Official Title:

Orthotic Treatment of Diabetic Foot Ulcers: Patient Adherence to Prescribed Wear and Effectiveness of Treatment

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Participant Name:	Date:
Title of Study: Orthotic Treatment of Diabetic Foot Ulcers: Patient Adherence to Prescribed Wear and Effectiveness of Treatment	
Principal Investigator: Muturi Muriuki	

SUMMARY

The research is being conducted to better understand how effective the Removable Cam Walker (RCW) boot is in treating diabetic foot ulcers. You are eligible to participate as a patient with a diabetic foot ulcer.

If you agree to join the study, you will be asked to complete the following research procedures:

1. Wear the provided Removable Cam Walker boot as directed by the doctor.
2. Meet with the Study Coordinator at each Podiatry Clinic follow-up visit.

Your participation will last until your diabetic foot ulcer heals. On average, 8 months.

Participants are not expected to gain any benefit.

The most common risk of participation is discomfort from wearing the Removable Cam Walker boot.

Please note that there are other factors to consider before agreeing to participate, such as additional procedures, use of your personal information, costs, and other possible risks not included here. If you are interested in participating, a member of the study team will review the full information with you. You are free to not participate or stop participating at any time during or after the consenting process.

INTRODUCTION

You are being invited to participate in a research study that is being carried out at the Edward Hines Jr. VA Hospital. Your participation is voluntary and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. The sponsor of the study is the Rehabilitation Research and Development Service of the Department of Veterans Affairs. If you have any questions about your rights as a human research participant at any time before, during, or after participation, please contact the Institutional Review Board (IRB) at (708) 202-2811 for assistance. If you have questions about this study, you may contact the Principal Investigator, Muturi Muriuki, [redacted].

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

Participant Name:	Date:
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BACKGROUND AND PURPOSE

Removable Cam Walker boots are prescribed as part of the usual treatment for diabetic foot ulcers. The research is being conducted to better understand how effective the Removable Cam Walker (RCW) boot is in treating diabetic foot ulcers. You will be provided with a modified RCW boot that will give researchers data on how the boot is being worn.

The clinical research study is sponsored by the Rehabilitation Research and Development Service of the Department of Veterans Affairs. The study will be conducted by personnel from Research Service and [redacted] and [redacted] from Podiatry at the Edward Hines Jr. VA Hospital.

Any patient prescribed a Removable Cam Walker boot by Podiatry for their diabetic foot ulcer is eligible to participate in this study.

160 patients will be enrolled in this study. Edward Hines Jr. VA Hospital is the only location where this research is taking place.

DURATION OF THE RESEARCH

Your individual participation in the project will be until your foot ulcer heals. On average, this takes 8 months.

STUDY PROCEDURES

If you decide to take part in this study, this is what will happen:

- Removable Cam Walker boots are provided as part of the standard treatment for diabetic foot ulcers. You will be provided with a modified Removable Cam Walker (RCW) boot by the Study Coordinator. [redacted] The modification does not change the way the RCW boot works. The boot is to be worn as directed by the doctor.
- You will meet with the Study Coordinator in the Hines VA Podiatry clinic when you have your follow-up visits. This meeting with the Study Coordinator will be for the purpose of the research study.
    - While in the waiting area before seeing the Doctor, the Study Coordinator may ask you to fill out a survey. You are free to skip any questions you prefer not to answer.
    - After meeting with the Doctor, the Study Coordinator may ask you questions about your experiences with wearing the RCW boot.
- While in the waiting area before seeing the Doctor, one of the Research team will download data from the boot and replace or fix any RCW boot that is no longer functioning properly.
- You will likely spend 10 to 15 minutes with one of the Research team at each visit. However, the total time spent with one of the Research team could total 45 minutes. Some of this time will be while you are waiting to be seen in the Podiatry clinic.

Health Care Provider Responsibilities

The RCW boot is provided as part of the usual care. Your health care provider will explain the potential risks and benefits of wearing the RCW boot. The health care provider will monitor your diabetic foot ulcer and document the clinical course of treatment. The health care provider will alert the participant if there is a problem with the treatment.

Research Team Responsibilities
The members of the research team that you may have contact with are [redacted] (Principal Investigator), [redacted] (Co-Investigator) and the Study Coordinator. The modified RCW boot will be provided to you by one of the Research team. [redacted] the modified RCW boot is identical to the boots provided by the Hines VA Podiatry clinic. The Research team will be responsible for administering surveys. You are free to skip any questions you prefer not to answer. The Research team will be responsible for administering interviews. An audio recording may be made of the interview. This recording will be used for continued training, supervision and assessment of the effectiveness of the interview. The recordings will not be shared outside the VA.

Joint Health Care Provider and Research Team Responsibilities
The joint team (Podiatrists and Researchers) will define if any adverse events are a result of usual care or research.

