CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY TITLE: Randomized Trial of Bifocal Spectacles vs. Single Vision Spectacles for Esotropia Greater at Near

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. An 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 have esotropia (crossed eyes) that is worse when you look at things up close than when looking at things farther away. The study is being done to see if bifocal glasses or regular (single vision) glasses work better for treating this type of esotropia (crossed eyes).**

- **You will be asked to be in the study for a little more than 3 years. The study will involve wearing either bifocal glasses or regular glasses. Regular (single vision) glasses have the usual prescription that would be prescribed to help you see clearly and comfortably. Bifocal glasses have two different prescriptions. The top part has your regular prescription. The bottom part has a special lens used to look at things close up. After starting the study (enrollment), you will see your eye care doctor for study visits at 3, 6, 9, 12, 18, 24, 30, 36, and 38 months. You may have extra visits or fewer depending on how you are doing.**

- **This study is called a minimal risk study. This is because the risk for the study is like the risk you would have if you were not in the study.**

- **The most likely risks to you are blurry vision, double vision, eye discomfort, and reduced depth perception. It also might look or feel odd at first when you are walking and look down through the bifocal lenses.**

- **The possible benefits are less crossing of the eyes and better depth perception. This is what the study is trying to find out.**

- **If you do not participate, you can still seek care for your esotropia. You can get bifocal glasses or regular glasses outside of the study. You may also get other treatment options.**

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.

Your 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 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.

Taking part is voluntary. You can choose whether you want to be part of the study or not. 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 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 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 glasses 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 esotropia (crossed eyes) that is worse when looking at things up close than when looking at things farther away. The goal of this study is to learn things that may help people with this type of esotropia.

Most children with esotropia need to wear glasses. Some doctors prescribe single-vision glasses (regular glasses) and some doctors prescribe bifocal glasses. However, no one knows which of these two types of glasses work better (or worse). That is what the study is trying to find out.

In this study, we are checking your depth perception and eye alignment (eye-crossing) by measuring them at every visit. If your depth perception or eye alignment worsen, you will be prescribed bifocals (if

you are in the regular glasses group) or continued bifocal glasses (if you are in the bifocals group) for 2 months. After you return for a recheck in bifocal glasses, your doctor can prescribe any type of treatment.

WHO CAN PARTICIPATE IN THIS STUDY?

The study will enroll about 444 children at up to 70 study sites in the US and Canada. The study will last just over 3 years.

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

- be 3 to <9 years old
- have esotropia (crossed eyes) that is worse when looking at things up close than when looking at things farther away
- be wearing glasses that meet study criteria for at least 4 weeks (if you need glasses)

Also, you must not have:

- worn bifocal glasses in the past
- had eye muscle surgery or Botox injection
- had treatment for the esotropia using eye drops in the last 3 months
- had vision therapy or prism glasses as treatment for the esotropia in the last 3 months
- had amblyopia treatment in the last 3 months

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

WHAT WILL HAPPEN IN THIS STUDY?

Study Treatments

Half of the children in the study will wear single-vision (regular) glasses. The other half will wear bifocal glasses (bottom part of glasses have a special lens used to look at things close up). If you decide to take part in this study, you and your doctor will not get to choose which glasses you will wear for the study. A computer program will be used to select whether you will get bifocal glasses or regular (single-vision) glasses. This is like flipping a coin to decide which group you will be in. Please do not agree to be in the study unless you are willing to wear either bifocal glasses or single-vision glasses for about 3 years.

Treatment and Follow-up Schedule

You will wear the study glasses all the time except for when you are sleeping. After starting the study (enrollment), you will return to your doctor for study visits at 3, 6, 9, 12, 18, 24, 30, 36, and 38 months.

- Children with reduced depth perception or increased eye-crossing at any time during the study will have 1-2 special study visits a few months after that happens. During this time, children who were wearing regular glasses will be asked to wear bifocal glasses for 2 months. Children who were wearing bifocal glasses will continue to wear them for 2 more months. After the last special study visit(s), these children will complete only the 12-month and 24-month visits (if they have not already

been completed), and the 38-month final study visit. None of the other study visits will be completed.

