

Consent Form for Participation in
Shoe A vs. Shoe B for Soccer Players Study

Funding Source: None.

IRB protocol #:

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For questions/concerns about your research rights, contact:
Human Research Oversight Board (Institutional Review Board or IRB)
Nova Southeastern University
(954) 262-5369/Toll Free: 866-499-0790
IRB@nsu.nova.edu

Site Information
NSU – Clinic
3200 S. University Drive
Fort Lauderdale, FL 33328

What is this research about?

You are being asked to let your child participate in a research study. This study is to find out if the type of shoe used can help when children have problems with their ankles while playing soccer. There will be approximately 45 children in the study.

What will my child be doing?

Dr. Shiloh will check your child's feet and ankles before the study begins. We'll then give your child shoe A to try for the first part of soccer season. We'll ask that your child wear them for practices and games. In the middle of the season (2 months later) we'll ask you to bring your child back so that we can examine his/her feet and ankles again. We'll then give your child shoe B to use for the rest of the soccer season. We'll ask you to bring your child back for a final check-up of his/her feet (at the end of 4 months). All of the doctor's visits should last no more than an hour each. Both shoes are regular soccer shoes; the only difference is the manufacturer of the shoe. If your child stops playing soccer, we will have to end your child's participation in the study.

What dangers are there for my child?

There are some risks with taking part in the study. Your child might have more ankle

Initials: _____ Date: _____

problems using the new shoes than if he or she stayed with the current ones. It is also possible that other staff in the clinic may know that your child is in the study; however, they will keep this information confidential. The new shoes may cause some minor feet irritation, but this should be no more than using any new shoe.

If you have any questions about the research or your research rights, or your child has a research-related injury, please contact Dr. Shiloh at (954) XXX-XXXX. You may also contact IRB at the numbers indicated above with questions as to your research rights.

What good things might come about for my child?

There may be some benefit to your child's participation. Your child may learn which type of shoe he/she likes to use. Your child may also have fewer ankle problems due to using the special shoes.

Do I have to pay for anything?

There are no costs to you.

Will I or my child get paid?

The only payments your child will get are free shoes and doctor's check-ups. If we find other problems with your child's feet or ankles not linked to the study, we will refer you to another doctor at the NSU Clinic. If your child needs to be seen by a doctor as a result of an injury related to the study, the cost of that visit will be covered by NSU. You will have to pay for any doctors visits that are not related to the study.

How will my information be kept private and confidentiality?

We will try to keep your child's research information private. We will give your child a number that we'll use on all of his/her information. We'll keep your child's research information in a locked cabinet in Dr. Shiloh's office for 36 months from the end of the study. It will be shredded after that time.

Some staff at the clinics may know that your child is in the study, but they won't share this information. If your child needs to see other doctors, we think you should let them know your child is in the study. Information collected as a part of care will be put in your child's clinic file. All information obtained in this study is strictly confidential unless disclosure is required by law. The IRB and government agencies may look at research records.

What if I don't want my child to be in the study or my child doesn't want to be in the study?

You have the right to refuse for your child to participate or withdraw your child at any time. Your child may also refuse to participate or withdraw. If you do withdraw your child, or your child decides not to participate, neither you nor your child will experience any penalty or loss of services that you have a right to receive. If you choose to withdraw your child, or he/she decides to leave, any information collected about your

child **before** the date of withdrawal will be kept in the research records for 36 months from the conclusion of the study and may be used as a part of the research.

Other Considerations:

If the researchers learn information that might change your mind about allowing your child to be involved, you will be told of this information.

Voluntary Consent by Participant:

By signing below, you indicate that

- this study has been explained to you
- you have read this document or it has been read to you
- your questions about this research study have been answered
- you have been told that you may ask the researchers any study related questions in the future or contact them in the event of a research-related injury
- you have been told that you may ask Institutional Review Board (IRB) personnel questions about your study rights
- you are entitled to a copy of this form after you have read and signed it
- you voluntarily agree for (you and) your child to participate in the study entitled "Shoe A vs. Shoe B for Soccer Players Study"

Child's Name: _____

Parent's/Guardian Signature: _____ Date: _____

Parent's/Guardian Name: _____ Date: _____

Signature of Person Obtaining Consent: _____

Date: _____