INTERMITTENT EXOTROPIA STUDY 1 (IXT1)
A Randomized Trial of Bilateral Lateral Rectus Recession versus Unilateral Lateral Rectus Recession with Medial Rectus Resection for Intermittent Exotropia Informed Consent Form

1. Introduction

We are asking you to have your child take part in a research study. The study is being conducted by the Pediatric Eye Disease Investigator Group. Your child's eye doctor is a member of this group. The Jaeb Center for Health Research is the coordinating center which is organizing the study. The National Eye Institute is providing the funding for the study. The institute is part of the federal government. This form is part of the process to inform you about the research study. We want to make sure that you understand that the study involves research. Research is a scientific way to learn about medical conditions and/or treatments.

First, we want you to know that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which your child is otherwise entitled and you may discontinue your child's participation at any time without penalty or loss of benefits to which your child is otherwise entitled. Before you decide whether to have your child take part in the study, please take as much time as you need to ask any questions. You may discuss this study with your child's doctor, the medical staff, your child's primary physician, family, and/or friends. For your child to be in the study, you will need to sign this form.

2. Information about the Study

Your child has a condition called intermittent exotropia. Intermittent exotropia is the medical term used when the eyes turn out some of the time and are straight at other times. Intermittent exotropia is one of the most common types of eye misalignment in children.

Intermittent exotropia is often treated with surgery on the eye muscles to make the eyes straight again. There are different ways to do this surgery to straighten the eyes. One way is to operate on two muscles on one eye. Another way is to operate on one muscle on each eye. Both ways of doing the surgery work well but we do not know if one way is better than the other. This is the reason why the study is being done.

You are being asked to have your child take part in the study because he/she has intermittent exotropia. Your child's eye doctor feels that your child needs surgery to make his/her eyes straight. The study will include about 475 children who, like your child, have intermittent exotropia. Children will take part at pediatric eye centers throughout North America. Your child will be in the study for about three years. To be in the study, your child needs to:

(1) be at least 3 years old and less than 11 years old
(2) have intermittent exotropia
(3) have had no eye muscle surgery before
(4) have a need for eye muscle surgery

In the study, your child either will have the surgery on two muscles on one eye or the surgery on one muscle on both eyes.

42 ***If your child is in the study, you will not have a choice of which type of surgery your child**
43 **receives. You must be willing to accept either type of surgery. If either or both of the**
44 **surgeries are unacceptable to you, you should not enroll your child in the study.*** 45 You
should not have your child be in the study if you are planning to move out of this area in the 46 next
3 years.
47
48 **3. Study Procedures**
49 If your child is in the study, you must be willing to follow the procedures described in this section.
50
51 Treatment
52 A computer program will be used to decide whether your child will be treated with surgery on one
53 eye or with surgery on both eyes. This is similar to flipping a coin to decide on the
treatment. 54
55 With both surgeries, your child will have surgery on two eye muscles, however:
56 • With surgery on one eye, your child's eye doctor will operate on two muscles on one of your
57 child's eyes.
58 • With surgery on two eyes, your child's eye doctor will operate on one muscle on each of
59 your child's eyes.
60
61 Close to the date of your child's surgery, the computer program will decide which surgery your 62
child will receive. You will find out which surgery your child will be receiving before your
child's 63 surgery is performed. *You will not be able to change what type of surgery your child has*.
64
65 Follow-up Visits
66 Your child will need to return for 8 follow-up visits over the next 3 years. The first follow-up visits
67 will occur 1 week and 8 weeks after your child has surgery. The next visits will be at 6, 12, 18, 24,
68 30 and 36 months after your child enters the study. These exams would be needed whether
your 69 child has surgery as part of the study or not.
70
71 Your child's eye doctor may decide that more follow-up visits are needed for your child, just as if
72 your child were not part of the study.
73
74 At each visit, the eye doctor will check to see if your child's eyes are straight. At most visits, your
75 child also will also have his/her vision and depth perception checked. Sometimes some of these 76
tests will be done more than once. At some visits, your child's eyes will be dilated and the
eye 77 doctor will determine whether your child needs eyeglasses or a change in his/her current
eyeglasses.

