

Intermittent Exotropia Study 6: A Pilot  
Randomized Clinical Trial of Base-in Prism  
Spectacles for Intermittent Exotropia

Informed Consent Form

June 18, 2019

NCT03998670

## CONSENT TO TAKE PART IN A RESEARCH STUDY

### **STUDY TITLE: INTERMITTENT EXOTROPIA STUDY 6 (IXT6) A Pilot Randomized Clinical Trial of Base-in Prism Spectacles for Intermittent Exotropia**

#### **STUDY DOCTOR'S INFORMATION**

Name:

Contact Number:

Site Name:

Site Address:

Emergency (24-hour) Number:

Study Coordinator Name/Contact:

#### **SUMMARY**

**In this form, when it says “your child” it is referring to the person under your care that would be in the study if you are a legally authorized representative (LAR). Please see the next section called “Legally Authorized Representatives (LAR)” for more information about who can be a LAR. This would be like a parent reviewing the information for their child to be in the study.**

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

- **Intermittent exotropia, or “IXT,” is when one eye drifts out some of the time and at other times both eyes are straight.**
- **The study is being done to find out if prism glasses (glasses with special lenses) help reduce how often an eye drifts out for children with intermittent exotropia (IXT).**
- **Your child will be asked to be in the study for about 8 weeks. The study will involve two eye exams without dilating eye drops, one telephone call, and wearing new glasses.**
- **The most likely risks to your child are eye strain, blurred vision, or halos or rainbows in their vision when wearing the glasses; these typically get better over time and also with removal of the glasses.**
- **The possible benefit is having your child’s eye drift out less often while wearing glasses, but that is what the study is trying to find out. Others may benefit from the information gained by this study.**
- **If your child does not participate, they may use regular glasses, glasses with a different type of special lenses (over-minus), patching, eye exercises, vision therapy, have eye muscle surgery, or not have any treatment.**

## **LEGALLY AUTHORIZED REPRESENTATIVE (LAR)**

A “minor” is a person under the age of 18 years. A legally authorized representative (LAR) for a minor is a natural or adoptive parent, a legal custodian, or a legal guardian.

## **WHAT IS INFORMED CONSENT?**

We are asking you to allow your child to take part in this research study because your child has intermittent exotropia (IXT). The goal of this study is to learn things that may help people with IXT.

The study doctor will be talking with you about this study and this form. You can take as much time as you need to think about whether or not you want your child 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 and your child’s questions have been answered.

Your child does not have to be in this study. If you decide not to be in this study, your child will not be treated differently as a person or a patient just because you didn’t want to be in this study. Also, your regular care will stay the same.

## **WHO IS DOING THE STUDY?**

This study is being done by the Pediatric Eye Disease Investigator Group (PEDIG). 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 child’s study doctor and clinic staff will use the funding to carry out this study. The name of the study doctor and the doctor’s contact information is listed on the first page of this form.

## **WHY IS THIS STUDY BEING DONE?**

Your child has a condition called IXT. IXT is the medical term used when an eye drifts out some of the time and at other times both eyes are straight. IXT is one of the most common types of eye misalignment in children. IXT is sometimes treated using glasses with special lenses (prism). Prism may help children control IXT by reducing how hard they have to work to align the eyes. The purpose of this study is to find out if prism helps children with IXT in the short term before doing a long-term study. We expect 64 to 100 children will take part in this 8-week study at about 40 different medical locations throughout North America.

## **WHO CAN TAKE PART IN THIS STUDY?**

In general, to take part in this study, your child must:

- (1) be at least 3 years old and less than 13 years old
- (2) have IXT that has not been treated in the past 1 month except with regular glasses or contact lenses
- (3) have never worn prism glasses

(4) have never had eye surgery

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

## **WHAT WILL HAPPEN IN THIS STUDY?**

### Enrollment Eye Exam

If you decide to allow your child to take part in this study, your child will have an eye exam to see if they are able to be in the study. This will include measuring how often and how far your child's eye drifts. On the same day, your child will wear "trial" prism glasses for at least 30 minutes. Your child will then be measured again to see how far their eye drifts while wearing the prism.

