# CONSENT TO TAKE PART IN A RESEARCH STUDY

If the participant/LAR cannot read this form (like when they cannot see or read well), then the study doctor must use an IRB approved short form process or a consent form in their language.
This form is not intended to be read to the participant/LAR as written.

**STUDY TITLE: A Randomized Trial of Dichoptic Treatment for Amblyopia in Children 4 to 7 Years of Age (ATS23)**

**STUDY DOCTOR'S INFORMATION**
Site PI Name:
Site Name:
Mailing Address:
Emergency (24-hour) Number:

**SUMMARY**
In this form, when it says "you" it is referring to you as the participant if you are an adult, or to the person under your care that would be in the study if you are a legally authorized representative (LAR). This would be like a parent reviewing the information for their child, a minor, to be in the study. In this case, "you" means "your child."

Informed consent is the process that tells you about what is involved in a research study. It tells you about the study, study procedures, and study treatments. It tells you about how study treatments are given and what side effects could happen. This process usually involves reading a form like this one, someone on the study team talking to you about the study, and getting your questions and concerns addressed. The goal is that you have all of the information you need so that you can decide if you want to participate in the study.

You do not have to be in this study. You can stop being in the study at any time. If you decide not to be in this study, you will not have any penalty or loss of any benefits that you normally get. You should read and discuss all of the information in this consent form with the study doctor. You can ask for a copy to share with other people to help you decide. Do not agree to be in this study unless all of your questions have been answered. Please take as much time as you need.

- This study is being done to evaluate treatment for amblyopia. Amblyopia is the loss of the ability to see clearly through one eye. The brain may start to ignore the image from the weaker eye. Amblyopia is also called "lazy eye." It is the most common cause of vision problems in children. About 238 children will be in this study at about 65 sites in the US and 5 sites outside of the US.

- Luminopia is approved by the Food and Drug Administration (FDA) for the treatment of amblyopia in children aged 4- to 7-years old for up to 12 weeks.

- You will be asked to be in this research study for about 26 weeks. The study will involve you wearing your glasses (if you need them) and then being randomized to wearing either a patch or to using the Luminopia virtual reality headset. You will see your eye doctor at 13 weeks and 26

weeks. Wireless internet is needed to use the Luminopia headset. If you do not have access to the internet in your home, the study will lend a Hotspot to you to be used only for the study device.

- If you are in the patching group and still have amblyopia at 26 weeks, you will be asked if you would like to continue treatment in the study. You would use the Luminopia headset for up to another 26 weeks. This would total 1 year in the study. At each visit you will have your eyes examined, your vision tested and complete questionnaires.

- Patching is part of regular care to treat amblyopia. The most likely, but still small risks is some mild skin discomfort from patching.

- The most likely risks from using Luminopia are mild headache, or a new eye turn. The most serious possible risk is the unlikely risk of seizure, but this is why people who have a history of light-induced seizures are not able to be in this study.

- The risks in this study are no greater than the risks of using technology and/or these products as part of your regular day-to-day activities outside of the study.
- Please note that Luminopia is considered "digital media" and the American Academy of Pediatrics recommends that children aged 2 to 5 years should be limited to no more than 1 hour per day of digital media use.

- The possible benefits are that your vision might improve more or might improve faster with either treatment, but that is what the study is trying to find out.

- If you do not participate, you may still seek care to treat your amblyopia like you normally would. Be sure to talk to the study doctor about other treatments, other possible studies, and how their risks and benefits compare to this study.

## WHO IS DOING THE STUDY?

This research study is being done by the Pediatric Eye Disease Investigator Group. It is being paid for by the National Eye Institute. The Jaeb Center for Health Research will use the funding to organize the study. Your study doctor and clinic staff will use the funding to carry out this study. The study doctor's contact information is listed on the first page of this form. If one of the study doctors gets money or benefits from a company that makes the devices in this study (or a competing device), then they have to tell the Jaeb Center.

## WHY IS THIS STUDY BEING DONE?

You are being asked to take part in this research study to find out if treating amblyopia with Luminopia is as good as treating amblyopia with patching. The goal of this study is to learn things that may help people with amblyopia.

