CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY TITLE: Randomized Trial of Occlusion Therapy for Intermittent Exotropia in Children

STUDY DOCTOR'S INFORMATION
Name:
Contact Number:
Site Name:
Mailing Address:
Emergency (24-hour) Number:
Study Coordinator Name/Phone:

SUMMARY
In this form, when it says "you" it is referring 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" would mean "your child." A "minor" is generally a person under the age of 18. A LAR for a minor is a natural or adoptive parent, a legal custodian, or a legal guardian.

This consent form will give you important information about this study. It will help you decide if you would like to take part in the study. You do not have to be in this study. You can stop the study at any time. You should read and discuss all the information in this consent form with the study doctor.

- You are being asked to take part in this research study because you have intermittent exotropia (IXT), a condition where one or both of your eyes sometimes turn out.

- The study is being done to see if wearing a patch all the time for three months helps children with IXT keep their eyes straight better than not wearing a patch.

- You will be asked to be in this research study for about three months. If you are asked to wear the patch, you will patch your right eye on even days and your left eye on odd days every day for three months. If you are not asked to wear the patch, you will not receive any other treatment for IXT other than your glasses for three months.

- If you are asked to wear the patch, you will have your patch time monitored. This will be done by placing a small temperature sensor under the eye patch using a silicone holder. The sensor is small and could be harmful if eaten. The sensor will record temperatures that will be used to estimate how much time the patch is worn. You will be given instructions on how to place the sensor. You will also be asked to record how much time you wear your glasses and patch on a calendar.

- The most likely risks to you are skin irritation from the patch, sensor, or silicone holder or possible reduced vision after wearing the patch.

- The possible benefit is better ability to keep your eyes straight, but that is what the study is trying to find out.

- If you do not participate, you may get patching, special glasses, exercises, or surgery for intermittent exotropia outside of the study.

WHAT IS INFORMED CONSENT?

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 answers to your questions and concerns. 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 can take as much time as you need to think about whether or not you want to be in this study. You can also take a copy of this form with you to discuss with friends, family, or other doctors to help you decide. Please read this document carefully. Do not agree to be in this study unless all of your questions have been answered.

You do not have to be in this study. If you decide not to be in this study, you will not be treated differently as a person just because you did not want to be in this study. Also, your regular care will not be impacted.

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 Institutes of Health. 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 name of the study doctor, the doctor's contact information, and the mailing address are listed on the first page of this form. If one of the study doctors gets money or benefits from a company that makes the eye patches in this study, 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 because you have intermittent exotropia (IXT), a condition where one or both of your eyes sometimes turn out. The goal of this study is to see if wearing a patch all the time helps children with IXT keep their eyes straight better than not wearing a patch.

WHO CAN PARTICIPATE IN THIS STUDY?

About 80 children with IXT from about 60 sites in the US and Canada will be in the study.

Children will be in the study for 3 months.

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

- Be 3 to 8 years old
- Have intermittent exotropia (eyes that turn out some of the time)
- Have good vision
- Be wearing glasses for at least 2 weeks if needed

Also, you must not:

- have a known allergy to adhesive bandages or silicone
- be born prematurely at <30 weeks
- have had eye surgery
- have had patching or other non-surgical treatment for IXT in the past year
- have been treated for amblyopia (lazy eye)

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

WHAT WILL HAPPEN IN THIS STUDY?

Enrollment
If you decide to take part in this study, you will be asked to complete a brief questionnaire about your quality of life and your IXT symptoms. If any questions make you or your parent uncomfortable, either of you can refuse to answer.

You will have an eye exam to see if you are able to be in the study. The exam will include measuring how often and how far your eye drifts, your ability to turn your eyes in and out, depth perception, and whether both eyes are seeing at the same time when one eye drifts out.

Treatment
If you are able and decide to take part in this study, a computer program will be used to select whether you will wear a patch for three months or whether you will not wear a patch for three months. This is like flipping a coin to decide which group you will be in.

If you are asked to wear a patch, you will patch your right eye on even days and your left eye on odd days every day for three months. You will have your patch time monitored. This will be done by placing a small temperature sensor under the eye patch using a silicone holder. The sensor is small and will record temperatures that will be used to estimate how much time the patch is worn. You will be given instructions on how to place the sensor. You will also be asked to record how much time you wear your glasses and patch on a calendar.

