or others involved in subject recruitment for your research records. Do not send these to HSD or the IRB.)

   Study participants will be exclusively recruited from Davidson Prosthetics, the only local prosthetics facility that routinely provides prostheses with ESF and mRSF to people with LLA. Informed consent will be obtained from all participants.

6. Explain who will approach subjects to take part in the study and how this will be done to protect subjects' privacy. (Attach letters of cooperation from agencies, institutions or others involved in subject recruitment.)

   Flyers will be posted at Davidson Prosthetics with study information and the phone number of the study coordinator (**Appendix 4**). In addition, Mr. Davidson will let potential participants know about the study and provide the phone number of our study coordinator. Potential participants can call our study coordinator to get more information about the study, decide if they are interested in participating, and schedule their first study session (**Appendix 5**).

7. Explain what steps you will take during the recruitment process to minimize potential coercion or the appearance of coercion.

Their prosthetic care provider (Mr. Davidson) will only inform potential participants about the study. All recruitment and enrollment procedures will be conducted by study investigators/coordinators. All interested participants will be informed that participation (or not) is completely voluntary and will in no way affect the clinical care they receive. No members of our study team are or will be involved in the clinical care of potential participants or participants.

8. Will you give subjects gifts, payments, services without charge, or extra course credit? ☐ No ☒ Yes If yes, explain:

Subjects will receive $30 for every hour of participation in the screening session (Session 1). Participants will receive $50 for every hour of participant in data collection sessions (Sessions 2 & 3). Participants will be paid after each session.

9. Will any of the subjects or their third-party payers be charged for any study procedures? ☒ No ☐ Yes If yes, explain:

N/A

10. **UW Locations and research sites.** Provide the following information in list or table format for all UW locations at which any research procedures will occur. Be sure to consider: screening, recruiting, consenting, observation, intervention, data collection, data analysis, specimen analysis, and location of any consultants and collaborators.

- Geographical location and/or address
- Name of organization, agency, group, site, institution
- What procedures will occur at each location (how the location is involved in the research)
- Whether subject contact or interaction will occur at each site
- Whether consenting of subjects will occur at each site
- Whether each site, or individuals at the site, will obtain, use, or have access to coded or individually identifiable private information about subjects for research purposes

	Site 1: University of Washington Department of Rehabilitation Medicine Health Sciences Building, BB tower, 8th floor	Site 2: Davidson Prosthetics, LLC 812 39th Avenue SW Suite D Puyallup, WA 98373
Screening	X (Screening will be done by study investigators/staff over telephone)	
Recruiting	X (The study will be described to potential participants by study investigators/staff. Potential participants will have the opportunity to ask questions and decide if they would like to schedule a data collection session at this time)	X (Mr. Davidson will post flyers and let potential participants know about the study)
Consenting	X (Study investigators, Dr. Hafner and Ms. McDonald, will obtain informed consent at the data collection appointment, prior to data collection activities)	N/A
Observation	N/A	N/A
Intervention	N/A	N/A
Data Collection	X (Study investigators, Dr. Hafner and Ms. McDonald, will perform all data collection activities)	N/A
Data Analysis	X (Study investigators, Dr. Hafner and Ms. McDonald, will	N/A

	perform all data analysis activities)	

E. RISKS AND BENEFITS

In order to approve the research the IRB must find that risks are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

1. Describe nature and degree of risk of possible injury, stress, discomfort, invasion of privacy, and other side effects from all study procedures, drugs and devices (standard and experimental), interviews and questionnaires. Include psycho-social risks as well as physiological risks. Include risks of withholding standard care or procedures if this is the case. Do not reference the consent form.

   Participants will be asked to walk for about 70 minutes total for this study (a maximum of 6 minutes at a time, and 30 minutes maximum per session). Because they are being asked to walk, there is the risk that they could become fatigued during the study procedures. In addition, there is a risk of falling. However, these risks are no larger than the risks that study participants generally undertake when walking outside of this study.

2. Explain what steps you will take to minimize risks of harm and to protect subjects' rights and welfare. (If you will include protected groups of subjects (minors; fetuses in utero; prisoners; pregnant women; unviable neonates; neonates of uncertain viability; decisionally impaired or economically or educationally disadvantaged subjects) please identify the group(s) and answer this question for each group. Please also complete the SUPPLEMENT: Protected and/or Vulnerable Populations.)

