



**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

(HFH IRB form rev: 02/2009)

DATE:

MRN:

NAME:

**PROJECT TITLE:**

**Female ACL Prevention program**

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Detroit Mi 48202**

**1. WHY IS THIS RESEARCH BEING DONE?**

To make reading this consent form easier, the word “you” refers to you or your child (if a minor) throughout the consent form. This research is being done to study the effects of an eighteen-session strengthening program and to see if there is a relationship between the female athletes improving their landing techniques which has been proven to decrease anterior cruciate ligament injuries. You have been asked to take part in a research study because you are a female athlete involved in a sport that has an increased anterior cruciate ligament injury rate. The purpose of this research study is to find out if an eighteen-session strengthening program will decrease your anterior cruciate ligament injury rate. There will be approximately ninety-four (94) people in this research study at Henry Ford Health System (HFHS).


**2. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?**

There will be two groups of female athletes that will partake in this study: Both groups will go through two functional tests which will be video recorded, as well as complete activity and injury questionnaires. The functional tests will assess an athlete’s strength, balance, coordination and flexibility. One group will then go through an eighteen-session strengthening program. The other group will not attend the eighteen-session program, but may continue their normal pre-season routine.

Both groups will be tested and video recorded before and after the eighteen sessions. After one calendar year, all participants will be complete the same functional tests (which will be again video recorded), and fill out the same activity questionnaires. All video recordings will only be used for the purpose of this research project. These video recordings will be done in order to accurately measure lower body movements to determine any improvements made over the course of the program. Dartfish is a computer-based program which we will use to analyze and measure the extent of hip, knee, and foot movements.

Each participant’s confidentiality will be protected by assigning each participant a number. All information, data, video recordings, and results will be stored on a password secure computer, in a locked office. The surveys will be stored in a locked file cabinet in the same locked office.

The strengthening program will be eighteen sessions, with each session lasting approximately one hour. Each testing session (a total of 3, over the course of one year as mentioned above) will also last

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approximately one hour. You should have had contact with the Certified Athletic Trainer via email already. Since you have expressed an interest in participating, you have met with the Athletic Trainer to receive this information, and have the opportunity to meet again to return these forms and address any questions or concerns. Overall, your commitment to this program will be 21 additional visits lasting approximately one hour each.

The nature of the exercises that you will perform during the eighteen sessions include: active warm-up, strength, balance, and landing techniques. The Certified Athletic Trainer at the high school will monitor all sessions to reduce the risk of injury during the sessions. You will fill out a Tegner and Lysholm questionnaire. The Tegner and Lysholm questionnaire will ask you to answer questions about injuries that you might have had in the past. The questionnaire will provide us with important information about how your hip, knee, and ankle functions during normal activities.

**3. WHAT ARE THE RISKS OF THE STUDY?**

Likely: You are likely to experience some discomfort secondary to muscle soreness if you have not done any prior conditioning or exercising.


Less Likely: You are less likely to strain/tear a muscle, sprain a joint due to the exercises performed during the study, than if you were to participate in an event or practice. Risks are not greater than working out at a fitness facility.

Rare but Serious: There may be some rare but serious effects of participating in this study such as a lower limb injury which would require surgical interventions.

There may be other discomforts that are not known at this time

**4. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?**

The benefits of participating in this study may include: increased lower extremity strength, increased strength of the deep and superficial muscles that help the trunk of the body stay in good posture, especially the abdominals and muscles of the back as well as increased ability to balance on one leg. All of these benefits have shown to decrease the likelihood of an anterior cruciate ligament injury or otherwise know as

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a knee injury .You may not be helped by participating in this study. However, others may be helped by what is learned from this research.

**5. WHAT OTHER OPTIONS ARE THERE?**

You do not have to participate in this study. Your other choices may include:

- Participating in a strengthening program at a fitness facility.

**6. WHAT ABOUT CONFIDENTIALITY?**

By signing this consent form, you agree that we may collect, use and release your personal and health information for the purpose of this research study.

We may collect and use:

- New health information created during this study.

We may release this information to the following people:


- The Principal Investigator and his/her associates who work on, or oversee the research activities.  
Government officials who oversee research.

Once your information has been released according to this consent form it could be released again and may no longer be protected by federal privacy regulations.

HFHS may publish the results of this study. No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This consent to use and release you're personal and health information will expire at the end of this research study.

You do not have to sign this consent to release your medical information and may cancel it at any time. If you decide not to sign this consent or cancel your consent, you cannot participate in this study. If you notify us that you wish to stop participating in this study, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the principal investigator at the address listed on the first page of this form.

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**7. WHAT IF I AM INJURED?**

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent form.

**8. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?**

Maria Blokdijk, AT or Nicole Schreiber, AT or his/her staff member has explained this research study and has offered to answer any questions. If you have questions about the study procedures, or to report an injury you may contact Maria Blokdijk/Nicole Schreiber at 313-972-4167. Medical treatment is available to you in case of an injury.

If you have questions about your rights as a research subject you may contact the Henry Ford Health System IRB Coordinator at (313) 916-2024. The IRB is a group of people who review the research to protect your rights.

**9. DO I HAVE TO PARTICIPATE IN THIS STUDY?**

No, your participation in this research study is voluntary. If you decide to participate, you can stop at any time. If this happens, you may be asked to return for a visit for safety reasons. There will be no penalties or loss of benefits to which you would otherwise be entitled if you choose not to participate or if you choose to stop your participation once you have started. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study.

**10. WHO ELSE CAN STOP MY PARTICIPATION?**

The Principal Investigator, sponsor or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

**11. WILL IT COST ANYTHING TO PARTICIPATE?**

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