At some visits you will also be asked to fill out 2 short questionnaires about how your child's eye condition affects you and your child. If your child is 5 years old or older, he/she will also fill out a short questionnaire about how he/she feels about his/her eye condition.

The 3-year visit is the last visit of the study. Once your child has finished study visits, the eye doctor will continue to see your child if it is needed, but this will not be part of the study.

4. Risks

Eye Examinations

The risks and discomforts of the eye examinations are the same whether or not your child takes part in the study. The drops used to dilate your child's eyes at some of the exams may sting for a few seconds. For a few hours they may make your child's vision blurry up close and make your child's eyes sensitive to bright light.

Surgery

The risks of the surgery are the same whether your child receives the surgery as part of the study or not. There is a very small chance of death (less than 1 in 100,000) with any surgery. The risk of death is the same whether your child would have surgery as part of the study or outside of the study and is the same for both types of surgery. There is also a very small chance of loss of vision.

Again, the risks of surgery are the same whether your child is in the study or not.

For some children, the eyes turn in or "cross" right after the surgery. This is not uncommon for both types of surgery. It may happen slightly more with the surgery on one eye, but we do not know for sure. The eyes should straighten out over several weeks. There is a small chance that your child's eyes may stay turned in. This turning in can often be helped by putting a piece of plastic called a prism on the child's eyeglasses. If your child needs treatment with prisms, prisms will be provided at no charge by the study. If your child needs treatment with prisms and is not wearing eyeglasses, a pair of eyeglasses to place the prisms on will be provided at no charge by the study. Sometimes if the eye turns in after surgery the vision in one eye may get worse. If this happens, your eye doctor may have your child wear an eye patch or prescribe other treatment. The turning in may also cause double vision. Very rarely the double vision does not go away on its own and your child might need another surgery. The chance of any of these things happening is the same whether your child has surgery as part of the study or not.

There is a small chance that your child's depth perception might get worse after the surgery. The chance of this happening is the same whether your child has that surgery as part of the study or not.

There is a small chance that your child's eyes will still turn out immediately after the surgery. There is also a chance that your child's eyes will turn out again even if his/her eyes are straight right after the surgery. This may happen after either type of surgery. It may happen slightly more with the surgery on two eyes, but we do not know for sure. If this happens, your child may need another surgery. The risk of this happening is the same whether your child has surgery as part of the study or not.

Unknown Risks

Although we have tried to list all possible risks and discomforts with this study, there may be others that we do not know about at this time. However, these unknown risks of the treatment would be the same whether your child was having surgery as part of this study or not.

5. Benefits of Participation

Your child may not directly benefit from being in this study. The information will help the doctors treat children with intermittent exotropia in the future.

6. Alternative Procedures or Treatment

The alternative to taking part in the study is to not take part. You do not have to allow your child to be in this research project in order to get the treatments being used in the study. Your child needs surgery for intermittent exotropia, but this can be done outside of this study if you desire.

7. CONFIDENTIALITY AND YOUR PROTECTED HEALTH INFORMATION (PHI)

(Section Required by the HIPAA Privacy Rule – 45 CFR 164.508)

> Note: If we are inviting you to have your child take part in this study, please note that this section refers to your child's participation in the study and your child's protected health information.

A. Purpose of Authorization

The HIPAA Privacy Rule is a federal law about privacy (45 CFR Part 160 and Subparts A and E of Part 164). It says how to guard the privacy of your protected health information, also called PHI.

This authorization explains who can use and disclose your PHI for the study and why.

You must sign this form if you want to be in the study. When you sign the form, you give permission for the use and disclosure of your PHI for the study. You will not be able to be in the study if you do not.

B. Use and Disclosure of the Protected Health Information (PHI)

As part of the study, you will have testing and examinations and/or will answer questions. Your study results will be given to the Jaeb Center for Health Research. The Jaeb Center is the coordinating center for the study. It is located in Tampa, Florida.

There are other people in the study. They are from this doctor's office and/or from other doctors' offices. Their study results will also be given to the Jaeb Center. A code number will go with the study results instead of the study participant name, address, telephone number, or social security number.

