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IRB EXPIRATION DATE: 11/16/2016

UNIVERSITY HOSPITALS
CASE MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v. 11.2012)

Project Title: The Impact of Achilles Tightness on Lower Extremity Injuries in Adolescent Athletes

Principal Investigator: Raymond Liu, M.D.

Introduction/Purpose

You/Your child, hereafter referred to as "You" is being invited to participate in a research study because you are actively involved in a sporting activity (football, basketball, soccer, volleyball) in which the physical demands of the sport could lead to injury. Stretching prior to athletic activity has been shown to be help decrease the rate of injuries to young athletes involved in competitive sports. Tightness of the Achilles tendon (tendon running from the back of the leg to the heel) may alter mechanics in the ankle and foot, having an impact on how one walks and runs. This may lead to increased injury rates in not only the foot and ankle, but also injuries in the arms, shoulders and back. The purpose of our study is to determine if reducing the tightness of the Achilles tendon by stretching in young, active athletes decreases the rate of injury over the course of a sporting season. The results from this study may help us find preseason, in-season and/or post-season exercises and stretches that can decrease the risk of athletic injuries, enabling athletes in Northeast Ohio area to achieve their full athletic potential. About 200 patients from 4 high schools located around Northeast Ohio will participate in this research study.

Participating in research is voluntary, which means the choice is up to you. Choosing not to participate will have no effect on the medical care that you receive. Furthermore, not participating in the study will have absolutely no impact on playing time during the season. As such, athletes or parent(s) wishing to not participate can be assured that declining enrollment will have no negative results. Declining enrollment will not change how the coaches or athletic trainers view you as an athlete. There is no pressure to participate. This form, called a consent form, explains everything that will happen to you if you decide to participate. Please read it carefully, and have all of your and your parent(s) questions answered before you make a decision. If you decide to participate, we will have you sign this consent form. You will be given a copy of this form to keep.

Study Procedures

If you agree to participate in this study, you will be asked to fill out a medical questionnaire which will be kept private and not seen by anyone except for the research team. You will also have your Achilles tightness measured by your school's athletic trainer prior to the season, multiple times during the season, and following completion of the season. This will be performed by lying on your back while your ankles and toes in dorsiflexion (toes pointed towards your head) to see how far your ankle can flex back. During the season, if any injuries occur, the athletic trainer will notify the research team. Your participation in this study will in no way have an impact on the medical care for any injuries that you will receive.

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For the study, all students from 2 of the 4 participating high schools will be randomly assigned to participate in a stretching protocol. As such, there is a 50% chance that you may be assigned to the stretching group. If you are assigned to the stretching group, you will be given a form that will show you the type of stretches you will be asked to perform on a daily basis during the sporting season. You will be asked to perform the stretches 3 times a day while enrolled and prior to any athletic activity (practice, conditioning, games). Your school's athletic trainers will serve as a resource to answer any and all questions regarding the study and point of contact with the investigative team. In addition, athletic trainers will serve to remind you to perform stretches as you are able to tolerate if you are selected to perform the stretching protocol. Athletic trainers will also be responsible for tracking all injuries during the course of the athletic season, which will be used to determine if any benefit exists from Achilles tendon stretches. If you are not assigned to the stretching group, you will not be given a stretching form and the research team will not ask you to perform certain stretches during the season, however stretching may still be recommended by your school's athletic trainer and coaches.

Risks

There is a small risk that stretching could lead to a small degree of pain or discomfort. There is also a small risk that stretching could contribute to rather than prevent injury, however your knowledge of your limitations should help avoid any potential stretching related injuries. As such, please do not stretch to the point of discomfort and if you experience any pain while performing the stretches, please stop and inform your athletic trainer. In addition, there is a risk that not being enrolled in the stretching protocol may increase the risk of injury during the athletic season. There is a risk that information about you could become know to others outside the research team. To protect your information, only members of the research team will have access to your information, which will be kept in secure files on protected computers within the University Hospitals network. Lack of compliance in the study will in no way impact an athlete's playing time.

Benefits

There is a possibility that being enrolled in the stretching protocol may help decrease your risk of injury over the course of the athletic season. Your participation may help us to learn new information that improves how we care for athletes in the future.

Alternatives to Study Participation

You or your parent(s) may choose not to participate in this study. If you decide to participate, you or your parent(s) can decide to stop participating at any time. You just have to let the athletic trainers know. Not participating in the study from the beginning or dropping out during the athletic season will have no impact on your playing time or medical care at any point.

Financial Information

You will not be paid for your participation in this study. No medical costs in case of injury will be covered.

Confidentiality

All of the information we collect about you will be kept confidential. You will be assigned a study

number, and this number will be used to identify your data. Information that identifies you will only be accessed by members of the study team, and will be kept secure on protected University Hospitals computers or on a password encoded flash drive.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "The Impact of Achilles Tightness on Injuries in Adolescent Athletes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Raymond Liu, MD and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: your name, your age, gender, recent injuries, underlying medical diagnoses, height, weight, and Achilles tightness measurement. This PHI will be used to assess multiple outcome variables as they relate to Achilles tightness and injury rates. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: co-investigators, other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to: Raymond Liu MD, Rainbow Hospital 3rd Floor Department of Orthopaedic Surgery, 11100 Euclid Ave, Cleveland, Ohio 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as

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permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Case Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Case Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Raymond Liu MD can also be contacted at 216-844-7200. . If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Case Medical Center's Research Subject Rights phone line at (216) 983-5633 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Case Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

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Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X	
Signature of Athlete	Date
X	
Printed name of Athlete	
X	
Signature of Parent/Legal Guardian	Date
X	
Printed name of Parent/Legal Guardian	
X	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

X	
Signature of person obtaining informed consent	Date
X	
Printed name of person obtaining informed consent	
X	
Signature of Principal Investigator	Date
X	
Printed name of Principal Investigator	

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