

Assent Form for Participation in the Research Study Entitled
Shoe A vs. Shoe B Study for Soccer Players

Funding Source: None.

IRB approval #

Principal investigator
Roxie Shiloh, DO
3200 S. University Drive
Fort Lauderdale, FL 33328
(954)555-5555

Co-investigator
Lola Zielinski, PhD
c/o Ashley Russom, EdD
Fischler College of Education
3301 College Avenue
Ft. Lauderdale, FL 33314
800-986-3223, Ext. 27838

Institutional Review Board
Nova Southeastern University
Office of Grants and Contracts
(954) 262-5369/Toll Free: 866-499-0790
IRB@nova.edu

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

What is a research study?

We're asking you to be in a research study. Research helps us learn new things. Only people who decide they want to help will be in the study. We'll tell you about the study and then you should take time to make your decision. You should talk to your parents or your guardian before you decide.

Why is this study being done?

This study is to find out if one type of shoe is better than another for young soccer players who have problems with their ankles.

What will happen to me?

Dr. Shiloh will measure your foot and look at your ankles. You'll then be given shoe A to wear for the first part of soccer season. We'll ask you to wear it every time you practice and for all games. In the middle of the season you'll come back for a check-up with Dr. Shiloh and we'll ask you questions about the shoes and whether you noticed a difference. This should take about an hour. We'll then give you shoe B. We'll ask you to wear it for the rest of the season, again, for all games and practices. You'll come back one more time to get a check up with Dr. Shiloh and give us your thoughts on shoe B. This second visit should take an hour.

Initials: _____ **Date:** _____

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What are the good things about being in this study?

There are three good things that might happen.

- 1. You may find out which shoe you like.
- 2. You may have fewer problems with your ankles.
- 3. You'll be given the shoes, but you won't be given anything else.

Will being in the study hurt me?

It is possible that you might have more problems with one type of shoe over another.

How long will I be in the study?

The study is for one soccer season or no more than 6 months. You'll come to three doctor's visits, which take about one hour each time.

Do I have other choices?

You can decide not to be in the study and use your own shoes.

Will people know that I am in the study?

The people at the doctor's office will know that you are in the study, but they won't tell anyone else. If the doctors talk about the study or write about it they won't use your name.

Who can I ask questions?

If you have any questions you can ask Dr. Shiloh. Remember, you should also talk with your parents or your guardian about this study.

Is it OK if I say "No, I don't want to be in the study"?

You do not have to be a part of this study if you don't want to. No one will be mad or upset. If you change your mind once you start the study, you can stop being in the study.

Do you understand and do you want to be in the study?

I understand. All my questions were answered.

- I want to be in the study.
- I don't want to be in the study.

Your name

Your signature

Date

Signature of person explaining the study

Date