

Parental Permission and Authorization Document

BACKGROUND

Your child is being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you will allow your child to take part in this research study.

The purpose of this study is to determine if a special coating, applied to the surface of glasses can reduce the frequency and severity of migraine headaches in children and adolescents. Researchers at Primary Children's Medical Center, The John Moran Eye Center, and the University Of Utah Department Of Electrical Engineering are conducting this study. We have determined that specific frequencies of light are particularly bothersome to migraine patients. The coatings we've developed are designed to block these frequencies of light. We would like your child to participate because they are being treated for migraines. Very few treatments are approved for the treatment of childhood migraine. We hope that these glasses will provide a safe way to improve headaches in children. The Food and Drug Administration (FDA) could consider the coatings we are using as an "investigational device". The FDA has not approved these coatings for the treatment of migraine.

STUDY PROCEDURES

Your child will continue to receive treatment for their headaches as prescribed by their doctor. This study is 12 weeks long. During the first and last 4 weeks, your child will not wear any study-related glasses. Study glasses will be worn during the middle 4 weeks. If your child already wears glasses, we will make a custom pair of glasses with their prescription and the coating. If your child does not wear glasses, we will make a pair of glasses with the coating, but no prescription.

There are two different study lenses to choose from. We will ask you to help your child decide which study lens they think will most likely help their headaches. We will then make a pair of glasses with these lenses to fit your child.

For every day of the 12 weeks, we will ask you to help your child maintain a headache diary. The diary is simply a quick way for us to tell how frequent and how severe your child's headaches are. At 4 points in the study, you will also be asked to help your child fill out a brief questionnaire. This questionnaire is designed to determine what effect your child's headaches have on their activities. You would be asked to attend up to 4 visits during the 12 weeks. Each visit can be scheduled at your convenience and should take no more than 30 minutes. You and your child may not need to meet with the study team in person as many times if you choose to do the surveys online or if travel is difficult for you. The study team will discuss this with you.



If at the end of the study your child reports that the glasses did not help, they will be given the option of trying the other kind of lenses for another 4 weeks. This additional part of the trial is strictly optional.

RISKS

We are not aware of any risks associated with wearing our experimental coatings. Adults have worn these coatings without any adverse effects. If your child does not wear glasses, they may feel self-conscious about wearing spectacles. If your child already wears glasses, they may feel self-conscious about wearing glasses that look unusual or different. It is possible that the glasses won't work, but there's no evidence that the glasses would make your child's headaches worse.

UNFORESEEABLE RISKS

Although we are not aware of any risks associated with wearing our experimental glasses, participation in the study may involve risks that are currently unforeseeable.

BENEFITS

We cannot promise any benefits to your child from being in the study. However, possible benefits may include an improvement in your child's migraine headaches.

ALTERNATIVE PROCEDURES

You may choose not to participate in this study. If you do not want to take part in the study, there are other choices such as wearing glasses with FL-41 tint. This tint has been shown to help some children with migraine and is commercially available. We hope that our coating will work better than FL-41. You may discuss this option with your doctor.

PERSON TO CONTACT

For any questions, complaints, or concerns about the research or related matters you may contact Dr. Katz at 801-585-6653. If you believe your child has been injured as a result of the study, please contact Dr. Katz. If you need to reach Dr. Katz urgently, you can call the above number 24-hours per day and ask to speak to the on-call physician.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your child's rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns that you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.



RESEARCH-RELATED INJURY

If your child is injured from being in this study, medical care is available at the Primary Children's Medical Center, as it is to all sick or injured people. Primary Children's Medical Center has not set aside any money to pay the costs for such care. Primary Children's Medical Center will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance) to the extent they are responsible for paying for medical care your child receives. Because this study is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If your child is injured in this study, and you want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that is in effect when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION

If you decide to allow your child to take part in this study, you are still free to withdraw your child at any time and without giving a reason. Refusal to allow your child to participate or the decision to withdraw your child from this study will involve no penalty or loss of benefits to which your child is otherwise entitled. If your child doesn't take part, your child can still receive all standard care that is available to your child. This withdrawal will not affect the relationship you or your child has with your child's doctor or other staff, nor decrease the standard of care that your child receives as a patient.