Depending on how far your child's eye drifts while wearing the prism:

- Your child will have finished the study that day.  
OR
- Your child will start the treatment portion of the study.

### Treatment

A computer program will be used to select whether your child will be given glasses with prism or glasses without prism. This is like flipping a coin to decide which group your child will be in. The glasses will be provided at no cost to you. Your child will wear these glasses all of the hours they are awake for the next 8 weeks.

With prism glasses treatment, your child will receive glasses that have prism. The prism glasses will also have a regular correction, if your child needs it. Your child must wear the glasses all day every day during the study.

With non-prism glasses treatment, your child will wear glasses without prism. The non-prism glasses will have regular correction, if your child needs it. If your child doesn't need glasses that have a prescription, they will be prescribed glasses with clear lenses that have no correction. Your child must wear the glasses all day every day during the study.

You will not be told which treatment your child is getting until the study is completed. This helps to make sure that none of the study results are affected by participants knowing which group they are in.

**You should not agree to allow your child to be in the study unless you are willing to have your child wear either type of glasses.**

### Questionnaires

Your child will be asked to complete a brief questionnaire about their IXT symptoms. You will be asked to complete a short questionnaire about your child's symptoms that might happen with wearing prism glasses. If any questions make you or your child uncomfortable, either of you can refuse to answer.

Phone Call

Your doctor’s office will call about 3 weeks after the enrollment exam to check if your child has received the glasses.

Follow-up Visit

You and your child will return 8 weeks after the start of the study. You will be asked how often your child has been wearing the glasses. The glasses will be measured to make sure they were made correctly. The doctor will measure how well your child can keep their eyes straight 3 times during this visit. The doctor will also measure how often and how far your child’s eye drifts out, and their ability to turn their eyes in. The vision in each eye, depth perception, and whether both eyes are seeing at the same time when one eye drifts out will be measured.

The table below shows what will happen at each visit:

<b>Test</b>	<b>Description</b>
Spectacle and Symptom Surveys	Two brief surveys of symptoms that may happen with prism glasses or your child’s eye condition. One survey is completed by you. The other survey is completed by your child.
IXT Control Assessment	Evaluates how well your child can hold their eyes straight
Randot Preschool Stereo	Evaluates depth perception
Ocular Alignment Testing	Evaluates how far the eye drifts
Fusional Convergence Amplitude Testing	Evaluates how well your child can turn their eyes in
Suppression	Evaluates if both eyes are seeing at the same time when one drifts out
Distance Visual Acuity	Evaluates how well your child can see in each eye
Prism Adaptation Test (at enrollment only)	Evaluates if the amount of drifting changes after wearing prism lenses for at least 30 minutes

**WHAT ARE THE RISKS OF THIS STUDY?**

If you choose to allow your child to take part in this study, you need to know that there are some side effects or risks of being in this study.

Eye Examinations

The risks and discomforts of the eye examination are mild and the same whether your child takes part in the study or not.

Treatment

The risks involved in the study are the same as those for a child treated with prism glasses who is not taking part in the study.

The more common side effects that are known:

- Eye strain
- Blurred vision

- Halos or rainbows in vision

The less common side effects that are known:

- Dizziness
- Nausea
- Headache

These symptoms usually get better over time or with removing glasses. How often these symptoms happen in children is not known.

**Unknown risks**

There may be additional risks from the prism glasses or the study tests 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 still want your child to be in the study based on this new information.

**Risks to confidentiality**

This study will be collecting some information about your child that includes personal information, like 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.

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

**WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?**

The possible benefits are less frequent drifting of your child’s eye while wearing glasses. That is what the study is trying to find out. People who take part in this study will add to new information that may help other children with IXT.

**ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?**

If your child does not take part in this study, your doctor may prescribe or recommend regular glasses, glasses with a different type of special lens (over-minus), an eye patch, eye exercises, vision therapy, prism glasses while not in the study, or eye muscle surgery. You may also choose for your child to be in other research studies, or you may choose not to do anything at all. Your study doctor will discuss these choices with you.

