Allegheny Health Network

INFORMED CONSENT FORM AND AUTHORIZATION TO DISCLOSE PROTECTED HEALTH INFORMATION FOR A RESEARCH STUDY

TITLE: Immediate Weight-bearing verses Non-Weight-bearing after Foot & Ankle Surgery: A Prospective Analysis.

IRB#: 2019-124JH

PRINCIPAL INVESTIGATOR: Ryan L. McMillen, DPM, FACFAS

CO-INVESTIGATOR: Christopher J. Betrus, DPM
Alan R. Catanzariti, DPM, FACFAS

INSTITUTE ADDRESS: Steel Valley Orthopaedic and Sports Medicine
1200 Brooks Lane, Suite #240
Clairton, PA. 15025
412-469-1660

CONCISE SUMMARY

This is a research study to determine the difference in outcomes between weight-bearing immediately following your foot and/or ankle surgery compared to the standard of care non-weight-bearing following your foot and/or ankle surgery. This project is considered "Research" and participation is voluntary. We are inviting you to participate in this research study because you are having an elective surgical procedure of your foot and/or ankle. Upon enrollment in the study you will be randomized to one of two study groups: immediate protected weight bearing in a CAM walking boot or strict non-weight-bearing for 6 weeks after your foot and/or ankle surgery. You will be monitored for a period of 2 years by way of 2 questionnaires, clinical visits and x-rays which is standard of care after your surgery.

Picture of Cam Walking Boot

There are risks to this study which are: Exposure to radiation from x-rays although this is minimal; the potential loss of confidentiality but will be minimized by only the research team accessing the research data and PHI; the immediate weight bearing group has the potential for pain associated with weight bearing on the surgical foot/ankle and potential wound complications with the surgical incision but we will minimize the risk by close monitoring and follow up with this group. If you are interested in learning more about this study please continue reading below.

WHAT YOU SHOULD KNOW ABOUT A RESEARCH STUDY:

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- Someone will explain this research study to you.
- Being in a research study is voluntary. You can choose to not take part in the research study or agree now and change your mind later.
- Whether or not you take part is your decision.
- You can choose to not take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide will not be held against you.
- Feel free to ask all the questions you want before you decide.
- "You" refers to you as a participant in this study.

Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Please tell the study doctor or study staff if you are taking part in another research study.

WHO CAN I TALK TO IF I HAVE QUESTIONS?

If you have questions, concerns, or complaints, or think the research has hurt you, you should contact the principal investigator, Dr. Ryan McMillen at (412) 469-1660 during regular business hours (Monday – Friday 7:30am until 4:30pm, EST) or Dr. Christopher Betrus any time by paging him at (734) 748-2435.

This research study has been reviewed and approved by AHN-RI Institutional Review Board (IRB). You may talk to them by calling this toll free number, 1-844-577-4621, for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research

WHY ARE WE INVITING YOU TO DO THIS RESEARCH?

We invite you to take part in this research study because you are having an elective surgical procedure of your foot and/or ankle. This study will examine if immediate weight-bearing following foot and ankle surgery will provide equal if not better results than the standard of care non-weight bearing course. We will measure the length of rehabilitation to recovery between the two groups through clinical follow-up, x-rays, and questionnaires you will answer which will help us determine patient satisfaction.

HOW LONG WILL THE RESEARCH LAST?

Your participation in this study is planned as 8 visits to the clinic over the course of 2 years. Once your screening visit is complete, if eligible you will undergo your surgical procedure. You will be randomized to one of 2 groups. You will have 6 visits to the clinic after your surgical procedure over the course of two years which is routine follow-up after your type of surgical procedure. During these visits you will have a physical exam and assessment, and x-rays or other images, which is standard of care. You will be asked to fill out 2 questionnaires where you will be asked to provide some information about your physical activity and physical abilities. The enrollment will conclude once we recruit 230 participants, which could take up to 3 years.

HOW MANY PEOPLE WILL BE STUDIED?

There will be 230 people asked to take part in this study.

WHAT HAPPENS IF I SAY YES, I WANT TO BE IN THIS RESEARCH?

- The surgical procedure will be discussed with you.
- The researchers will review the research study with you and review the informed consent form where you will be asked to sign.
- You will undergo radiographs/x-rays or advanced imaging of your effected foot which is standard of care prior to your surgery.
- The physician will review your medical records to determine if you are eligible to participate in the research study and randomize you to one of the two study groups. Randomization will be 1:1, like the flip of a coin. There is an equal chance of you will be assigned to either of the two study groups.
- You will be asked to fill out 2 questionnaire surveys, where you be asked to provide some information about your physical activity and physical abilities.