This doctor's office will not disclose study results that have a direct personal identifier except as explained later in this authorization or when required by law. Name, address, telephone number, and social security number are examples of direct personal identifiers. The Jaeb Center and this doctor's office will guard the privacy of your study PHI.

Study results appear in medical journals. They are shared at scientific meetings, too. No one will disclose the identity of a study participant in a medical journal or at a scientific meeting. Your records will be confidential. They will be kept according to the requirements of federal and state law.

It is very important that your study doctor's office has your current contact information. You will be informed of the study results when they are made public.

C. Authorized Recipients and Users

The following people may receive, see, use, and disclose your study PHI. The information will have a code number with it instead of your name, address, telephone number, or social security number.

1. The people who work for this doctor's office
2. The people who work for the Jaeb Center
3. The scientific investigators who help run the study
4. Any review board that oversees human investigations rules for your doctor's office
5. Any federal agency that oversees clinical trials

The following people may also receive, see, use, and disclose your study PHI. The information will

not have a code number with it. If it is reviewed by any of these people, they may need to review your whole medical record. For example, they may need to see it if you have an adverse (unfavorable) event that is related to the study.

1. The people who work for this doctor's office
2. The people who work for the Jaeb Center
3. The scientific investigators who help run the study
4. Any review board that oversees human investigations rules for your doctor's office
5. Any federal agency that oversees clinical trials
6. If you have an adverse (unfavorable) event, the people outside this doctor's office who assist in your care

Other Considerations

We will send the information about your child's eyes to a central computer. The computer is located at the Jaeb Center for Health Research in Tampa, Florida.

In addition, separately from your child's research data, the Jaeb Center for Health Research in Tampa will be provided with information on how to contact you.

- Within one month of starting the study you will receive a phone call from a staff member at the data center to check on your child's condition and to see if you have any questions. You will be called again about twice each year. You will be called at a time that you indicate is most convenient for you. If you are not available at the time of the call and prefer to call the data center yourself, you will be given a toll-free phone number for that purpose.
- You will also be able to use this toll-free number (888-797-3344) to call the data center should you have any questions at any time.
- During the study, you may receive additional calls if necessary to help schedule an office visit for your child. If we are not able to locate you when we try to schedule your child's follow-up visit, we will try to contact you through the other information you have given us. If this is not successful, we may use the information you have given us to try to locate you through the use of a third-party search service.
- You will also receive updates and information about the study in the mail.

If your child needs eyeglasses, he/she must already be wearing the correct eyeglasses before he/she can be in the study. The study will not pay for eyeglasses that are needed before the study because this is part of normal care. While your child is in the study, the study will pay to change the prescription of your child's eyeglasses to keep them within the study guidelines. If the prescription change is not needed to keep your child's eyeglasses within study guidelines, the study will not pay for it. If your child does not wear eyeglasses now, the study will pay for a complete pair of eyeglasses if your child later meets the study guidelines for requiring eyeglasses.

LensCrafters has agreed to provide the study with a discount on eyeglasses. Your child's eye doctor may send you to LensCrafters or another contracted optician to get new eyeglasses. In order to provide your child with new eyeglasses, the optician or LensCrafters will receive information on your child. Your child's name, birth date, and study identification number will be given to the optician who is making the eyeglasses. If your child is to receive study-paid eyeglasses through LensCrafters, this information will be given to LensCrafters by the Jaeb Center, via the EyeMed/Eye Care Plan of America website, to help process the making of your child's eyeglasses.

D. Reasons for Access and Use

The people named above (see section C) may receive, see, use, and disclose your study PHI. They need it to help run the study and to analyze the results. They may also need it to meet the requirements of federal or state law.

This doctor's office will provide the study PHI to the Jaeb Center and to the other people named above as needed and/or requested by them. The study PHI will typically be provided to them via the Jaeb Center, because it is the coordinating center.

E. Potential for Redisclosure

The HIPAA Privacy Rule may not require the people named above (see section C) to guard the privacy of your study PHI. It is possible that they may give it out again.