**CAN MY CHILD STOP BEING IN THE STUDY?**

Your child can stop being in the study at any time. If you decide that your child should stop being in this study, your child will not be treated differently as a person or patient. Also, your child’s regular care will not change. Please talk to your child’s study doctor or staff so they know why your child is withdrawing from the study and can help your child do so safely.

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 let your child to continue in the study based on this new information.

The study may stop or the study doctor may decide to take your child 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 your child from the study. You will be told if this happens.

Some reasons why your child may be removed from the study include:

- If the doctors feel that it is in your child's best interest
- If the doctors think that being in the study may cause your child harm
- If your child experiences an injury related to the study
- If your child needs additional or different treatment
- If your child does not follow the study instructions

If you withdraw, if your child is removed from the study, or if the study is stopped, your child may continue to receive care like they normally would if they were not in this study. Your child's study doctor will be able to help you decide if your child should continue to wear the study glasses after the study ends.

### **ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?**

The study will pay for visits that are done just for the research study. You and your insurance company will not be responsible for the cost of visits done just for the research study. The study will not pay for usual care visits. Usual care visits are those that would occur whether or not your child is in the study. The cost of usual care visits will be your or your insurance company's responsibility like they would be normally.

- The study will pay for the 8-week study visit, as it is done just for the research study. You and your insurance company will not be responsible for the cost of the 8-week study visit.
- The study will pay for your child's study glasses.
- The study will not pay for contact lenses, tinted lenses, or antireflective coating.

### **IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?**

If your child takes part in the study, you will receive up to \$100 for participation. These payments will be paid as follows: \$50 for each completed visit (up to 2 visits) by gift card or check. If you withdraw your child from the study, you will still be paid for the visits that your child has completed. You will not receive extra payments for visits that are required as part of your child's normal care or for visits that are for treating an illness or injury.

Because payments made to you for your child 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 child's study

doctor's office. These will not be shared outside of your child's doctor's office, other than as required to the IRS.

## **WHAT HAPPENS IF MY CHILD HAS AN ILLNESS OR INJURY FROM BEING IN THE STUDY?**

If your child has an illness or injury that is related to being in the study, then your child can get care like they normally would. If your child has an emergency, please seek emergency care as soon as possible. Please tell the emergency doctor that your child is in a research study. Please also tell your child's study doctor about the emergency as soon as you can. The study does not plan to provide costs for care or other expenses relating to illnesses or injuries. Your child's study doctor, the study doctor's office, the Jaeb Center, and National Eye Institute are not planning to cover payment for lost wages, direct losses, or indirect losses.

## **CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS**

If you have: questions about this study, a research illness or injury, or have concerns, or suggestions about the study, then contact your child's study doctor using the contact information on the first page of this form. You can also contact the Pediatric Eye Disease Investigator Group toll-free at 1-888-797-3344.

Contact the Jaeb Center for Health Research Institutional Review Board (IRB) Administrator at 813-975-8690 or [irb@jaeb.org](mailto:irb@jaeb.org) if you:

- Have questions about your rights as a research participant
- Wish to talk about your concerns or suggestions about the research
- Want additional information about the research, or
- Want to provide comments about the research.

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

As required by law, study-related records with identifying information will be kept confidential. Safety measures for the access, security, and privacy of your child's information have been put in place by law. Your child's date of birth and initials may be used in the study to help the researchers keep the right information together. This information will be protected as described below. Unless the law requires it, your name, address, social security number, telephone number, or any other direct identifying information will not be used to identify your child.

### **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 your child and allows us, in some cases, to refuse to give out information that could identify your child without your consent. This could be done when the information is requested by a federal, state, local court or public agency. If your child needs medical help, we may still share their 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

child's identifiable information. Your child's 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 your child plan to harm self or someone else

### **Purpose of Authorization**

We have rules to protect information about your child. Federal and state laws also protect your child's information. By signing this form, you are giving your permission, called your "authorization," for the use and disclosure of information protected by the law.

