

Assent to Participate in a Research Study

Who are we and what are we doing?

We are a group of researchers that work at the University of Utah, Primary Children's Medical Center, and the Moran Eye Center. We would like to ask if you would be in a research study.

Have you ever wondered how doctors come up with new treatments? It is by doing "research": you find people who are willing to try a new treatment, to see if it works. We've invented a coating that can be applied to glasses. We think that kids who wear glasses with this coating may have fewer migraine headaches. We will test these glasses by having a bunch of kids wear them to see if they work!

Why are we asking you to be in this research study?

In order to figure out if the glasses work, we need to test them on kids with migraines. We're asking you to be in the study because your doctor says you have migraines.

What happens in the research study?

If you decide to be in this research study and your parent or guardian says it's "OK", we will ask you to fill out a questionnaire. A questionnaire is a bunch of questions that we'll ask you to answer. Then we'll ask you to try on two different kinds of glasses. You get to decide which pair of glasses you think will help your headaches. We won't give you the glasses right away because we'll need to make a new pair that is made to fit you.

For one month, we will ask you to keep a "headache diary". The diary is a paper that you fill out each day (or you can do this online), telling us if you had any headaches that day. Your parent/guardian can help you with this. After keeping the diary for one month, we will give you the glasses you chose to wear. If you already wear glasses, we will make a new pair for you with the coating. If you don't wear glasses, we will give you glasses with that just have the coating on them. We will ask you to wear the glasses, while you're awake, every day for one month.

During that month, you will have to keep a new headache diary each day. When the month is over, you will give us back the glasses, but we will ask you to keep a diary for one more month. You would be in the study for a total of 3 months, but you would only have to wear the glasses for one month.



Will any part of the research study hurt you?

There is a chance that during the research study you could feel afraid or uncomfortable. We will try to help you feel better if this happens. We hope the glasses will make you feel better, but if they do not, you can stop being in the research.

Will the research study help you or anyone else?

We hope the glasses we've invented will help you. They may help other kids too! But, we don't know for sure if the glasses will help. That's why we're doing this research.

Who will see the information about you?

Only the researchers or others who are doing their jobs will be able to see the information about you in this research study. We will talk about this information with you, your doctors, and your parents/guardian.

What if you have any questions about the research study?

It is always okay to ask questions. If you don't understand something, you can ask us. We want you to ask questions now and anytime you think of them. If you have a question later that you didn't think of now, you can call Dr. Katz at 801-585-6653 or ask us the next time we see you. You may call at any time to ask questions about your migraines, the treatments you're receiving for your migraines, or this research.

Do you have to be in the research study?

You do not have to be in this study if you don't want to. Being in this study is up to you. No one will be upset if you don't want to do it. Even if you say yes now, you can change your mind later and tell us you want to stop. You can take your time to decide. You can talk to your parent/guardian before you decide.

We will also ask your parent/guardian to give their permission for you to be in this study. But even if your parent/guardian says yes, you can still decide not to be in the research. Your doctors will continue to take care of you, even if you decide not to be in this research study.



Agreeing to be in the study

I was able to ask questions about this study. Signing my name at the bottom means that I agree to be in this study. My parent/guardian and I will be given a copy of this form after I have signed it.

Printed Name

Sign your name on this line

Date

Printed Name of Person Obtaining Assent

Signature of Person Obtaining Assent

Date

The following should be completed by the study member conducting the assent process if the participant agrees to be in the study. Initial the appropriate selection:

_____ The participant is capable of reading the assent form and has signed above as documentation of assent to take part in this study.

_____ The participant is not capable of reading the assent form, but the information was verbally explained to him/her. The participant signed above as documentation of assent to take part in this study.