F. Cancellation of authorization

You may stop your permission for the use and disclosure of your study PHI at any time. You need to contact your study doctor and give him/her a notice of cancellation in writing.

When you cancel your permission or when you withdraw from the study directly, you are <u>no</u> longer part of the study. No new information about you will be gathered for the study except when it is on an adverse (unfavorable) event that is related or potentially related to the study. If one happens, your entire medical record may need to be reviewed.

The Jaeb Center will receive all the information that has already been collected for the study up to the time of cancellation or withdrawal. Any new information about any adverse (unfavorable) event that is related or potentially related to the study will be sent to the Jaeb Center, too.

G. 50 Year Expiration Date <u>and</u> Indefinite Expiration Date

Some of your study PHI does <u>not</u> have a code number with it. Your permission for the use and disclosure of this PHI lasts 50 years from the date of your signature or until the end of the study, whichever is sooner. The end of the study is when no one has to monitor the study anymore, the funding agency data analyses are done, and the primary articles are accepted for publication.

The rest of your study PHI does have a code number with it. When it is collected, it becomes a research report. Your permission for the use and disclosure of these coded data will never end. These coded data do not have your name, address, telephone number, or social security number.

8. Costs

- The National Eye Institute will provide funds for services specific to the research study, but will not cover patient services considered to be routine patient care.
- All of the follow-up visits in this study are considered to be part of usual care. Since these visits would be needed whether your child was in the study or not, the costs of the visits will be your or your insurance company's responsibility.
- The surgery, any additional surgeries that are needed, and any costs involved with treating surgical complications will be your or your insurance company's responsibility. The surgery on two eyes can sometimes cost more than the surgery on one eye.
- The study will pay to change the prescription to keep your child's eyeglasses within the study guidelines while he or she is in the study. If the prescription change is not needed to keep your child's eyeglasses within study guidelines, the study will not pay for it. If your child does not wear eyeglasses, the study will pay for a complete pair of eyeglasses if later during the study your child meets the study guidelines for requiring eyeglasses. The study will not pay for contact lenses.
- If your child requires treatment with prisms, prisms will be provided at no charge. If your child needs a pair of eyeglasses to put a prism on as part of the study and is not already wearing eyeglasses, the study will pay for these eyeglasses.

9. Compensation

You will be given $30 for completion of each of the 8 required follow-up visits (up to $240). This is meant to cover your time involved in the study and any travel expenses involved with coming to the visits. Payment will be made directly to you by the central coordinating center in Tampa, Florida. Payments will be made for any completed visits in the month following each completed visit. You will receive payment for completed visits even if your child leaves the study before the end. If your expenses exceed $30 per visit and you will be unable to complete a visit without additional funds, please discuss this with the study staff. Additional funds may be available.

10. Research-Related Injuries

Medical care is available if your child has a research-related injury. If your child has an emergency, your child can get emergency care. If possible, you should tell the emergency care medical staff

that your child is in a research study. You should also tell your child's eye doctor about the emergency as soon as possible.

The costs of care will be your or your insurance company's responsibility. Compensation for lost wages and/or direct or indirect losses is not available. The study will not provide compensation for medical expenses or any other compensation for research-related injuries.

You can get more information about research-related injuries from your child's eye doctor (see contact information on the last page) or from the coordinating center staff at the Jaeb Center (toll-free at 888-797-3344).

11. Withdrawal from the Study

It is up to you whether your child takes part in this study. You can withdraw your child from the study at any time by contacting your child's eye doctor and by letting him/her know in writing that you are withdrawing your child (see contact information on the last page).

Over the course of the study, you will be told of any new scientific findings that might affect your willingness to have your child stay in this study.

Your child's doctor or individuals in charge of this study may stop your child's participation in the study. Some possible reasons for this include:

- It is determined that your child was not eligible for the study.
- The investigator decides that continued participation would be harmful to your child.
- Your child receives a treatment not allowed in the study.
- The study is stopped.
- There are unanticipated circumstances.

If your child leaves the study early for any reason, the data which were already collected will still be used in evaluation of the study results.