You must sign the Protected Health Information Authorization at the end of this form if you want your child to be in the study. When you sign the form, you give permission for the use and sharing of your child's Protected Health Information (PHI) for the study. PHI is health information that identifies your child. Your authorization is beneficial and important for the study. Without your authorization, your child will not be able to be in this study.

### **Using and Sharing Your Child's PHI**

Your study doctor will collect information about your child. This information includes things learned from study procedures as well as your child's name, address, date of birth, and information from your child's medical records. These are examples of identifiable information. A code number with your child's initials and date of birth will replace their name, address, telephone number, or social security number in the results given to the Jaeb Center for Health Research in Tampa, Florida.

The following people or companies involved in this study may see your study results with things like your child's date of birth, initials, and date of procedures:

- Your child's study doctor's office
- Jaeb Center for Health Research

The study doctor's office **will not** share study results that can identify your child except as explained in this form or when required by law. The Jaeb Center and your study doctor's office will guard the privacy of your child's study PHI.

### **Who Can Receive and Use Your Study Information?**

It is possible that people outside of this doctor's office and the Jaeb Center may need to see or receive your information from this study. Some examples include government agencies (such as the Food and Drug Administration), committees that monitor safety, other sites in the study, and companies that are providing either funding or supplies for the study, laboratories, and centers that may receive images. In most cases the information will have a code number with it instead of your child's name, address, telephone number, or social security number.

There are some situations where the information will not have a code number but may include your child's name, address, telephone number, or social security number (PHI). Once PHI is disclosed by your study doctor and the clinic staff, it may no longer be covered by the privacy laws. Everyone who

needs to see your child's information will be told it is confidential, but we cannot guarantee full confidentiality once it leaves the doctor's office.

### **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 information that could identify your child. There may still be a chance that someone could identify your child, 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 information that could identify your child.

Study results without the identifiable information may be shared in medical journals and at scientific meetings. Your child's records will be confidential. No one will share your child's identity in a medical journal or at a scientific meeting.

Results from the study will be sent to you in a newsletter after all participants have completed the study.

### **Contact from the Jaeb Center**

Separately from your child's 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 a 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.

### **Clinical Trial Reporting**

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by law. This Web site will not include information that can identify your child. 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.

### **Can You Cancel Your Authorization?**

You may cancel your permission for the collection of your child's study PHI at any time. You will need to contact your study doctors and give them a written notice of cancellation, or you may contact the JCHR IRB Office at 813-975-8690 or [irb@jaeb.org](mailto:irb@jaeb.org). When you cancel your permission or when you withdraw your child from the study directly, your child is no longer part of the study. No new information about your child will be gathered for the study, except when there is a safety concern related to the study. If there is a safety concern, your child's entire medical record may need to be reviewed.

The Jaeb Center will receive all the information that was collected for the study up to the time that you cancel or withdraw from the study. The Jaeb Center will receive any new information about any safety concerns that may be related to the study.

### **When Will the Use and Sharing of Your Child's PHI Stop?**

Some of your child's study PHI does not have a code number with it. Your permission for the use and sharing of your child's PHI lasts 50 years from the date that you sign this form or until the end of the study, whichever comes first.

The rest of your child's study information that is not PHI does have a code number with it. When it is collected, it becomes part of a research report. Your permission for the use and sharing of this coded information will never end. This coded data does not have your child's name, address, telephone number, or social security number.

Some of your child's information from this study may be stored separately from or added to the medical record. You will not be able to see this information until the study ends. If your regular doctors require it for your child's care, they will be able to view it.

**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 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

**Designated Person Obtaining Consent**

**I certify that to the best of my knowledge the participant or LAR(s) understand(s) the nature, demands, risks, and benefits involved in the participation of this study.**

\_\_\_\_\_  
**Investigator or Designee's  
Printed Name**

\_\_\_\_\_  
**Investigator or Designee's  
Signature**

\_\_\_\_\_  
**Date**