- You will be scheduled for your surgical procedure, sign the operative consent and the surgery will be performed.
- Both study groups will be scheduled for the following post-operative follow-up visits:
    - 2-3 week Post-op to include radiographs, suture removal, medical record review and physical exam.
    - 6-8 week Post-op to include radiographs, physical exam, medical record review and post-op survey/questionnaires.
    - 3 month Post-op to include radiographs, physical exam, medical record review and survey/questionnaires.
    - 6 month Post-op to include radiographs, physical exam, and medical record review.
    - 12 month Post-op to include radiographs, physical exam, medical review and survey/questionnaires.
    - 24 month Post-op to include radiographs, physical exam, medical record review and survey/questionnaires.

WHAT HAPPENS IF I SAY NO, I DO NOT WANT TO BE IN THIS RESEARCH?

You may decide not to take part in this research and it will not be held against you. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. Your alternative is to not participate in this study. You may choose to have your surgical procedure without participating. You will receive your standard of care for your surgical procedure regardless if you participate or not.

WHAT HAPPENS IF I SAY YES, BUT I CHANGE MY MIND LATER?

If you agree to take part in the research now you may stop at any time and it will not be held against you. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. This authorization will not expire unless you revoke it in writing. You may revoke or end this authorization by writing to the Principal Investigator:

Dr. Ryan L. McMillen
Steel Valley Orthopaedics and Sports Medicine
1200 Brooks Lane, Suite #240
Clairton, PA 15025

If you revoke your authorization, you will be removed from the study. Revoking your authorization only affects the use and sharing of your health information after the written request is received. You will be asked if you only want to discontinue from treatment and questionnaire and still allow your medical records to be reviewed. Any information that has been previously collected prior to withdrawal from the research may continue to be used for research purposes.

IS THERE ANY WAY THAT BEING IN THIS STUDY COULD BE BAD FOR ME?

There may be some risks in this study as outlined below.

- During your visit to the clinic you will undergo radiographs/x-rays of your surgical ankle/foot. This is standard of care for your post operative surgical procedure.
- X-rays expose you to radiation, but generally the dose involved in general x-rays is quite small.
- There are no increased risks associated with the control arm of the study, which is a traditional non-weight-bearing period of 6 weeks following foot and ankle surgery.
- The risks associated with the study arm, which is immediate weightbearing following foot and ankle surgery, include evidence of higher than expected potential pain with weightbearing on the surgical extremity; potential wound complications associated with the surgical incision sites; possible hardware failure; possible non-union, mal-union, or delayed union during osseous healing; and/or possible non-healing or delayed healing of soft tissue structures.
- All of the potential risks, including pain, non-union, non-healing, infection, wound complications, and others are possible regardless of the post-operative course.
- There is a potential risk for loss of confidentiality in this study which will be minimalized by only the research team accessing the research data and your PHI.
    - Unique patient study specific identifiers will be used during data collection and all data forms will be maintained in a locked cabinet in the research coordinator's office.
    - No PHI will be transferred, shared or stored on personal computers.
- You will be asked to fill out questionnaires. Because the questionnaire has study specific identifiers they pose a minimal risk at best of your protected health information. In addition, you can skip any questions that you are not comfortable answering.

WILL BEING IN THIS STUDY HELP ME IN ANY WAY?

You may not directly benefit from taking part in this study, however by gaining a greater understanding of the treatment results following surgery of the foot and ankle, physicians may more effectively make treatment decisions using the information acquired from this study based on medical evidence. With this knowledge we can institute a treatment guideline. The potential benefits based on previous immediate weight bearing studies are:

- Reduced muscle loss of the surgical foot and/or ankle.
- Reduced stress on the non-surgical leg, foot and/or ankle.
- Reduced need for rehabilitation following healing of the surgical foot and/or ankle.
- Return to activity sooner than the non-weight-bearing group.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Your identity and medical records and data related to this study will be kept confidential, except as required by law and except for inspections by the U.S. Department of Health and Human Services (HHS), Allegheny Health Network, the Allegheny Health Network Research Institute, the AHN RI Institutional Review Board (the committee formed to protect the rights and welfare of human subjects involved in research activities being conducted under its

authority) and the AHN Compliance Office. Results of the research may be published for scientific purposes or presented to scientific groups, however, your identity will not be revealed.
Federal law provides additional protections of your personal health information. These are described below in the **HIPAA Authorization Statement below.**

WHAT HAPPENS TO MY COLLECTED DATA?

