

## RESEARCH SUBJECT CONSENT FORM

**TITLE:** Optical Treatment of Migraines

**PROTOCOL NO.:** None  
WIRB® Protocol #20190592

**SPONSOR:** Avulux

**INVESTIGATOR:** Name  
Address  
City, State, Zip Code  
Country

**STUDY-RELATED  
PHONE NUMBER(S):** Name  
Phone Number(s) (24 hours)  
[24 hour number required]

You are being invited to take part in a research study to evaluate the effectiveness of a device used to treat patients with non-chronic migraine headaches. The device is a pair of glasses with a filter on the lenses that will block some light that is known to trigger or affect migraine symptoms. You were selected as a possible research subject because you have been diagnosed with having non-chronic migraine headaches. A person who takes part in a research study is called a research subject, or research participant.

We ask that you read this form and ask any questions you may have before agreeing to participate in the study.

This study is being conducted by [investigator name] at [site name]. Avulux, Inc., who is funding this study, is the manufacturer of the investigational glasses being used in the study. The Avulux glasses are an investigational device. The term investigational device means the device is not approved by the Food and Drug Administration (FDA). The purpose of this study is to collect information that will be used to see if the FDA will approve the investigational device.

### What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.

- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

## **Why is this research being done?**

The purpose of this research is to assess how well the Avulux migraine glasses work in reducing the impact of migraine headaches as measured by improvement in Headache Impact Test (HIT-6™) scores at three weeks when compared to a control device. The long-term goal is to reduce the impact of headaches in patients with migraines.

About 50 subjects will take part in this research at two institutions.

## **How long will I be in this research?**

We expect that your total participation in this research study will last about seven (7) weeks.

## **What happens to me if I agree to take part in this research?**

If you agree to participate in the study and sign this informed consent form, then you will be asked to participate in the screening process. The screening process will determine whether you are eligible to participate in the study. After signing the informed consent form, the study team will ask you some questions about your headache history and treatments for your migraines. Based on this screening information, it will be determined whether or not you fit the criteria (are eligible) to be able to participate in the study.

If you are determined to be eligible for the study, you will be put into a study group by chance (like a coin toss/ like drawing straws). You have a one out of two chance of being placed in either group, which means that you have a 50% chance of receiving the investigational (research) glasses and a 50% chance of receiving the non-investigational (control) glasses at the start of the study. You cannot choose your study group. During the study, you will not know which group you are in. There will be 50 subjects who will be participating in this research.

All procedures described below are related to the research study:

At your initial (baseline) study visit, you will be asked to complete a questionnaire called the 6-item Headache Impact Test (HIT-6™). You will also be given a pair of study spectacles (glasses) and an explanation for how to use them. The glasses given to you will either have the investigational (research) lenses or will have the non-investigational (control) lenses. You will be asked to use the glasses for three weeks, putting these on at the first signs or symptoms of a migraine headache. You should leave the glasses on until your migraine headache has resolved.

Finally, you will also be asked to complete a daily diary throughout the course of the study (eight weeks total), which will be given to you at this first visit. This diary should be used to record the frequency and severity of your headaches, a numerical pain score for your headaches, and any medications you use to treat your headaches, in addition to using the study glasses.

After three weeks, you will be asked to return to the site to complete the HIT-6<sup>TM</sup> questionnaire and return your glasses. You will then go one week (seven days) without the use of any glasses to treat your migraine symptoms. At the end of this week, you will be asked to return to the site to complete the HIT-6<sup>TM</sup> questionnaire again, and you will receive new glasses for the opposite treatment group. This means that if you were given the investigational (research) glasses at first, you will be given the non-investigational (control) glasses at this time; if you were given the control glasses at first, you will be given the investigational glasses at this time. As a reminder, you will not know either of your treatment groups throughout the duration of the study.

You will then repeat the treatment above for three weeks, putting on the glasses at the first signs or symptoms of a migraine headache and leaving the glasses on until your migraine headache has resolved. At the end of this three-week treatment, you will be asked to return to the site for a final time to complete the HIT-6<sup>TM</sup> questionnaire and return the glasses.

Throughout the seven-week course of the study, you will receive phone calls from the study research coordinator each week, when they will remind you to use your glasses as needed, to complete the daily diary, and will also address any questions you may have.