RIGHT OF INVESTIGATOR TO WITHDRAW

The investigators can withdraw your child without your approval. Possible reasons for withdrawal include refusal of your child to wear the study glasses, failure to complete the headache diaries, or failure to attend scheduled study visits. We do not anticipate any adverse effects on the health or welfare of your child if they're withdrawn from the study.

COSTS AND COMPENSATION TO PARTICIPANTS

You will not be charged, nor will your insurance company be charged, for any test or visit that is completed solely for the purpose of this study.

Each time you/your child completes a required survey (end of month 1, 2, and 3) your child will be able to choose from one of the "prizes" below in the form of a gift card worth up to a maximum of \$20.

Prizes:

- 7 Peaks Water Park
- Amazon
- Barnes and Noble
- Baskin Robbins
- Boondocks Fun Center
- Clark Planetarium
- Cold Stone Creamery
- Dinosaur Park
- Domino's Pizza
- Google Play gift card
- Heber Valley Railroad
- Hogle Zoo
- iTunes gift card
- Living Planet Aquarium
- Momentum Indoor Climbing Gym
- Papa John's Pizza
- Spotify premium gift card
- Thanksgiving Point: Museum of Ancient Life
- Thanksgiving Point: Nat Geo Mammoth Screen Theater
- The Leonardo Museum
- Tracy Aviary
- wAIRhouse trampoline park

At the end of the study, your child may choose to keep the study glasses or return them and receive a \$20 check or a \$20 gift card. If your child completes the entire study, we expect him/her to receive up to a maximum total of \$80.

NEW INFORMATION

It is possible that during the course of this research project, new information may become available about the glasses that are being studied. If this happens, your child's research doctor will tell you about it and discuss with you whether you want your child to continue in the study.

If you decide to withdraw your child at that time, the research doctor will make arrangements for your child's medical care to continue. If you decide to allow your child to continue in the study, you will be asked to sign an updated consent form. Also, on receiving new information the research doctor might consider it to be in your child's best interests to withdraw your child from the study. He/she will explain the reasons and arrange for your child's medical care to continue.

NUMBER OF PARTICIPANTS

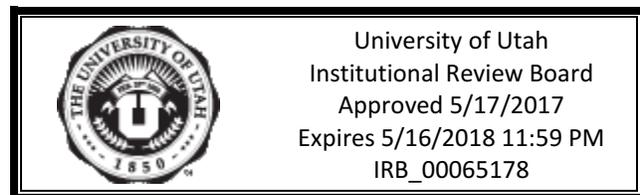
We expect to enroll approximately 50 patients at Primary Children's.

AUTHORIZATION FOR USE OF YOUR CHILD'S PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your child's health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information, such as name, address, telephone number, and email address.
- Related medical information about your child like family medical history, allergies, current and past medications or therapies.



- All tests and procedures that will be done in the study

How we will protect and share your child's information:

We will do everything we can to keep your child's information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your child's medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research. Others who may review the research records included authorized members of 1) the research team, 2) the Primary Children's Hospital, and 3) the University of Utah Institutional Review Board (IRB). The IRB reviews research involving people to make sure the study protects your rights;

If we share your child's information with groups outside of Primary Children's Hospital or the University of Utah Health Sciences Center, we will not share your child's name or identifying information. We will label your child's information with a code number, so they will not know your identity.

If you do not want us to use information about your child's health, your child should not be part of this research. If you choose not to participate, your child can still receive health care services at Primary Children's Hospital

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want your child to be in this study and do not want us to use your child's health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about your child, and your child will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your child's health care. However, your child's information from this study will not be available during the study; it will be available after the study is finished.

CONSENT:

I confirm that I have read this parental permission document and have had the opportunity to ask questions. I will be given a signed copy of the parental permission form to keep.

I agree to allow my child to participate in this research study and authorize you to use and disclose health information about my child for this study, as you have explained in this document.

Child's Name

Parent/Guardian's Name

Parent/Guardian's Signature

Date

Relationship to Child for Parent/Guardian

Name of Person Obtaining Authorization and Consent

Signature of Person Obtaining Authorization and Consent

Date

	<p>University of Utah Institutional Review Board Approved 5/17/2017 Expires 5/16/2018 11:59 PM IRB_00065178</p>
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