During this research private identifiable information may be obtained from records or collected as you complete study procedures and visits.

None of you records or images collected as part of this research, even if your personal identifiers are removed, your information and x-rays will not be used or distributed for future research studies.

CAN I BE REMOVED FROM THE RESEARCH WITHOUT MY APPROVAL?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal includes lack of adherence to the study treatment, visit schedule or if the P.I. determines this to be in your best interest.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

ARE THEIR COSTS OF PARTICIPATING IN THIS STUDY?

You will not be paid for your participation in this research study, however you will be provided with discounted parking for each visit to the (WPH) clinic, should you go there for your care. All of the other facilities offer free parking. There are certain tests and examinations that are part of the normal standard of care for patients that have had a foot and/or ankle surgery. The cost for the standard of care items will be billed to you or your insurance company as usual. If you require medical care for your surgery procedure or other health problems, as part of your routine care (care you receive even if you do not participate in this research study), either you or your insurance carrier will be billed for these charges.
Please also talk with the study doctor about any expected added costs or health insurance problems.

WHAT IF I AM INJURIED WHILE TAKING PART IN THIS STUDY?

- If you experience a research related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.
- If you are injured or made sick while taking part in this research study, emergency medical treatment will be provided at the usual charge. No funds have been set aside by Allegheny Health Network or Allegheny Health Network Research Institute to pay you in case you are injured. You do not waive any of your legal rights to compensation, if any, by signing this form.

AUTHORIZATION TO USE AND DISCLOSE INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION FOR A RESEARCH STUDY

Before you can take part in this research study, the Allegheny Health Network is required to obtain your authorization to use and/or disclose (release) your health information. This section describes to you how, and to whom, your health information will be used and/or disclosed (shared) while you are participating in this research study. It is important that you read this carefully. Allegheny Health Network and its' researchers are required by law to protect your health information.

The following is a list of health information that will be used and/or disclosed:

- Date of birth/age
- Sex
- Medical history
    - History of Smoking
    - History of Diabetes
- Date of admission/surgery
- Surgical procedure performed
- Results of the physical exam
- Radiographs with results
- CT with results
- Height and Weight (BMI)

The following is a list of entities that may use and/or disclose your health information as part of this study:

Internal Oversight

Those who oversee the study will have access to your health information, including the following:

- Allegheny Health Network (AHN)
- Allegheny Health Network Research Institute
- AHN Compliance Office
- The AHN IRB
- The study doctor and study staff

Governmental Oversight

Your health information may also be shared with government agencies that have oversight of the study or to whom access is required under the law:

- U.S. Department of Health and Human Services

In order to participate in this study, you must agree to share your health information with the persons and organizations listed above. If these persons or organizations that you authorize to receive and/or use protected health information, are not health plans, covered health care providers or health care clearinghouses subject to federal health information privacy laws, they

may further disclose the protected health information and it may no longer be protected by the federal health information privacy laws.

EXPIRATION OF AUTHORIZATION

This authorization will not expire unless you revoke it in writing. You may revoke or end this authorization by writing to the Principal Investigator:

Dr. Ryan L. McMillen
Steel Valley Orthopaedic and Sports Medicine
1200 Brook Lane, Suite #240
Clairton, PA 15025

If you revoke your authorization, you will be removed from the study. Revoking your authorization only affects the use and sharing of your health information after the written request is received. Any health information obtained prior to receiving the written request may be used to maintain the integrity of the study.

AUTHORIZATION

By signing this document (authorization), you authorize that your health information can be used and/or disclosed as described. Your access to your protected health information created or obtained by Allegheny Health Network in the course of the research (that includes treatment) may be temporarily suspended for as long as the research is in progress. By signing this document, you are agreeing to the denial of access to your protected health information, created for research, while you are participating in this research study. Your access to your protected health information will be reinstated upon completion of the research.

If you choose to not sign this document, you will not be permitted to participate in this research study.

CONSENT- SIGNATURE BLOCK FOR CAPABLE ADULT

Your signature below indicates your permission to take part in this research and to the use and disclosure of your protected health information. A copy of this signed document will be provided to you:

_____ _____am/pm
Signature of subject Date/Time

_____
Printed name of subject

_____ _____am/pm
Signature of Witness to Signature Date/Time

_____
Printed name of Witness to Signature

_____ _____am/pm

Signature of Physician Investigator Date/Time

_____

Printed name of Physician Investigator