   This study will not require participants to perform activities at a level of endurance that they would not typically do outside of the study session. To minimize risks of fatigue and falling during the study session, the participants will be asked to take breaks after each walking measure is collected. The maximum time that each participant will be asked to walk continuously is 6 minutes. They are also instructed to take a break, including a sitting break, at any time during the data collection session, including in the middle of walking measures. If at any time it appears that the participant is at risk of falling or other harm, the data collection session will be stopped.

3. Is it possible that you will discover a subject's previously unknown condition (disease, suicidal intentions, genetic predisposition, etc.) as a result of study procedures? ☐ No ☐ Yes If yes, explain how you will handle this situation.

4. Describe the anticipated benefits of this research for individual subjects in each subject group. If none, state "None."

   None

5. Describe the anticipated benefits of this research for society.

   The mRSF is a promising advancement in prosthetic technology. However, currently, Mr. Davidson is one of few prosthetists in the United States that is providing this foot. Empirical evidence that supports its provision for people with LLA will help the mRSF become available to others who may benefit from its use.

F. ADVERSE EVENTS OR EFFECTS

1. Who will handle adverse events? ☒ Investigator ☐ Referral ☐ Other, explain:

   N/A

2. Are your facilities and equipment adequate to handle possible adverse events? ☒ Yes ☐ No, explain:

   A first aid kit will be available, if needed, to address minor injuries (e.g., scrapes or minor cuts). The investigators will contact emergency services (911) if a serious adverse event occurs. The UW Medical Center emergency room is located 5 floors below the researchers' laboratory.

G. CONFIDENTIALITY OF RESEARCH DATA

1. Will you record any direct subject identifiers (names, Social Security numbers, patient, hospital, laboratory or claim numbers, addresses, telephone numbers, locator information, etc.) ☐ No ☒ Yes If yes, explain why this is necessary and describe the coding system you will use to protect against disclosure.

Subject identifiers will be recorded (name, telephone number, social security number). Name and contact information are needed to schedule participant data collection sessions. Social security information is required by UW when payments of more than $50 are made to study subjects. Identifying information will be linked to a 5-digit numeric study code. The file containing identifying information and the linked subject code will be stored separately from all other study data in a secure and password protected computer only accessible to study researchers.

2. Will you retain a link between study code numbers and direct identifiers after the data collection is complete? ☐ No ☒ Yes If yes, explain why this is necessary and for how long you will keep this link.

   This research is a pilot study in a new line of investigation for our research lab (i.e., same PI and research team). We are currently pursuing funding for parallel studies of prosthetic foot technologies. We wish to combine data from related studies to maximize our ability to recruit from the small local population of people with lower limb loss. Combining data from multiple studies would increase our power to detect differences and avoid participation of individuals in both studies (participation in both studies would lead to including a participant's data twice in the same dataset). To allow for accurate longitudinal tracking of participants, we will retain the link between identifiers and study code numbers until 2026. Participants may request that we destroy their link at any point during the study, or any time thereafter.

3. Describe how you will protect data against disclosure to the public or to other researchers or non-researchers. Explain who (other than members of the research team) will have access to data (e.g., sponsors, advisers, government agencies, etc.).

   Data will be stored on a study specific password protected computer which will be stored in a locked cabinet in the PI's office. Only members of the research team will have access to the information.

4. Will you place a copy of the consent form or other study information in the subject's medical or other personal record? ☒ No ☐ Yes. If yes, explain why this is necessary.

   N/A

5. Do you anticipate using any data (information, specimens, etc.) from this study for other studies in the future? ☐ No ☒ Yes If "Yes," explain and include this information in the consent form.

   As noted above, this research is a pilot study in a new line of investigation for our research lab. We are currently pursuing funding for similar (parallel) studies of the prosthetic foot technologies included in this study. To maximize available resources and address larger research questions, we will combine data from this study with data obtained in subsequent studies. We have added this information to the consent form.

H. ADDITIONAL INFORMATION

1. If the study will involve radiation exposure to subjects, e.g., X-rays, radioisotopes, what is status of review by the UW Radiation Safety Committee (RSC): ☐ Pending ☐ Approved (Attach one copy of approval.) ☒ NA

2. Does this research require approval from the UW Institutional Biosafety Committee (IBC) for recombinant/synthetic DNA human Gene transfer or vaccines?