## WHO CAN PARTICIPATE IN THIS STUDY?

In general, to take part in this study, you must:

- Be 4 to <8 years old
- Have amblyopia
- Have normal vision in your good eye
- Reside in the US or Canada

Also, to take part in this study, you must not:

- Have known skin reactions to patch or bandage adhesives.
- Have any history of light-induced seizures
- Have previously used dichoptic treatment for more than 2 weeks
- Have used dilating eyedrops for treatment in the last 2 weeks
- Have double vision (seeing two of things)

Your study doctor and staff will review more health-related requirements with you.

**WHAT WILL HAPPEN IN THIS STUDY?**

You will have your vision tested in your current glasses (if you need them) and be shown the Luminopia virtual reality headset. If your vision meets the study guidelines and you are willing to wear the Luminopia headset or a patch, you can decide if you would like to take part in the study.

If you decide to take part in this study, and your prescription is incorrect, you will receive new glasses. You will come back for a new enrollment visit after your vision is stable. If your vision meets the study guidelines and is stable in the glasses, a computer program will be used to select whether you will start the study wearing a patch or using Luminopia. This is like flipping a coin to decide which group you will be in. Both groups should wear glasses (if you need them) all day, every day when awake. Patching in the study will be for two hours per day, seven days per week. Luminopia treatment will be for 1 hour per day, 6 days a week.

If you start the study wearing a patch, you will be asked to record on a calendar how much time you wear your patch every day. If you start the study using Luminopia, you will be asked to record treatment time on a calendar, and the Luminopia device will record how much treatment you do.

You will receive a phone call after 1 week to see if you have questions about your treatment. You will then need to come back to the eye doctor at 13 weeks and at 26 weeks. At each visit, you will have your vision and alignment tested and you will answer questions about your eyes and how you feel. If you agree to receive text messages for the study, you may receive a text message before each visit to remind you of your appointment.

At 13 weeks, your eye doctor will determine if your amblyopia has gone away. If you still have amblyopia, you will continue study treatment until your visit at 26 weeks. If your amblyopia has gone away, you will stop treatment and come back at 26 weeks.
The table below shows what will happen at each visit for the first 26 weeks of the study:

| Visit | Informed Consent (and Assent if required) | History | Distance Vision Testing | Depth Perception Testing | Eye Alignment | Vision Questionnaire | Quality of Life questionnaire | History of Double Vision | Side Effect Questionnaire | Treatment Questionnaire |
|---|---|---|---|---|---|---|---|---|---|---|
| **Enrollment** | X | X | X | X | X | X | X | X | | |
| **13-weeks** | | | X | X | X | | X | X | X | X |
| **26-weeks** | | | X | X | X | X | | X | X | X |

If you start the study wearing a patch and you still have amblyopia at 26 weeks, you can choose either to continue treatment by using Luminopia for 26 weeks, or you can end the study. If you decide to continue treatment by using Luminopia you will receive a phone call after 1 week to see if you are managing ok with your treatment. Then you will come back for visits at 39 weeks and 52 weeks.

The table below shows what will happen at those visits:

| Visit | Informed Consent (and Assent if required) | History | Distance Vision Testing | Depth Perception Testing | Eye Alignment | Vision Questionnaire | Quality of Life questionnaire | History of Double Vision | Side Effect Questionnaire | Treatment Questionnaire |
|---|---|---|---|---|---|---|---|---|---|---|
| **39-weeks** | | | X | X | X | | | X | X | X |
| **52-weeks** | | | X | X | X | | | X | X | X |

## WHAT ARE THE RISKS OF THIS STUDY?

If you choose to take part in this study, you need to know that there are some side effects or risks. There is a small risk of mild irritation or an allergic reaction to the patch. If this happens, a different type of patch will be given to you.

There is a very small chance with patching and with Luminopia that the vision in your better eye may get worse. This almost always goes away when treatment is stopped. There is also a very small chance that patching or Luminopia treatment could cause your eyes to turn out of alignment, or cause you to see double, but this is very rare.

