

ASSENT FORM

For Children 7 – <13 years old

STUDY: A Randomized Trial to Evaluate Sequential vs Simultaneous Spectacles plus Patching for Amblyopia in Children 3 to <13 Years Old

A research study is like a science project at school and it is a way to learn new things. We are doing a study to find out more about how glasses and a patch help amblyopia (one eye that doesn't see as well as the other). We are asking you to be in the study because you have amblyopia. You do not have to be in this study if you do not want. It is up to you. You can even say okay now and you can change your mind later. All you have to do is tell us. No one will be mad at you if you change your mind. You can still get help with your amblyopia if you are not in the study.

If you agree to be in this study, you will be asked to wear glasses alone or glasses with a patch over one eye. You will need to come to the doctor every eight weeks for 56 weeks (just over one year). When you come in you will have your vision checked and answer some questions about your eyes and how you feel.

You will wear a small temperature sensor with a silicone holder under the patch (if you have to wear a patch), so that we can measure how much you wear it. The temperature sensor is small and could be harmful if eaten.

When you wear the patch with the silicone holder, your skin might hurt or itch a little. When you are given the questions to answer, some of the questions might make you feel upset. You do not have to answer any question that you do not want to answer.

We do not know if you will be helped by being in this study. We may learn something that will help other children with amblyopia.

This study was explained to your parent and they said that you could be in it. You can talk about this with them before you decide. Before you say yes to be in this study, we will answer any questions about the study that you may have. If you have other questions after you sign this form, you can ask us and we will answer them or get an answer for you. You can stop being in the study at any time. No one will be mad at you if you change your mind.

Child's Name (print): _____

Child's Permission

Signing below means:

- You have read this form and that you choose to be in this study

If you don't want to be in this study you do not have to sign. Being in this study is up to you, and no one will be mad at you if you don't sign, or even if you change your mind later. If you want to be in this study, please sign your name. You will get a copy of this form in case you want to read it again.

Sign Your Name

Date

Parental/LAR Attestation

Where we say “parent” in this form, we mean a natural or adoptive parent, a legal custodian, or a legal guardian (collectively known as “Legally Authorized Representatives” or “LARs” for short)

I, _____ (print name of LAR) attest that I am one of the following individuals authorized to provide consent for the child named above as I am one of the following LARs (checkbox):

☐ Natural or Adoptive Parent; ☐ Legal Custodian; or ☐ Legal Guardian

I am signing below to confirm that the study has been explained to the child in my presence in a language that the child could understand. The child was told to ask questions and the questions were answered so the child could understand.

Sign Your Name

Date

Person Obtaining Consent

I certify that to the best of my knowledge the child understands the nature, demands, risks, and benefits involved in the participation of this study.

Investigator's or Designees Printed Name

Investigator or Designee's Signature

Date