   ☒ No ☐ Yes. If yes, what is the status of review by IBC? ☐ Pending ☐ Approved (Attach one copy of approval.) ☐ NA

3. Protected Health Information (PHI). Will you or any member of your research team obtain, access, or use a subject's protected health information by any method, and for any purpose including "pre-screening"?

   "Methods" may include but are not limited to: directly looking at a medical record (electronic or paper), requesting medical record information from a service such as the UW Center for Health Excellence, or viewing surgery schedules, clinic records, appointment books, etc.

   Examples of where PHI may be located include: medical records, dental records, clinical lab tests that you will have performed on subject samples, pharmacy records, medical billing records, clinical databases, etc.

   ☐ No ☒ Yes. If "yes":

   a. Describe the type of records/data, location and how you will obtain the information:

We will collect information on the participants' prostheses, including delivery schedule, components, and problems experienced by the participants (related to fit and function of their prostheses) while they are part of the study. Information will be collected directly from the participant's practitioner (Mr. Davidson). Participants will be asked to complete a HIPAA authorization to allow us to collection information about their prosthesis directly from their practitioner (**Appendix 6**).

b. Will you obtain any of the information without HIPAA authorization from each subject?

☒ No ☐ Yes. If "yes": Complete and attach the SUPPLEMENT: Waiver Request, HIPAA Authorization, and the SUPPLEMENT: Waiver Request, Consent Requirements. If the records are owned by the University of Washington or a state agency, complete and attach a UW Confidentiality Agreement.

c. Will you obtain HIPAA authorization from subjects for any of the information?

☐ No ☒ Yes. If "yes", attach the HIPAA Authorization form you propose to use

See attachment (**Appendix 6**).

d. Will you be obtaining any of the data as a Limited Data Set?

☒ No ☐ Yes

4. Other Records. Will you or any member of your research team obtain, access, or use academic, employment, or any other type of records about subjects, by any method, and for any purpose including "pre-screening"?

"Methods" may include but are not limited to: directly looking at a record (electronic or paper), requesting records from offices such as Payroll or the UW Registrar's Office, obtaining records from the state Department of Health, etc.

☒ No ☐ Yes. If "yes":

a. Describe the type of records/data, location, and how you will obtain the information.

N/A

b. Will you obtain any of the information without the subject's consent?

☐ No ☐ Yes.

If the records are owned by the University of Washington, complete and attach a UW Confidentiality Agreement.

5. Will you use the Clinical Research Center (CRC) at the UW or Seattle Children's for any of your research activities?

☒ No ☐ Yes.

If you answered "yes":

A medical record will be created for your subjects at UW Medicine and CRC staff may need to access those medical records for you. This may be because they are performing procedures or collecting data for you. It may also be required if an event happens on the CRC that requires treatment (such as fainting during a blood draw). This means that you must obtain a signed HIPAA Authorization form from each subject and give a copy of it to the CRC. ***Complete and attach the UW research HIPAA Authorization template, available on the HSD Forms webpage. There is guidance in the template about how to describe the information that the CRC staff may access and disclose to you.***

6. Does your research involve any of the following:

- Students age 21 or younger who may be participants in your research?
- Access to, or use of, personally identifiable information from student (current or past) education records from any institution or agency of education (including, but not limited to, pre-elementary, secondary, post-secondary, job training, adult education, career and technical education, special education)?
- Conducting any research procedures in an educational setting?

☒ No ☐ Yes.

If you answered "yes":

Your research may be subject to the requirements of the **Protection of Pupil Rights Amendment (PPRA)** and/or the **Family Education Rights and Privacy Act (FERPA).**

Consult with the SOP Research Involving Students to determine whether PPRA or FERPA regulations apply to your research.

Check the appropriate box.

☐ PPRA regulations apply to my research

☐ FERPA regulations apply to my research

☐ Both PPRA and FERPA regulations apply to my research

☐ Neither set of regulations apply to my research

7. Will you make audio-visual or tape recordings or photographs of subjects? ☐ No ☒ Yes. If yes, explain what type of recordings you will make, how long you will keep them, and if anyone other than the members of the research team will be able to see them.