There is a low risk of mild headache or eye strain when using Luminopia but this almost always goes away when treatment is stopped. Other possible rare effects are worsening vision in either eye, eye

twitching, facial redness, increase in frequency of night terrors, and mild dizziness. When people use technology like televisions, computer monitors, or virtual reality, it may trigger seizures in rare cases. For this reason, no one with a history of light-induced seizures can be in this study

**Unknown Risks**
There may be additional risks from the study that are not known. If we find out that there are any new risks, you will be told about them. You will be able to decide if you want to continue in the study based on the new information.

**Risks to Confidentiality**
This study will be collecting some information about you that includes identifiable, personal information, like your date of birth. The study has plans in place to protect that information. There is a chance that a loss of this confidentiality could occur. Please see the "How will my information be protected and kept confidential" section below for more information.

**Study Questionnaires/Surveys**
This study will involve asking you some questions about your treatments and how you feel about having amblyopia. These questions might make you feel uncomfortable. If any questions make you uncomfortable, you can choose not to answer. You can decide to take a break or stop taking part in the study at any time.

**Shipping Supplies**
The study team may need to send supplies to you. If they do, they will use a study shipping account that belongs to the Jaeb Center for Health Research (JCHR). This means that JCHR may have access to your contact information through the shipper, like FedEx. Your shipping information will not be used for any other purpose.

**Text or Email Messaging**
The study doctor and staff may use your contact information to call, text, email, or video (like FaceTime or Skype) you during the study. They may do this to send you things like appointment reminders. There is a chance that someone could see or hear the conversation like they could if you were speaking or texting with anyone. They are not allowed to send you private information by text or regular email because it is unsecure. This means that there is a risk that a message may be seen by someone that is not supposed to see it, like when an email gets hacked. Your email, phone number and your child's name will likely be in the text or email. If you think that the study doctor's office has texted or emailed information that they should not have, please contact JCHR at 813-975-8690 and ask to speak to the IRB Administrator. If you text or send a regular email to the study doctor's office, it is unsecure and what you put in the text or email is not protected.

You may receive text messages from the Jaeb Center through a third-party texting service before each study visit. The text messages will be sent automatically using a computer program from the Jaeb Center database. You can decide to stop getting text messages at any time. You will need to tell the study doctor if you would like to stop receiving text messages. You can still be in the study if you do not want to get text messages anymore.

Please discuss the risks with your study doctor or any other health care provider.

## CAN I STOP BEING IN THE STUDY?

You can stop being in the study at any time. If you decide to stop being in this study, you will not have any penalty or loss of any benefits that you normally get. You can get regular care like you normally would.

Also, if at any time you don't want to participate in or finish a test or procedure, then tell the study doctor. It is up to you. The study doctor will tell you if you can stay in the study without the tests or procedures, or if it means that your part in the study will be over.

You can even tell the study doctor if you want to stop study treatment but want to keep giving information to the study. Information can only keep being collected this way if you say that it is okay in writing, like with a letter or an email. You can also use the JCHR IRB Withdraw Letter found on our website at www.jaeb.org/research-participants.

If we find out that there is any important new information, you will be told about it. You will be able to decide if you want to continue in the study based on this new information.

The study may stop or the study doctor may decide to take you out of the study at any time too. You do not have to give permission for the study to stop or for the study doctor to remove you from the study. You will be told if this happens. Some reasons why you may be removed from the study include:

- The doctors feel that it is in your best interest
- You do not follow the study instructions

## ARE THERE COSTS RELATED TO THE STUDY?

The study will pay for patches, Luminopia treatment and any new glasses needed during the study. Wireless internet is needed to use the Luminopia headset. If you do not have access to the internet in your home, the study will lend a Hotspot to you to be used only for the study device.

At the end of the study, or if you withdraw, you must return the Luminopia headset and the Hotspot, if provided to you, to the Jaeb Center for Health Research.

Any regular office visits or additional tests and procedures will be billed to you or your insurance company like they would be normally. If you receive new glasses from the study but need to return for non-study visits to demonstrate stable vision, these visits will be billed to you or your insurance. You will get to keep your glasses at the end of the study.

**Please ask to speak to someone at your study doctor's office if you want more information about what you or your insurance will be expected to pay.**

## IS THERE PAYMENT FROM THE STUDY?

If you take part in the study, you will receive up to $500 for your participation. These payments will be paid to the parent/LAR as follows:

- $100 for each completed visit up to 5 visits.