If you have any questions about the study at any time, you should speak with your child's eye doctor or one of his/her staff (see contact information on the last page). If you have questions about your child's rights as a research subject, you should contact the Jaeb Center Institutional Review Board office at 888-797-3344. You may also call the coordinating center staff toll-free at 888-797-3344 should you have any questions at any time.

Note: If we are inviting you to have your child take part in this study, please see **all** the text in parentheses.

Subject's Name *printed* _____

Description of Representative's Authority to Act for the Subject: _____

Protected Health Information Authorization

By signing, you authorize the use and disclosure of your (child's) protected health information. This information is collected as part of your (child's) participation in this study.

_____ _____

Signature Date

Study Enrollment

INTERMITTENT EXOTROPIA STUDY 1 (IXT1)
A Randomized Trial of Bilateral Lateral Rectus Recession versus Unilateral Lateral Rectus Recession with Medial Rectus Resection for Intermittent Exotropia Informed Consent Form

By signing, you agree to (have your child) take part in this study. Your signature means that:

- ***you have read this informed consent form about the study named below;***
- ***you have been given the chance to discuss the study and to ask questions;***
- ***you have verbally summarized your understanding of the study to the person who is explaining it to you; and***
- ***you freely choose to (have your child) participate.***

Name of Study: A Randomized Trial of Bilateral Lateral Rectus Recession versus Unilateral Lateral Rectus Recession with Medial Rectus Resection for Intermittent Exotropia

_____ _____

Signature Date

I certify that to the best of my knowledge the subject (parent/guardian) understands the nature, demands, risks, and benefits involved in his/her (child's) participation in this study.

_____ _____

Investigator's Signature Date

You will be given a signed copy of this document in case you want to read it again.

Investigator Contact Information

Name of Investigators: [*list all investigators at site*]

_____

_____

_____

_____

Address: _____

_____

Telephone: _____

INTERMITTENT EXOTROPIA STUDY 1 (IXT1)
A Randomized Trial of Bilateral Lateral Rectus Recession versus Unilateral Lateral Rectus Recession with Medial Rectus Resection for Intermittent Exotropia
Subject Assent

You have a problem with your eyes called intermittent exotropia. This means that your eyes turn out some of the time and are straight at other times. Your doctor thinks that you need eye surgery to fix your eyes. We are doing a study to find out which type of eye surgery is best.

The study is looking at two types of eye surgery. One type of surgery involves operating on one eye. The other type of surgery involves operating on both eyes. In this study, you will have surgery on one eye or on both of your eyes at the same time. You will not get to choose which type of surgery you will receive. A computer program will decide which type of surgery you will receive. This is like flipping a coin to decide the type of surgery.

In the study, you will come back 8 times over the next 3 years to have your eyes checked. The eye doctor will check how straight your eyes are and how well your eyes work together. Sometimes these things will be checked more than once. At some visits, you will get drops in your eyes that will help the doctor find out if you need glasses or a change in your glasses. These drops may sting for a few seconds and will make lights seem brighter for a few hours. At some visits you and your parent/guardian will also be asked to answer some questions about how you feel about your eyes.

There is a chance the surgery may not fix your eyes. There is a chance you may need to have surgery again. The chance of this happening is the same whether you are in this study or not.

If you are in this study:

- You understand that you will have surgery on one or both of your eyes but you won't be able to choose which.
- You understand that you will need to come back to the doctor 8 times over the next 3 years.
- You understand that your parent/guardian and you will have to answer some questions about your eyes.

You don't have to be in this study if you don't want to. If you are in the study, you can stop being in it at any time by telling this to the eye doctor. Nobody will be upset with you if you don't want to be in the study or if you want to stop being in the study. The doctors and their helpers will take care of you just as they have before. If you have any questions or don't like what is happening, please tell the eye doctor. Your parent or guardian knows about this study. You have had it explained to you and you have been given a chance to ask questions about it. By writing your name below, you are saying that you know what will happen to you in the study and that you want to be in it.

Your signature means that you understand that your personal health information may be used by people connected with the study.

_____ _____ _____

Subject's Name (Printed) Subject's Signature Date

_____ _____

Investigator's Signature Date