   With participant's consent, we will take video and/or photographs of study procedures for use in grant applications, presentations, or publications (**Appendix 7**). Consent for photos/videos is not required to participate in the study. We will not destroy photos and/or videos.

8. Will your study involve use of equipment involving energy input to the subjects (EMG, EKG, MRI, ultrasound, etc.)? ☒ No ☐ Yes. If yes, attach documentation that all equipment will be tested regularly by the Scientific Instrument Division (call (206) 543-5580 for information) or describe safety testing procedures you will use.

   N/A

9. Confirm by checking the box that the principal investigator on this IRB application has ensured that all investigators (as defined by UW policy GIM 10) are aware of policy GIM 10 and their responsibility for complying with its relevant requirements.

   ☒ Confirmed

10. Does the individual who is the principal investigator on (1) this IRB application or (2) any grants or contracts supporting this research have a financial conflict of interest with respect to this research? ☒ No ☐ Yes.

    If yes, has it been disclosed to the University? (Since August 24, 2012, all disclosures are made through the University's online Financial Interest Disclosure System.) Final review of this application cannot occur until the disclosure has been made and reviewed by the University, and the outcome has been incorporated into the IRB's review. ☐ No ☐ Yes ☐ Not applicable, because there is no financial conflict of interest.

11. Is your research:

    - Clinical research that will bill subjects or their health insurance for UW Medicine professional or facility services, items, or tests*, **AND/OR**
    - An "applicable clinical trial" as defined below" **

      ☐ No ☒ Yes

      If you selected "yes", you must register your research at the federal site ClinicalTrials.gov

      See the HSD document titled: ClinicalTrials.gov – Instructions for Registering Your Trials for step-by-step instructions about how to register your research.

      ***New Requirement**

      As of January 1, 2014, a new federal requirement will require you to provide the clinical trials registration number assigned to your research in order to bill most UW medicine professional or facility services, items, or tests to research participants or their health insurance. This new billing requirement applies to some clinical research, such as Phase I studies, that don't meet the federal registration definition of "applicable clinical trials". *See also*: Clinical Research Budget & Billing Support (CRBB)

      ***Applicable clinical trial is defined as:*

      (1) a pediatric postmarket surveillance study required by the FDA ***OR***

      (2) an interventional study (with one or more arm) of an FDA-regulated drug, biological product, or device that involves health outcomes and meets one or more of the following conditions:

      - *The trial has at least one site in the United states; or*
      - *The trial is conducted under an FDA investigational new drug application or investigational device exemption; or*

- *The trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research*

The source of funding (e.g., industry, federal, nonprofit) is irrelevant.

See this website for additional information: http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf

I. CONSENT

Obtaining informed consent is a process that involves more than obtaining a signature on a form. It is a process of information exchange that may include subject recruitment materials, verbal instructions, question-and-answer sessions, and measures of participant understanding. Obtaining voluntary informed consent is one of the central protections required by all human subjects regulations and ethical principles. The key features of the consent process include:

- Disclosure of the information needed to make an informed decision about participation
- Facilitation of comprehension by the potential participant
- Promotion of the voluntariness of the potential participant's decision

Refer to the SOP Consent and SOP Consent Documentation for more information.

1. Description of consent process for adult subjects. How are you going to obtain informed consent from your adult subjects? Describe in detail your consent methods, process, and settings. Identify who will provide the information to subjects and who will interact with them during the consent process. If there is more than one consent process, describe each one separately. For subjects who do not speak English: Describe the process that will be used, and whether anyone on the research team will speak the subjects' language. **Complete this section if you will obtain consent from any subjects for any aspect of the research.**

   Potential participants will provide informed consent at their scheduled study session, but before any data collection procedures. A study investigator will describe the study to the participant using the written consent form (**Appendix 1**) as guide, allow time for the potential participant to read through the consent form, ask if the participants have any questions, and ask them to sign the form if they are interested in participating. If the potential participant is not interested, they will not be asked to perform any study procedures.

2. Description of assent process for children subjects. Describe in detail how you will obtain assent from children subjects, following the instructions provided in the question above. Also, describe how these processes will differ based on age/cognitive ability. Finally, describe how you will determine whether a child is assenting or dissenting throughout the research (if applicable). **Assent means a child's affirmative agreement to participate in the research. Mere failure to object should not be interpreted as assent.*

   N/A

3. Special issues or considerations. The standard concept of consent is based on the Western ethical tradition of individual autonomy and privacy. This may not apply well to your research. Your research may be subject to specific cultural or other contextual issues that affect the consent process. Describe any special issues and considerations about obtaining consent for your research. If none, state: "Not Applicable".