These payments will be paid by electronic gift card, or check. If you withdraw from the study, you will still be paid for the visits that you have completed. You will not receive extra payments for visits that are required as part of your normal care.

The study may reimburse you or your study doctor's office for your extra direct and reasonable travel expenses. If you would like reimbursement for these travel expenses, then please tell the study doctor's office. Direct and reasonable travel expenses are the actual costs of the most sensible travel option to and from the required study visits. If you drive in a personal vehicle more than 50 miles round trip, mileage reimbursement will be made based on the current standard federal mileage rate for mileage over the first 50 miles. If you take a taxi or ride-share service, then the actual cost noted on your receipt will be reimbursed. The distance traveled will be verified by your study doctor's office. You will be asked to provide receipts or proof of mileage.

Requests for these extra travel expenses must be approved by the Jaeb Center for Health Research study team before they can be reimbursed and preferably before making any travel arrangements. Parking validation or reimbursement for parking may also be available. Please speak to someone at your study doctor's office to obtain more information about this reimbursement.

Because payments made to you for participating in this study may be reportable to the Internal Revenue Service (IRS) as income, you may need to provide a Tax Form W-9 to your study doctor's office. These will not be shared outside of your doctor's office, other than as required by the IRS.

Since payments made to you for participating in a study are considered taxable income, here are a few things that you should know:

- If you get certain benefits from the government, like food assistance, then getting paid by the study might affect your benefits. You may need to talk to your benefits representative.
- If you are a non-US citizen, then the IRS may require some of the payment be withheld for taxes. If you are a non-US citizen, you may need to provide a W-8BEN (Certificate of Foreign Status of Beneficial Owner for United States Tax Withholding and Reporting) form to the Jaeb Center.
- If you have a US Visa, then your status may have earning limits. You may need to review your Visa requirements.

You can choose not to get paid for your participation in this study. You will need to tell the study team or study doctor if you do not want to get paid. You do not have to tell them why.

## WHAT HAPPENS IF I HAVE AN ILLNESS OR INJURY FROM THE STUDY?

This study does not have any more risk than you would have if you were not in the study. It is not expected that there would be any study related illness or injury. If you have an illness or injury that is related to your participation in the study, then you can get care like you normally would.

**Signing this form and agreeing to be in this study does not mean that you lose any of your legal rights or release anyone involved in the research from their responsibilities.**

## CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have questions about this study or a research illness or injury, or if you have concerns, suggestions or questions about the study, then contact your study doctor using the contact information on the first page of this form.

If you have questions, comments or suggestions about the research you can contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org . You can also contact the IRB if you want more information about your rights, injury reimbursement, or the future use of your information or samples.

## HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

This section tells you about the use and disclosure (or "sharing") of your personal Protected Health Information (PHI). This is like the information that is usually found in your medical records that will be collected for the study. Only the health information about you that is needed for this study will be used or disclosed. This information will be kept confidential and private as required by law. The specific types of information that will be released and used for this study are:

- Diagnostic tests
- Medical history / treatments

You are being asked to give your permission for your PHI to be shared from your doctors, clinics, and hospitals to the researchers doing this study. This is called giving your Authorization. The PHI is needed to do the study, so you will have to give your Authorization in order to be in the study. If you do not want to give Authorization, then you will not be able to be in the study.

Your Authorization for PHI lasts 50 years from the date that you sign this form or until the end of the study, whichever comes first. You may cancel your Authorization at any time. You will need to contact your study doctor's office in writing, or you may contact the JCHR IRB Office at 813-975-8690 or irb@jaeb.org. When you fully cancel your Authorization, you are no longer part of the study. No new PHI will be collected or shared for the study, except if there is a safety concern. If there is a safety concern, you may be asked for more information, or your entire medical record may need to be reviewed. The researchers will have all the information that was collected for the study up to the time that you canceled your Authorization or are no longer in the study. Any information that has been received will remain in the study database after you withdraw.

