**UNIVERSITY OF WISCONSIN-MADISON**

**Subject ASSENT and Parental CONSENT to Participate in Research**
**And**
**AUTHORIZATION to Use and/or Disclose Identifiable Health information for Research**

**Title of the Study:** The Onset, Impact and Outcomes of Acute Ankle Injuries in Adolescent Athletes**.**

**Principal Investigator:** Tim McGuine, PhD LAT **(phone:608-263-8786) (email: tmcguine@uwhealth.org)**

**Mailing Address:** 621 Science Drive, Madison WI 53711

**INVITATION**

You are invited to participate in this research study about ankle injuries in high school athletes age 14 to 18. You are invited to take part because you are a high school athlete and susceptible to have an ankle injury while playing sports. Approximately 1200 individuals will participate in this study.

Your participation in this research study is voluntary. If you decide not to participate, the health care provided to you by the University of Wisconsin-Madison (UW-Madison) and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) will not be affected in any way.

Your decision to participate or not participate in this study will not affect your team status or participation in other high school sports.

**A. WHAT IS THE PURPOSE OF THIS STUDY?**

The purpose of the study is to investigate how ankle injuries affect your health, ankle function and ability to play sports for up to a year.

**B. WHAT WILL MY PARTICIPATION INVOLVE?**

If you decide to participate in this research you will be asked to complete 1 short survey prior to the start of the sports season. The survey gathers information regarding 1) your sport participation, 2) previous ankle injuries you may have had and also includes a measure of 3) how you are feeling (quality of life) 4) the function of your right and left ankles and 5) your activity level. The total time to complete the initial survey is 10 minutes.

If you have an ankle injury while playing your sports, your school athletic trainer will notify the research staff at the University of Wisconsin who will contact you by phone. If you have an ankle injury you will be asked to take a shorter (5 minute) survey, with similar questions, 6 more times at specific intervals (7 days and at 1, 3, 6, 9 and 12 months) after your injury. The post injury surveys can be completed at your school with your licensed athletic trainer, or at your home. We will send you the surveys through the US mail or electronically to your email account or you may be asked to complete them over the phone by talking with one of our research staff. Completing the surveys will not interfere with the standard clinical care that is given to you by your licensed athletic trainer or your physician.



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If you don't have an ankle injury, there is a slight possibility (7% chance) that you may be asked to be in the control group for this study. We will ask people in the control group to complete the same series of surveys to see how athletes without an ankle injury answer the surveys.

**We will also collect the following information about you for this research study:**

1. From you: Your name, birth date, mailing address, phone numbers, school name.

## C. ARE THERE ANY BENEFITS TO ME?

You are not expected to benefit directly from participating in this study. Your participation in this research study may benefit other people in the future by helping us learn more about how high school student athletes recover from or are affected by an ankle injury.

## D. WILL I BE PAID FOR MY PARTICIPATION?

You will not be paid for your initial participation in this study. However, injured subjects and non injured controls who take part in the data collection will be paid $10 for each survey they complete ($60 total).

## E. ARE THERE ANY SIDE EFFECTS OR RISKS TO ME?

The main risk of taking part in this study is that your study information could become known to someone who is not involved in performing or monitoring this study. A breach of confidentiality could result in damage to you or your reputation, but the chances that this will happen are very small.

## F. HOW WILL MY PRIVACY BE PROTECTED AND WHO WILL USE MY HEALTH INFORMATION?

All subject data that is recorded on paper forms will be safeguarded by: a) Assigning each subject a unique subject identification number not related to name, birth date or any other identifiable information b) Locking the research files while they are unsupervised and c) Shredding excess copies of paper documents. Each subject's number will be kept on a password-protected personal computer in the Principal Investigator's locked office and separate from collected data. Study data will be stored in a password protected electronic research database maintained by the University of Wisconsin Department of Orthopedics. Access to the folder will be restricted to research project staff. The study data will not include any subject identifiers, and no identifiable subject information will be used in final publication.

The information collected from you during this study will be used by the researchers and research staff of the UW-Madison and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) for this study. It may also be shared with others at the UW-Madison and outside the UW-Madison.

**Others at UW-Madison and its affiliates who may need to use your health information in the course of this research:**

• UW-Madison regulatory and research oversight boards and offices



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**Others outside of UW-Madison and its affiliates who may receive your health information in the course of this research:**

• NONE

People outside the UW-Madison and its affiliates who receive your health information may not be covered by privacy laws and may be able to share your health information with others without your permission. Usually when we share information from research studies with others outside the UW-Madison and its affiliates, it is not shared in a way that can identify an individual.

## G. IS MY PERMISSION VOLUNTARY AND MAY I CHANGE MY MIND?

Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you refuse to sign this form, however, you cannot take part in this research study.

You may completely withdraw from the study at any time. You also may choose to cease participation or skip any questions that you do not feel comfortable answering.

**IF YOU DECIDE NOT TO PARTICIPATE IN THIS STUDY OR IF YOU STOP WHILE THE STUDY IS UNDERWAY, THE HEALTH CARE YOU RECEIVE FROM THE UW-MADISON AND ITS AFFILIATES OR YOUR SCHOOL LICENSED ATHLETIC TRAINER WILL NOT BE AFFECTED IN ANY WAY.**

## H. HOW LONG WILL MY PERMISSION TO USE MY HEALTH INFORMATION LAST?

By signing this form you are giving permission for your health information to be used by and shared with the individuals, companies, or institutions described in this form. Unless you withdraw your permission in writing to stop the use of your health information, the end date for its use for this research study is 6/30/2015. You may withdraw your permission at any time by writing to the person whose name is listed below:

Tim McGuine, PhD LAT  621 Science Drive, Madison WI 53711

Beginning on the date you withdraw your permission, no new information about you will be used. Any information that was shared before you withdrew your permission will continue to be used. If you withdraw your permission, you can no longer actively take part in this research study.

## I. WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

Please take as much time as you need to think over whether or not you wish to participate. If you have any questions about this study at any time, contact the Principal Investigator Tim McGuine, PhD LAT at (608)-263-8786.

If you are not satisfied with response of research team, have more questions, or want to talk with someone about your rights as a research participant, contact the UWHC Patient Relations Representative at 608-263-8009 or University of Wisconsin Medical Foundation Patient Relations Representative at 800-552-4255 or 608-821-4819.



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**AGREEMENT TO PARTICIPATE IN THIS STUDY**
**AND**
**PERMISSION TO USE AND/OR DISCLOSE MY HEALTH INFORMATION**

I have read this consent and authorization form describing the research study procedures, risks, and benefits, what health information will be used, and how my health information will be used. I have had a chance to ask questions about the research study, including the use of my health information, and I have received answers to my questions. I agree to participate in this research study, and permit the researcher to use and share my health information as described above.

**Name of Participant (please print):**_____

_____ _____
Signature of Participant Date

**** If you are under the age of 18 we also need your:**

**Name of Parent / Guardian (please print):**_____

_____ _____
Signature of Parent / Guardian Date

**Signature of person obtaining consent and authorization:**

_____ _____
Signature of Person Obtaining Consent/Authorization Date

**YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT.**



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