   Example issues:

   - Who is the appropriate person(s) for providing consent?
   - The desirability of a group consent process, or a surrogate consent process
   - Research that occurs in a setting with a blurred sense of what is public versus private
   - The cultural acceptability of the consent process (or documentation)
   - Cultures or groups in which it is considered impolite to refuse a request and/or in which people are fearful of refusing requests that they regard as coming from authorities

   N/A

4. Undue influence. Describe how you will minimize any undue influence on your subjects' decision about participating in your research. If this is not an issue for your research, describe why. *This is an important consideration when persons recruiting or consenting subjects are in a position of authority or influence – for example, the subject's teacher, doctor, or employer.*

   Potential participants will be identified via flyers (**Appendix 4**) posted in their prosthetic office. However, all other recruitment and consenting procedures will be

done by study investigators who are not involved in potential participant's health care. Study investigators will stress that participation is voluntary and in no way will participation (or non-participation) in the study affect their prosthetic (or other health) care.

5. Subject comprehension. Describe anything that you will do to facilitate or verify your subjects' comprehension of the information you provide them during the consent process.

Potential participants will be encouraged to ask questions throughout the consent process.

6. Do you expect that all of your participants will be **fluent** in spoken and/or written English? ☐ No ☒ Yes.

If "No", please answer the following questions.

6.1. In what language(s) will they be fluent?

N/A

6.2. Translation of documents into another language. Federal regulations require that consent, assent, and authorization documents must be presented to participants in a language that is understandable to them. The UW IRB expects that translated documents will be:

- Linguistically accurate;
- At an appropriate reading level for the subject population; and
- Culturally sensitive for the locale in which they will be used.

Describe how you will obtain translations of relevant documents, and how you will ensure that the translations meet these requirements.

N/A

6.3. Interpretation. Describe how you will provide interpretation, and when. Specifically:

a. For what situations will you provide interpretation? (At a minimum, an interpreter should be available for the consent process, unless the IRB has waived consent.)

N/A

b. Who will be the interpreter?

N/A

c. Describe the qualifications of the interpreter – for example, background, experience, language proficiency in English and in the other language, native language fluency, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

N/A

d. How will you ensure that the subjects will understand ongoing study-related communication? If the subject has questions, complaints, or adverse events, how will that be communicated to the researchers?

N/A

7. Check all that apply:

☒ **Written** *Attach copies of all consent forms for each subject group. Include a footer identifying the version date of each form and a header or title that identifies each different form. If you propose to delete one or more of the required elements of consent from a consent form, attach and complete the form called SUPPLEMENT: Waiver Request, Consent Requirements.*

See attachment (**Appendix 1**).

☒ **Waiver of written documentation of consent** *This means that you are requesting a waiver of the requirement to obtain written documentation of consent. Complete and attach the form called SUPPLEMENT: Waiver Request, Consent Requirements. . Also, attach the Information Statement, oral consent or assent protocol and script, or other materials you will use to communicate the necessary elements of consent to the subjects.*

See attachment (**Appendix 8**).

☐ **Waiver of consent** *This means that you are requesting a waiver of the requirement to obtain consent. Complete and attach the form called SUPPLEMENT: Waiver Request, Consent Requirements.*

☐ **Assent** *Attach copies of any written materials or scripts you will use with minor subjects (individuals under the age of 18) to obtain their assent to being in your research.*

☐ **Parental permission** *Attach copies of any written materials or scripts you will use with parents, to obtain their permission to enroll their minor children in your research. See also SUPPLEMENT: Protected and/or Vulnerable Populations for waivers or alterations of consent requirements.*

UNIVERSITY OF WASHINGTON
SEATTLE, WASHINGTON 98105-6613

Human Subjects Division, Box 3594722
Office of Research

February 19, 2015

PI: Associate Professor Brian Hafner, PhD
Rehabilitation Medicine/Prosthetics & Orthotics

Contact: Cody McDonald

Re: Human Subjects Application #49150, "Evaluation of a Modified Running Prosthesis"

Dear Dr. Hafner,

The Human Subjects Division received your application on 7/29/2014. Subcommittee E/A has reviewed this application under "expedited" minimal risk category #5 and #7. Thank you for your responses and for forwarding the revised materials. The above Human Subjects Application has been approved by Subcommittee E/A. The researcher copy of the approved application will be sent to you through campus mail.