The researchers will use a code that may have your initials or date of birth to keep your study information (or "study results") together at the Jaeb Center for Health Research in Tampa, Florida. Your Authorization for the use and sharing of the coded study results will never end. Also, the following people or companies involved in this study may see your study results with things like your date of birth, initials, and date of procedures:

- your treating healthcare providers and their staff
- associated healthcare institutions and hospitals where you receive care
- Jaeb Center for Health Research (JCHR)
- Luminopia
- FedEx will see your contact information only for the purpose of sending you supplies

Sometimes people not directly working on the study need to see your PHI. For example, the Food and Drug Administration (FDA), other federal agencies, and committees that monitor safety may look at your information in the study. In most cases, the information will be coded instead of having your PHI, but not always. For example, if you are in this study, then this form could be reviewed and it would have your name on it. Once PHI is shared, it may no longer be covered by the privacy laws. Only the people that need to see your information are allowed to see it.

You have the right to see your records too. During the study, you may not be able to see or get copies of everything. The study doctor will be able to tell you if you will have to wait to get some information. When the study is over, you have the right to see all of your study records.

**Certificate of Confidentiality**
The National Eye Institute has given us a Certificate of Confidentiality for this study. This adds special protection for study information that identifies you and allows us, in some cases, to refuse to give out information that could identify you without your consent. This could be done when the information is requested by a federal, state, or local court, or public agency. If you need medical help, we may still share your identifiable information. As described in this form or in other cases, we may share identifiable information. For example, if the government inspects us, they may see your identifiable information. Your study doctor and research team will follow local laws and will tell the local or state authorities:

- if certain diseases are present;
- if they suspect neglect, abandonment, or abuse of you; and
- if your study doctor or research team learn that you plan to harm yourself or someone else.

**Clinical Trial Reporting**
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. A copy of one of the study consent form templates will also have to be posted on a federal Web site.

**Other Considerations**
The information collected in the study may be used in future studies without additional permission from you. This may include research done by other researchers. The information that may be shared will not contain any PHI that could identify you. There may still be a chance that someone could identify you, but this is not likely. A copy of the information collected as part of the study will be made public in a dataset. This will be done after the study ends. This dataset will not contain any PHI. The study results will also be made public. These results will not have any PHI either. Study results without PHI may be shared in medical journals and at scientific meetings.

A limited dataset that contains some PHI may be provided to certain researchers. This PHI will not include things like your name, address, identifying pictures, or medical record numbers. Any researcher would need to sign an agreement to protect your PHI before getting this dataset as required by law.

Overall results from the study will be sent to you in a study results newsletter after the study has been published.

**Contact from the Jaeb Center**

Separately from your research data, the Jaeb Center for Health Research in Tampa, Florida will be provided with information on how to contact you for the phone calls described earlier. Also, if your study doctor's office is not able to locate you when they try to schedule your follow-up visit, a third-party search service may be used to try to contact you.

## Minor's Legally Authorized Representatives (LARs) Permission and Authorization

**Minor's Full Name** (printed)**:** _____

I, _____ (print name of adult) 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; or if not the parent, then
☐ Legal Custodian; or
☐ Legal Guardian

**By signing below, I agree to allow the child to take part in this study. My signature means that:**

- the consent form was provided in a language that I understand, and I have read this informed consent form
- I have been given the chance to discuss the study, in a language that I understand, and to ask questions to my satisfaction
- I freely choose to allow the child to participate; the child and I can withdraw at any time
- The child has been told that they will be in a study to look at treatment for their eyes, they have seen the headset and eye patches and understands that they will be asked to wear one or the other, and they have stated that they would be willing to do so
- I will receive a copy of this consent form
- I authorize the use and disclosure of the child's protected health information. This information is collected as part of participation in this study. The child cannot be in this study if I do not provide this permission.

_____ _____
LAR Signature Date

## Investigator's Certification

**I certify that to the best of my knowledge:**

- **The participant and/or LAR(s) are who they say they are**
- **That the study information and written materials were provided to the participant and/or LAR(s) in a language that they understand, and that they understand the nature, demands, risks, and benefits involved in the participation of this study**
- **The child has verbally stated that they are willing to be in the study at this time**

**I attest that I will ensure that study records will show that the participant/LAR provided consent and that I have co-signed *before* any study procedures, including data collection.**

_____ _____ _____
**Investigator's Printed Name** **Investigator's Signature** **Date**