If you are not asked to wear a patch, you will not receive any other treatment for IXT other than your glasses for three months.

You should not agree to participate in the study unless you are willing to wear a patch all the time for three months.

Phone Call
Your doctor's office will call about 4 weeks after the enrollment exam to check if you are having any problems.

Follow-up Visit
You will return 12 weeks after the start of the study. You will be asked how often you have worn your glasses and how often you wore a patch if necessary. Your doctor will repeat the same measurements as done at the time of enrollment.

The table below shows what will happen at enrollment and at 3-month visits:

Test	**Description**
Quality of Life Survey	One brief survey to evaluate your vision and whether you are bothered by your eyes. One survey is completed by you if you are age 5 or older. The other survey is completed by your parent.
IXT Symptom Survey	One brief survey of symptoms that may happen with your eye condition. One survey is completed by you if you are age 5 or older. If you are younger than 5, then only one question will be asked regarding whether you see double. The other survey is completed by your parent.
Distance Visual Acuity	Evaluates how well you can see in each eye
Randot Preschool Stereo	Evaluates your depth perception
IXT Control Assessment	Evaluates how well you can hold your eyes straight
Ocular Alignment Assessment	Evaluates how far your eye drifts
Divergence Amplitude Testing	Evaluates how well you can turn your eyes out
Convergence Amplitude Testing	Evaluates how well you can turn your eyes in
Suppression Testing	Evaluates if both eyes are seeing at the same time when one drifts out
Retinal Correspondence Testing	If you are age 6 or older, evaluates how well your eyes focus light on the part of the eye that sends an image to your brain

WHAT ARE THE RISKS OF THIS STUDY?

If you choose to take part in this study, you need to know that there are some risks of being in this study.

- There is a small chance that you may have skin irritation from wearing the patch, the sensor, or the silicone sensor holder. The study has things in place to make that risk as low as possible.
- There is a very small chance that you might develop an allergy to the glue of the patch.
- There is a very small chance that you may develop amblyopia (worse vision in one eye). If this happens, you may need to wear a patch over one eye. With treatment, the vision gets better most of the time.
- The temperature sensor worn under the patch is small and could be harmful if eaten. Data collected from other studies so far have shown that the sensors did not get into the eye because it is stuck to the patch and is pressed to the skin, but this is possible.

Risks to Confidentiality

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

Text or Email Messaging

The study doctor and staff may use your contact information to call, text or email you during the study. They may do this to send you things like appointment reminders. 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 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.

Other Information

The information collected by the temperature sensor on your patch will be sent to a secure data server over the internet. Your data will have a code to identify that the data is from your sensor. This information may be seen by the company that makes the temperature sensor. This information includes the temperature recorded by the sensor, the date and time the temperature is recorded, and a sensor code. The information sent may identify you to the company that makes the sensor. It is possible that information about you might be uploaded. There are steps in place to make sure this does not happen. If it does happen, the company that makes the sensor also has steps in place to protect your data. If uploaded, any data that may identify you will be removed as soon as possible.

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

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

The possible benefits are being able to hold your eyes straight easier but that is what the study is trying to find out. People who take part in this research study will add to new knowledge that may help other children with IXT.

ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?

If you do not take part in this study, your options include standard treatments like patching, special glasses, exercises, and surgery, other research studies, or you may choose not to do anything. Your study doctor will discuss these choices and the risks and benefits of each with you.

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 be treated differently as a person. Also, your regular care will not be impacted. Please talk to your study doctor or staff so they know why you are stopping the study and can help you do so safely. Also, if you

want to stop study treatment but want to stay in follow-up and allow ongoing data collection during the study, you will need to tell the study team.

If we find out that there is any important new information about the study, 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. 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
- If you do not follow the study instructions
- The doctors think that being in the study may cause you harm
- If you experience an injury related to the study
- If you need additional or different treatment

If you withdraw, are removed from the study, or the study is stopped, you may continue to receive care like you normally would if you were not in this study.

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

The costs of routine treatment, office visits, and tests that are part of your child's regular care will be billed to you or your child's insurance company like they normally would if your child were not in a study. The study will pay for the visits, procedures and items listed below. Any additional tests and procedures for standard care will be billed to you or your child's insurance company like they normally would.