The dates of the initial approval period are from: 2/19/2015 – 2/18/2016.

The approved number of subjects is: 24. In the event you want to enroll additional subjects for this study, please submit 2 copies of an **APPLICATION: Modification, Approved Project** form (available on the HSD website, under Forms).

Waiver of documentation of consent
The IRB has waived documentation of consent for researchers to ask screening questions during the recruitment process according to the stamped "approved" recruitment script.

IRB – approved consent forms
Located at the back of the approval packet are the stamped "approved" recruitment materials and consent forms. Per HSD policy, it is necessary for you to make copies of the stamped "approved" consent form to use with potential subjects.

The researcher copy of the approval packet will be sent through campus mail. It is the PI's responsibility to maintain all IRB materials.

- In the event you will revise the purpose, procedures and/or population of this application, be sure to send 2 copies of a Modification for review and approval prior to implementing the changes.

- Be sure to close the study upon completion of the study (or alternatively, renew the study) by sending 2 copies of a Status Report.

Be sure to reference the Human Subjects Application number and investigator on all materials sent to the Human Subjects Division, Box 359470.

Best wishes for your study -

Geri C. Faris, HSR Administrator
Human Subjects Division
(206) 616-2345

UNIVERSITY OF WASHINGTON CONSENT FORM

Evaluation of a Modified Running Prosthesis

Researchers: Brian Hafner, PhD, Associate Professor, Division of Prosthetics and Orthotics, Department of Rehabilitation Medicine, 206-685-4048

Patricia Kramer, PhD, Associate Professor, Department of Anthropology, 206-616-2449

Cody McDonald, L/CPO, Graduate Research Assistant, Division of Prosthetics and Orthotics, Department of Rehabilitation Medicine, 206-221-6347

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

The purpose of the study is to evaluate walking in people who use different types of prosthetic feet. In this study, we will compare people's ability to walk in a typical "energy storing" foot to their ability to walk in a modified running foot.

STUDY PROCEDURES

If you choose to take part in this study, the study procedures will take place across three study sessions over approximately a three month period. The first session will occur before you receive the first of the two prostheses that will be provided to you during the course of this study. The second session will occur one month after you receive the first prosthesis. The third session will occur one month after you receive the second prosthesis. The sessions are expected to each take between 1.5-3 hours to complete.

Session 1: Session 1 is expected to take about 1.5 hours. At the first session, you will be asked to complete a survey and walk on a treadmill using your current prosthesis. The survey will ask your age, ethnicity, income, military status, education, and height and weight. We will also ask questions about the date and cause of your amputation. You do not have to answer every question.

Next, you will be asked to walk on a treadmill at three speeds: comfortable, slow, and fast. You will be allowed to choose these three speeds by increasing and/or decreasing the speed on the

treadmill. You will then be asked to walk for 6 minutes at your preferred fast speed. You may reduce the speed as needed to ensure that you can continue at this pace for 6 minutes.

You will also be informed about the prosthetic foot that you will receive first (the energy storing foot or the modified running foot). You will receive this prosthesis from Greg Davidson at Davidson Prosthetics at a time that you schedule with his office. You will be asked to wear this prosthesis in place of your current prosthesis for a period of one month. Please adhere to your normal wear schedule, as recommended by your prosthetist.

You will also be given an activity monitor to attach to your study prosthesis. This device measures the number of steps you take throughout the day. We will show you how to attach the monitor to your prosthesis. We request that you leave the monitor on your prosthesis until we remove it.

Session 2: Session 2 is expected to take about 3 hours. You will come to this session wearing the first prosthesis you were assigned. At this session, you will be asked to complete a survey that will ask you questions about your ability to move around with your prosthesis, tiredness, balance, activities that you engage in, and satisfaction with your prosthesis. Throughout this session, you will be able to rest when you feel like it and we will give you water to drink.

You will be asked to wear a lightweight oxygen mask and waist pack during the some of this session. The oxygen mask helps us determine how much energy you use when you walk. You will be asked wear the mask while you sit for 5 minutes and then to stand for 5 minutes so we can measure your breathing while you are not active. You will then temporarily remove the oxygen mask.