Testing at Office Visits

At each visit, your vision, depth perception, and eye alignment will be checked. This will be done both with the glasses you normally wear at home, but also with glasses that are kept in the office to help during the exam. Sometimes, we will check how well you use both eyes together too. At certain visits, the doctor will put drops in your eyes to see if your glasses prescription needs to be changed. This will happen once a year. It will also happen if your eye-crossing or depth perception measurements worsen.

The table below shows what will happen at each visit:

Eye Tests	Enrollment and Randomization	3-Month Visit	6-Month Visit	9-Month Visit	12-Month Visit[c]	18-Month Visit	24-Month Visit[c]	30-Month Visit	36-Month Visit	38-Month Visit in Bifocal Glasses	Retest Visit	Early Outcome Visit in Bifocal Glasses[b]
Vision	X	X	X	X	X	X	X	X	X	X	P	P
Depth Perception[a]	X	X	X	X	X	X	X	X	X	X	P	P
Eye Alignment[a]	X	X	X	X	X	X	X	X	X	X	P	P
Eye Drops to Check Eyeglass Prescription					X		X	X				
Prescribe Bifocal Glasses to Regular Glasses Group									X		P	

X = visits that occur for all children.

P = visits that occur only if depth perception or eye alignment get worse.

[a]If the depth perception or eye alignment seem to get worse at any visit, you will get eye drops to check the glasses prescription. If your depth perception or eye alignment gets worse and your glasses need to be changed, then you will have an extra office visit to do testing in the new glasses.

[b]Early Outcome Visit: If your depth perception or eye alignment gets worse at any visit (including a Retest Visit) and your glasses are correct at that time, children wearing regular glasses will be prescribed bifocal glasses, and all children will come back for an Early Outcome Visit in 2 months. All children will be wearing bifocal glasses.

[c] If depth perception or eye alignment worsen , the 12-month and 24-month visits may have less study testing.

New Glasses

You will be given a prescription for new study glasses at enrollment, 12 months, and 24 months. You also may be given new glasses at other visits if your prescription changes. If you are in the regular glasses group, you will receive bifocal glasses at 36 months, or earlier if your eye crossing increases or depth perception worsens. You will wear these glasses all waking hours. The study will pay for the new glasses at enrollment and for all changes in glasses that are needed for the study.

You will also be prescribed a pair of glasses that will be worn only for certain testing in your doctor's office. These "testing glasses" will have a special prescription that will be different from the study glasses you wear all the time. LensCrafters or another contracted optician will mail these "testing glasses" directly to your doctor's office, where they will be stored for you and used only for testing purposes at study visits.

Phone Calls
You will receive a phone call 1 month after you are given new glasses or a change in glasses. The primary purpose of the call is to determine whether the new glasses have been received and are being worn.

If your eye crossing increases or your depth perception worsens before 3 years
If your eye crossing increases or your depth perception worsens before 3 years, the following things will happen. If you are in the regular glasses group, you will be given bifocal glasses to wear for 2 months. If you are in the bifocal glasses group, you will continue to wear bifocal glasses for 2 more months. Both groups return after 2 months to have their vision, depth perception, and eye alignment measured. Afterwards, your doctor may prescribe any type of treatment or no treatment. You will come back for only the 12-month and 24-month visits (if not already completed) and the 38 month-visit. You will not have as much study testing done at these visits.

End of the Study
You will have a visit at 3 years (36 months) unless your eye-crossing increases or depth perception worsens at an earlier visit (see previous paragraph). At the 3-year (36 month) visit:

- If you are in the regular glasses group, you will be given bifocal glasses to wear for 2 months.
- If you are in the bifocal glasses group, you will continue to wear bifocal glasses for 2 more months.

All study participants return for the 38-month visit to have vision, depth perception, and eye alignment measured. Then the study is finished.

WHAT ARE THE RISKS OF THIS STUDY?

It is not expected that there would be any significant risks from being in this study.