The study will pay for:

- Office visits that are part of the study (enrollment visit and the visit at 3 months) and the procedures performed at these visits as part of the study (see "What Will Happen in This Study").
- All eye patches, sensors, and silicon sensor holders used during the study (if applicable). At the end of the study, or if you decide to remove your child from the study, you must return any remaining sensors and silicon sensor holders to your child's eye doctor.

The study will not pay for:

- Prescription eyeglasses or contact lenses.

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 FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will receive up to $200 for your participation. These payments will be paid to the parent/LAR as follows: $100 for completion of the enrollment exam, and $100 for

completion of the study visit at 3 months. These payments will be paid by electronic gift card, 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 or for visits that are for treating an illness or injury.

The study may reimburse you or your study doctor's office for your extra travel expenses. If you would like reimbursement for travel expenses, then please tell the study doctor's office. Direct and reasonable travel expenses for study required visits will be reimbursed if you are unable to drive yourself or if you must travel more than 50 miles round trip to attend the required study visits. If you must drive in a personal vehicle more than 50 miles round trip, mileage reimbursement will be made based on the current federal mileage rate for mileage over the first 50 miles, and the distance traveled will be verified by your study doctor's office. You will be asked to provide receipts or proof of mileage. Direct and reasonable travel expenses are the actual cost of the most sensible travel option to get you to and from required study visits, like taking a taxi or ride-share service. 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. 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 reported to the IRS as income, you may need to provide your social security number or a 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.

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

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. If you have an emergency, please seek emergency care as soon as possible. Please tell the emergency doctor that you are in a research study. Please also tell your study doctor about the emergency as soon as you can. Care will be billed to you or your insurance like it normally would. The study does not have funds set aside for care or other expenses relating to illnesses or injuries.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

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

Contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org if you have questions, comments or suggestions about the research. 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/or disclosure (sharing) of your personal Protected Health Information (PHI) if you decide to participate in this study. Your health information that may be used or disclosed is described below. 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 research 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 research are:

- Medical history / treatments
- Diagnostic tests

You are being asked to not only be in this study, but also to give your permission for your PHI to be released from your doctors, clinics, and hospitals to the researchers doing this study. This is called giving your Authorization. The PHI is necessary for the study to be done, so you do 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 shared for the study, except if there is a safety concern. If there is a safety concern, your entire medical record may need to be reviewed. The researchers will receive 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 (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
- Jaeb Center for Health Research
- Theramon ® MC Technology GmbH

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 inspect health and study records. In most cases, the information will be coded instead of having your PHI, but not always. For example, if you participate 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.

You have the right to see your records. During the study, you may not be able to see or get copies of everything. For example, if you are not supposed to know which study group you are in, then we

wouldn't want to tell you before the study ends. 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 the full records.

Certificate of Confidentiality
The National Institutes of Health 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, 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.

Results from the study will be sent to you in a newsletter after the study is 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.

You may also have communication with the study doctor's office by phone, text, or by video (like FaceTime or Skype). There is a chance that someone could see or hear the conversation like they could if you were speaking or texting with anyone.

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

Minor's Legally Authorized Representatives (LARs) Permission

I, _____ (print name of LAR) 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;
☐ Legal Custodian; or
☐ Legal Guardian

By signing below, you agree to allow your child to take part in this study. Your signature means that:

- you have read this informed consent form
- you have been given the chance to discuss the study and to ask questions to your satisfaction
- you freely choose to allow your child to participate, you and your child can withdraw your child at any time, and you will receive a copy of this consent form
- you authorize the use and disclosure of your child's protected health information. This information is collected as part of participation in this study. Your child cannot be in this study if you do not provide this permission.

_____ _____
LAR Signature Date

Permission to Notify Primary Provider About Participation

It might be a good idea for your child's regular provider or doctor's office to know that your child is in this study. With your permission, we can contact your child's regular provider or doctor's office for you and give them information about the study and your child's health.

☐ I ***do*** give my permission for the study team to contact my child's regular provider or doctor's office to tell them about my child's participation in this study. This may include some health information about my child too. I understand that I will be asked to provide the contact information of my child's regular provider or doctor's office. I may need to sign a release of information form at the study doctor's office too.

☐ I ***do not*** give my permission for the study team to contact my child's primary physician to inform them about my child's participation in this study

_____ _____
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, and understand(s) the nature, demands, risks, and benefits involved in the participation of this study.

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