## **What are my responsibilities if I take part in this research?**

If you take part in this research, you will be responsible for following the requirements of the protocol as described above. This includes the following:

- Completing a daily diary throughout the duration of the study (approximately 7 weeks)
- Wearing the prescribed glasses for weeks 1 – 3 whenever migraine symptoms begin until they have resolved
- Returning to the site at the end of week 3, week 4, and week 7
- Wearing no glasses for 7 days following the week 3 visit
- Wearing the prescribed glasses for weeks 4 – 7 whenever migraine symptoms begin until they have resolved
- Completing a HIT-6<sup>TM</sup> questionnaire at the end of week 3, at the end of week 4, and at the end of week 7

There are no warnings or precautions associated with the use of the study device. If you have start any new medications or have any new medical issues occur throughout the duration of the study, you should tell your study doctor or research team member.

## **Could being in this research hurt me?**

There are no known risks associated with the use of the study device. However, taking part in this research may harm you in unknown ways.

## **Will it cost me money to take part in this research?**

Taking part in this research may lead to added costs to you, such as transportation to the clinic. No other added costs are expected due to your participation in this research.

## **Will being in this research benefit me?**

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include having relief from your migraine headache symptoms when using the study glasses as prescribed. Once the study has ended, you will not continue to receive any direct benefits through the use of the study glasses.

Information learned in this study may help other patients who suffer from migraine headaches in the future.

## **What other choices do I have besides taking part in this research?**

Your alternative to taking part in this research study is to not participate. Your doctor may continue to assist you with managing your migraine headache symptoms using normal, standard of care, even if you do not participate in this research study.

## **What happens to the information collected for this research?**

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

## **Who can answer my questions about this research?**

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, [help@wirb.com](mailto:help@wirb.com) if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

## **What if I am injured because of taking part in this research?**

If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

## **Can I be removed from this research without my approval?**

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include, but are not limited to:

- It is in your best interest
- You have a side effect that requires stopping the research
- The research is canceled by the FDA or the sponsor
- You are unable to use the research device
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

## **What happens if I agree to be in this research, but I change my mind later?**

You can choose to stop participating (withdraw) in this research study at any time. If you decide to leave this research, contact the research team so that the investigator can: determine whether or not you need to be seen at the site to return any study devices.

## **What if new information is found during the study?**

If during the conduct of the study new findings are found or changes to the study plan are made, which are important for your participation in the study, you will be informed accordingly. If these findings affect your participation in the study you will be asked to sign a new study consent.

## **Will I be paid for taking part in this research?**

For taking part in this research, you may be paid up to a total of \$150. Your compensation will be broken down as follows:

- \$50 at the completion of your three-week visit
- \$100 at the completion of your seven-week visit
- If you drop out of the research prior to either one of these visits, you will not be paid for that visit.

## **AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES**

This authorization section describes how your health information may be used and/or disclosed by your study doctor, the hospital or clinic, and their respective staffs. The term “researchers and providers” will be used to include the group of people who may get personal information about you.

These include the:

- Study doctor
- Study staff
- Hospital or clinic (involved with a study procedure)
- Other health care providers involved in your care during the study.

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The researchers and providers must get your authorization (permission) to use or give out any health information that might identify you.

## **What information may be used and given to others?**

If you choose to be in this study, the study doctor will get personal information about you from the researchers and providers. This may include information that might identify you. The study doctor may also get information about your health including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about:
  - Reportable infectious diseases
  - Physical exams
  - Diaries and questionnaires
- Records about any medications you received
- Records about the study device

## **Who may use and give out information about you?**

Information about your health may be used and given to the persons listed below by the researchers and providers. These persons might see the research information during and after the study.

## **Who might get this information?**

Your information may be given by the researchers and providers to the sponsor of this research, Avulux. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor.

Information about you and your health which might identify you may also be given by the researchers or the providers to:

- Other researchers participating in the study
- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Other U.S. governmental agencies and governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported (if applicable)
- Western Institutional Review Board (WIRB)
- The sponsor of this study and the people or groups it hires to help perform this research
- Other parties as required by law

### **Why will this information be used and/or given to others?**

Information about you and your health that might identify you may be used and given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

### **What if I decide not to give permission to use and give out my health information?**

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

### **Can I review or copy the information obtained from me or created about me?**

You have the right to review and copy your health information in your medical record.

### **Can I withdraw or revoke (cancel) my permission?**

Yes, but this permission does not have an expiration (ending) date.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address listed on page 1 of this consent form. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others as described in this form. For example, this would be done if it were necessary for the research to be reliable.

**Is my health information protected after it has been given to others?**

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

**Statement of Consent:**

I have read and understand the above information. I agree to participate in this study. I understand that I must be given a signed and dated copy of this form for my own records.

Your signature documents your consent to take part in this research.

\_\_\_\_\_  
Signature of adult subject capable of consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of person obtaining consent

\_\_\_\_\_  
Date