Consent and Authorization Document

for Minimal Risk Research

STUDY TITLE:	**Spectacle Tints and Thin Films to Reduce Headache Frequency in Patients with Migraine**
SPONSOR:	**Axon Optics, LLC**
STUDY DOCTOR:	**Bradley Katz, MD, PhD**
STUDY SITE:	**University of Utah John A. Moran Eye Center** **65 Mario Capecchi Drive** **Salt Lake City, UT 84132**
STUDY PHONE:	**801-585-6647**

BACKGROUND

You are 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 the research doctor or staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

Almost all people who get migraines report that they are light sensitive during a headache, many people will report that certain kinds of light can trigger a migraine, and some people are light sensitive even when they don't have a migraine. Some doctors have recommended special kinds of glasses to reduce light sensitivity in their migraine patients. The purpose of this study is to determine the best kind of glasses for reducing migraine headaches.

Axon Optics, a company that makes different kinds of glasses for migraine, is sponsoring the study. The principle investigator is Dr. Bradley Katz, a neuro-ophthalmologist and researcher at the University of Utah. Dr. Katz is also a Founder and the Chief Executive Officer (CEO) of Axon Optics.

Kathleen Digre, a co-investigator of this research study is an inventor of the licensed intellectual property (Axon Optics), which is being evaluated in the study. She has a significant financial interest in AXON OPTICS, LLC, the sponsor of this study as determined by the University of Utah conflict of interest policy.

STUDY PROCEDURE

Each person in this study will be "randomized" to wear glasses with either a tint or a thin-film coating. In a "randomized trial" people are put into one group or the other by random chance. This means that a computer will decide by chance which group you are assigned to. Neither you nor the doctors running

the trial can decide which group you are in. Your chance of being asked to wear either the glasses with a tint or the glasses with a thin-film coating is 50:50.

Although tints and thin films are currently used in glasses, they have some differences. Tints are dyes: A plastic lens is dipped into the dye and the lens takes on a specific color. A thin-film coating is an ultra-thin layer of a transparent material that is applied to the surface of lens. Thin-film coatings are already used in glasses to make anti-reflective coatings. Both tints and thin films have been shown to be effective treatments for light sensitivity and migraine.

The purpose of the lenses is to reduce the frequency and severity of headaches and their impact on daily activities. For this reason, you will be asked to wear the glasses during all waking hours. Do not wear the glasses at night.

If you do not wear glasses, you will be given glasses without any prescription. If you already wear glasses, we will make glasses for you with your prescription. If you wear contact lenses, you will be asked to wear glasses with no prescription over your contact lenses.

If you agree to be in the study, in addition to today's visit, you will have to make four more visits for the study. For the first four weeks, you will not wear any special glasses: During this time we just want to keep track of your headaches.

For the following 12 weeks, you will be asked to wear the glasses full time. The total length of the study is 16 weeks. The research team will check in with you weekly during the study to answer any questions you may have about the study, to make sure you're wearing the glasses appropriately, and to make sure you're completing the headache diary.

The research team may contact you 6 months and then again at 12 months after you exit the study to find out if you are still wearing the glasses.

RISKS

We do not think wearing the glasses will expose you to any medical risks. If you don't already wear glasses, you may find that it is uncomfortable to wear glasses. We will make every effort to make sure the glasses fit you comfortably. There is also the possibility that some of your private health information could accidentally be disclosed.

BENEFITS

We cannot promise any benefits to you from your being in the study. In other words, we cannot promise that the glasses will make your headaches better. In a previous study, no participants reported that the glasses made their headaches worse. However, possible benefits may include reduced light sensitivity during your headaches. The results of this research will also help other patients with migraine determine if spectacle tints or thin-films would be helpful to them.

ALTERNATIVE PROCEDURES

Research studies include only people who choose to take part. You can tell us that you don't want to be in this study. If you do not want to take part in the study, there are other choices such as continuing your current medication regimen. You may discuss these options with your doctor. If you use medications to prevent or treat your migraines, you may continue to use these medications while participating in this research. We ask that you not make any changes in these medications while you are participating in this research. If it's necessary to make a change in any of your prescription medications during the trial, please let us know.

You can start the study and then choose to stop the study later. We will still give you medical care and answer any questions you have. Your decision will not affect your relationship with your doctor or the study team in any way.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, you can contact this study's clinical research coordinator, Ms. Susan Bracken 801-585-6647 or by email at susan.bracken@hsc.utah.edu. If you think you may have been harmed from being in this study, please contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which 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.

VOLUNTARY PARTICIPATION

Research studies include only people who choose to take part. You can tell us that you don't want to be in this study. You can start the study and then choose to stop the study later. This will not affect your relationship with the investigator.

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.

If you complete the first four weeks of the study and you are withdrawn from the study by the investigator, you will receive a check for $25. If you complete the entire 16-week study, you can either keep the glasses you wore during the study, or return the glasses and receive a check for $100.

NEW INFORMATION
Sometimes during the course of a research project, new information becomes available about the glasses being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study.

AUTHORIZATION FOR USE OF YOUR 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 health for this research study.

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

- Demographic and identifying information like name, address, telephone number and email address
- Related medical information about you like medication allergies, current and past medications or therapies, and information from physical examinations such as blood pressure reading
- All tests and procedures that will be done in the study

How we will protect and share your information:

We will do everything we can to keep your 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 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.

- In order to conduct this study and make sure it is conducted as described in this form, the 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:
    - Members of the research team and the University of Utah Health Sciences Center
    - The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights
    - The study sponsor: Axon Optics
    - A research contract organization (CRO): ECommunity Research
    - The Food and Drug Administration

- If we share your information with groups outside of the University of Utah Health Sciences Center, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at the University of Utah Health Sciences Center.

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 to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you 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 health care. However, your 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 consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

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

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date