Some minor risks are that you might notice blurry vision, double vision, mild eye discomfort, or reduced depth perception when wearing the study glasses. It may take a few days to get used to the new glasses. This can happen with the regular glasses and the bifocal glasses. There is a chance that your eye crossing or your depth perception might get worse. Either of these could occur with bifocal glasses or with single-vision glasses. These things could also occur with no treatment. The risk of these things happening for each treatment (bifocal glasses or single-vision glasses) or for any procedure is the same whether you receive the treatment as part of the study or not.

Another possible risk is to confidentiality. This study will be capturing some information about you that includes identifiable, personal information, like your name, address and date of birth. This information needs to be collected as part of the study so that the study team can contact you about the study if

needed. 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 identifiable health information by text or regular email because it is unsecure. This means that there is a risk that an email or text 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 name or 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.

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 less eye crossing (better eye alignment) and better depth perception. This 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 people with esotropia in the future.

ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?

If you do not take part in this study, your options include standard treatments like regular glasses, bifocal glasses, prism glasses, vision therapy/exercises, eye surgery, botulinum toxin, 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, or just stop study treatment, at any time. If you decide to stop being in the study, or to stop using the study treatment, you will not be treated differently as a person. Also, your regular care will not be impacted. If you just want to stop study treatment, then you may be asked if the study can still collect your health information. It is up to you whether you agree to this or not, but the study cannot keep getting your health information unless you say it is okay. Please talk to your study doctor or staff so they know why you are stopping the study or stopping treatment so they can help you do so safely.

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

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. Your doctor will help you decide if it is best for you to continue wearing the glasses you are given in the study.

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

The costs of your regular care will be billed to you or your insurance company like they normally would if you were not in a study. The study will pay for study visits performed only for research purposes. The study will pay for the glasses worn during the study and all changes that the study requires be made to those glasses. The study will not pay for prescription sports glasses or goggles if you choose to wear them. Also, any additional tests and procedures will be billed to you or your insurance company like they normally would.

- The study will pay for the visits at enrollment, 3 months, 9 months, and 38 months, and any additional research visit(s) that might be needed if your eye alignment or depth perception worsens. The reason the study pays for these visits is because these visits are done only for the research study.
- The study will not pay for the 6-, 12-, 18-, 24-, 30- and 36-month visits because these visits are done as part of your usual care.
- You will be given new study glasses at enrollment, 12 months, and 24 months. You also may be given new glasses at other visits if your prescription changes. If you are in the regular glasses group, you will receive bifocal glasses at 36 months, or earlier if your eye crossing increases or depth perception worsens. The study will pay for all new glasses and changes in glasses that are needed for 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 FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will receive $100 for each study visit (to pay for travel, parking, time and other expenses associated with attending the visit). You will receive a total of $1000 if you complete all 10 of the set study visits (enrollment, 3-, 6-, 9-, 12-, 18-, 24-, 30-, 36- and 38 months). If you are asked to complete any extra visits, you will receive $100 for each of these completed visits, also. These payments will be made to the parent or legally authorized representative 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. Travel reimbursement is not taxable income per the IRS.

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

This is a study with minimal risk. This means that the study does not have any more risk than you would have if you were not in the study. For this reason, 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. 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:

- Hospital discharge summaries
- Medical history / treatments
- Laboratory / diagnostic tests
- Operative report (about an operation)
- Diagnostic imaging report relating to your eyes

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,
- associated healthcare institutions and hospitals where you receive care
- Jaeb Center for Health Research

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 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, 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.

Your child will receive glasses as part of the study. They will be provided at no cost to you. Your child's eye doctor may send you to LensCrafters or another contracted optician to get the 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. You will also be prescribed a pair of single-vision glasses to be used for testing in the office only. These glasses will be sent on your behalf to your doctor's office by LensCrafters or another contracted optician where they will be stored and used only for testing purposes at study visits.

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 newsletter after the study is published. Your individual study results can be obtained from your eye doctor, if you request them.

Social Media
We would like to ask you not to share any of the specific details of this study publicly, like in social media posts. This is one way we can help protect the confidentiality of the study. You do have the right to discuss the study with others to help you decide if you want to be in the study or stay in the study at any time.

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

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**