You will next be asked to complete a walking test called the Six-Minute Walk Test. For this test, you will be asked to walk back and forth between two cones for 6 minutes. While walking back and forth between the cones, you will be asked to walk across a mat. This mat records the steps you take while walking. You may rest at any point and a chair will be brought to you if you would like to sit during the test. You will be instructed to walk as quickly as possible during this test. You may use an assistive device, such as a cane or walker, when performing this test. We will record the total distance you walked during the test. Following the Six-Minute Walk Test, we will ask you to report your level of exertion on a scale from 0-100. A rating of 0 indicates no exertion at all and a rating of 100 indicates maximal exertion. This test will take under one minute.

You will next be asked to put the oxygen mask on again. You will wear this mask while walking at your comfortable, slow, and fast walking speeds for a total of 18 minutes (6 minutes at each speed). You will be asked to rest for at least 5 minutes between each period of walking to make sure your breathing returns to normal. You will be able to rest when you feel like it and we will give you water to drink.

Following this session, you will return to Davidson Prosthetics to receive your second prosthesis at a time that you schedule with his office. You will be asked to leave your first prosthesis at the office and wear the second prosthesis as your primary prosthesis for an additional month.

Session 3: Session 3 is expected to take about 3 hours. You will come to this session wearing the second study prosthesis. Study activities for Session 3 will be identical to those in Session 2 (above).

You may choose not to complete any of these tests at any time during the session.

We would like your permission to take photographs and videos of you during this study so that we have an accurate record. Please indicate below whether or not you give your permission.

We may ask for your additional permission to use the photographs and recordings outside this research study. We may want to use them publicly and keep them indefinitely. We will give you opportunity to review the photographs and recordings before giving your permission.

RISKS, STRESS, OR DISCOMFORT

We ask you to walk for about 30 minutes during the study session. Some people may become tired. The risk of falling is about the same as walking in your daily activities. You can take a break or sit down whenever you like. If the researchers notice fatigue or risk of falling, they will end the study session.

ALTERNATIVES TO TAKING PART IN THIS STUDY

The alternative to taking part in this study is to not take part in this study.

BENEFITS OF THE STUDY

You will not directly benefit from participating in this study. However, the Modified Cheetah is a promising prosthetic foot. Research involving this foot will help make it available to others who may benefit from its use.

SOURCE OF FUNDING

The study team is receiving financial support for this research from the University of Washington Royalty Research Fund.

CONFIDENTIALITY OF RESEARCH INFORMATION

The information you provide to us during the study is confidential. We will protect the information we collect about you using a unique code. The link between your name and this code will be kept in a safe place apart from the information we collect about you. We will keep this link until 2026 so that we contact you if we have any questions. You may request that we destroy this link at any point during or after the study.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

The U.S. Food and Drug Administration (FDA) reserves the right to review study data that may contain identifying information.

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.

OTHER INFORMATION

Taking part in this study is voluntary. You can stop at any time. You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

You are responsible for your transportation to and from the study session.

You will be offered payment for your participation in this study. You will receive $30 per hour for the first session and $50 per hour for the second and third sessions.

It is UW policy that we record your name and address for any participant payments made to you.

We will give you a sticker that will pay your parking costs while you are attending study sessions.

You will also be allowed to keep both prostheses at the end of the study. Warranty terms for your modified running prosthesis will be provided by Davidson Prosthetics. The energy storing prosthesis is yours to keep, but does not include a warranty of any kind.

We may combine information we collect from you in this study with information from similar studies in the future. We may use your study information in the future for related studies.

We may ask you to keep photographs or video recordings indefinitely and to use them publicly. We will give you an opportunity to review the photographs and video recordings before giving your written consent.

RESEARCH-RELATED INJURY

If you think you have a medical problem or illness related to this research, contact Brian Hafner at 206-685-4048 or Cody McDonald at 206-221-6347 right away. They will refer you for treatment.

Printed name of study staff obtaining consent	Signature	Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

☐ I give my permission for the researchers to photograph the study procedures as described above in this consent form.

☐ I give my permission for the researchers to videotape the study procedures as described above in this consent form.

Printed name of subject	Signature of subject	Date

Copies to: Researcher
Subject