This study uses a procedure similar to a coin flip so that you will have a 1 in 2 chance of being in the group that completes surveys at each Podiatry clinic visit and participates in the interviews. The health care provider will not know which group you have been assigned to.

You will be asked if you are participating in any other research studies.

Your responsibilities as a participant are:

- To wear the Removable Cam Walker boot as directed by the Doctor.
- To meet with the Study Coordinator or one of the Research team at each follow-up visit.
- Complete your surveys as instructed.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this research, as well as that of the other studies.
- Return the modified Removable Cam Walker boot at the completion of the study or if you are withdrawing from the study. A replacement un-modified RCW boot will be provided by the health care provider to withdrawing participants.

POSSIBLE RISKS OR DISCOMFORTS

If in the opinion of the Principal Investigator a participant is no longer appropriate for the study, he or she may be discontinued without regard to the participant's wishes. This would apply if a participant does not

comply with the requirements for participation, if it becomes medically unsafe for the participant to continue, if a study is stopped by a sponsor, if the Department of Health and Human Services withdraws approval, etc.

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

- Participation in research may involve a loss of privacy. Audio recordings that may be made during interviews may include private information. Your research records and any audio recordings made will be kept as confidential as possible.

POTENTIAL BENEFITS

There are no direct benefits to you from your taking part in this research study. However, the information we get from this study might help us treat future diabetic foot ulcer patients.

CONFIDENTIALITY

Taking part in this study will involve collecting private information about you. Information will be protected in the following ways:

- Study data and records will be locked in filing cabinets in a restricted access, secured Research area at Hines. Data will be stored in a secured folder on the Hines Research service partition of the VA server. Access to the secured folder will be controlled through password protection (VA PIV Computer/Network Access) and folder Read/Write access privileges. Only members of the research team will have access to the data and records.

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

The information collected for this study will be kept confidential. There are times when we might have to show your records to other people. Only authorized persons will have access to the information gathered in this study. Authorized persons may include regulatory agencies such as the Food and Drug Administration, (FDA), the Government Accounting Agency (GAO) or the Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), as well as members of the Research Administration staff of Edward Hines Jr. VA. The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for all veteran and non-veteran research participants. By signing this document, you consent to such inspection.

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

This informed consent form does not give the study doctor permission to access, record, and use your private health information. You will be given a separate HIPAA form which provides more information about how your private health information will be used in this study, who will have access to your records, and how you can revoke (take back) your permission in the future. You will not be able to participate in this study if you do not sign the separate HIPAA authorization form.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants*:*

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

Payment Offered for Participation:

You will receive a one-time payment of $100 by check or electronic fund transfer upon completion of the study of if they are withdrawn from the study because it is medically unsafe for the participant to continue the study. Participants who elect to withdraw from the study will not receive payment. An IRB 1099 form will be issued to you for this payment. This will require the use of your Social Security Number.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

According to federal regulations (Title 38 CFR17.85), the VA will provide necessary medical treatment to you as a research participant if you are injured by participation in this research project approved by the Research & Development Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, this care will be provided at this VA facility.

This does not apply to treatment for injuries that result from non-compliance by you with study procedures.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

Dr. Muturi Muriuki at [redacted] and

AFTER HOURS:

Dr. Muturi Muriuki at [redacted].

Emergency and ongoing medical treatment will be provided as needed.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

PARTICIPATION IS VOLUNTARY

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

Contact a member of the research team if you decide to withdraw from the study so that arrangements can be made to retrieve the modified Removable Cam Walker boot and provide you with an un-modified boot. The investigators may continue to review and use any data collected prior to notification of withdrawal from the study and retrieval of the RCW boot.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

The Principal Investigator may terminate participation if a participant does not comply with the requirements for participation, if it becomes medically unsafe for the participant to continue, if a study is stopped by a sponsor, if the Department of Health and Human Services withdraws approval, etc.

Arrangements will be made to retrieve the modified Removable Cam Walker boot and provide an un-modified boot at the patient's next Podiatry clinic visit.

FUTURE USE OF DATA

After removal of identifiers from identifiable private information, data collected in this study may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative. Data will be stored in a secured folder on the Hines Research service partition of the VA server. Access to the secured folder will be controlled through password protection (VA PIV Computer/Network Access) and folder Read/Write access privileges.

CLINICALLY RELEVANT RESEARCH RESULTS

Clinically relevant research results will not be shared with participants.

ADDITIONAL CONTACT INFORMATION

If at any time before, during or after your participation in this study you have questions or concerns, want to get additional information, lodge a complaint or offer your input with a person who is not part of the study team, you can contact the IRB Administrator at 708-202-2811.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ _____ has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

_____ / /

Signature of Participant Date Written by Participant