CONSENT TO TAKE PART IN A RESEARCH STUDY

If the participant/LAR cannot read this form (like when they cannot see or read well), then the person obtaining consent may read this form to the participant/LAR as written. When this form is read to a participant/LAR, an impartial witness must be present, and the accompanying IRB approved short form must be used and signed by the participant/LAR and witness.

STUDY TITLE: A Randomized Placebo-controlled Trial of Spectacles with Highly Aspherical Lenslets or 0.05% Atropine to Slow Progression of Myopia in Children

STUDY DOCTOR'S INFORMATION

Site PI Name:
Site Name:
Site Phone Number:
Mailing Address:
Emergency (24-hour) Number:

SUMMARY

Informed consent is the process that tells you about a research study, including procedures, treatments, and possible side effects. This process involves reading this form, talking to the study team, and addressing your questions and concerns. The goal is to make sure that you have all the information needed to decide if you want your child to participate in the study.

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

- This study is being done to measure how effective atropine eyedrops (0.05% atropine, 99.95% inactive solution) and/or special eyeglass lenses are for slowing down how much nearsightedness (myopia) increases over two years. We expect that about 400 children will participate in this study at up to 25 sites in the US.

- The diluted atropine eyedrops and special eyeglass lenses are not approved by the Food and Drug Administration (FDA) for myopia. For this reason, they are called "investigational" in this study.

- We are asking that your child be in this research study for two and a half years. Your child would have a study visit every three months. Half of the visits will be eye exams. The other half will be eyedrop pickup visits where your child won't see the eye doctor; your child does not have to attend the eyedrop pickup visit with you. Your child will also have five visits to get fitted with new study glasses. The study will involve testing how well your child can see, how well their eyes focus, and how nearsighted their eyes are. Your child will also be asked to answer questions about how well they can see in their everyday activities.

- If your child is female and has started her menstrual periods, or begins having menstrual periods while participating in the study, she will also give a urine sample for a pregnancy test at each study visit. This is a safety precaution required by the FDA. If the test is positive for pregnancy, the study doctors will tell you and your child. Your child would stop the eyedrops, continue study glasses, and continue to participate in the study.

- The most important difference between this study and regular care for your child's nearsightedness is that the special eyeglass lenses are not currently available in regular care. In addition, in regular care you may only have one office visit a year, but in the study, you will have at least two office visits a year.

- The most likely risks to your child are that the atropine eyedrops may cause sensitivity to light, enlarged pupils, and/or blurry vision when your child looks at things up close. The most likely risk to your child from the special eyeglass lenses is that they may cause blurring of their side or peripheral vision. The most serious risk is an unexpected allergic reaction to the eyedrops, but this is unlikely.

- The possible benefit to your child is that the treatments slow down any increase in nearsightedness, but this is what the study is trying to find out. Your child may not directly benefit, but others may benefit in the future.

- You may discuss alternative treatments such as different eyedrops or special contact lenses with your child's eye doctor. Some of the risks for the alternative treatments will be like those for the study treatments. Be sure to talk to the study doctor about other treatments, other possible studies, and how their risks and benefits compare to this study. If your child participates in this study, your child will not be able to use any alternative treatments for the 30 months they are in the study.

WHO IS DOING THE STUDY?

This research study is being done by the Pediatric Eye Disease Investigator Group (PEDIG). It is being paid for by the National Eye Institute of 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 study doctor's contact information is listed on the first page of this form. If one of the study doctors gets money or benefits from a company that makes the drugs or devices in this study, then the doctor must tell the Jaeb Center.

WHY IS THIS STUDY BEING DONE?

Nearsightedness means that vision is blurry when looking at far-away objects without glasses. This condition is also called myopia. Nearsightedness in a child is usually caused by an eye that is too long. If the eye continues to grow, children become more nearsighted. Once a child becomes nearsighted, it tends to get worse during childhood and teenage years, and stronger glasses are usually needed to correct the vision. More importantly, larger amounts of nearsightedness can potentially increase the risk

of complications that could cause visual impairment. Because wearing regular glasses only corrects the vision, other treatments are needed to slow down the eye growth (myopia progression).

Some studies have shown that the low-concentration atropine eyedrops may slow down myopia progression. The U.S. Food and Drug Administration (FDA) has not approved atropine for treating myopia (nearsightedness). Therefore, it is considered an experimental drug when used to treat myopia.

The special eyeglasses have lenses that modify your child's side (i.e. peripheral) vision. Some studies have shown that the special eyeglasses may slow down myopia progression. The special eyeglass lenses are not approved by the FDA and are considered experimental. The purpose of this study is to see if low-concentration atropine eyedrops and/or special eyeglass lenses can help prevent myopia from getting worse. The study will also see if any benefit lasts after the eyedrops and special lenses are stopped.

We expect about 400 children will take part in this study at up to 25 different medical practices in the US.

Your child is being asked to take part in this research study because they have a mild to moderate level of nearsightedness (myopia) and are between 5 and 11 years old. The goal of this study is to learn things that may help people with myopia.

WHO CAN PARTICIPATE IN THIS STUDY?
In general, to take part in this study, your child must:

- Be between 5 and 11 years old (cannot be within four weeks of 12th birthday)
- Have nearsightedness (myopia)
- Have never used atropine eyedrops, light therapy, special glasses or special contact lenses to treat myopia progression
- Wear regular glasses nearly all the time
- Have no known allergy to atropine
- Agree not to wear contact lenses during the study

There are some other criteria your child must meet to be part of the study. Your study doctor will check if your child meets these or not. If your child meets the criteria but their current glasses do not meet the requirements for the study, the study will pay for new glasses or a change in your child's glasses, if you get them from the study doctor's office or another study contracted optician.

Your child will be in the study for about 2 ½ years. You should NOT have your child be in the study if you are planning to move out of this area in the next 2 ½ years.

Female children cannot participate in the study if they are pregnant or breastfeeding. If your child is female, you should not have her take part in the study if she is pregnant or is nursing. If your child has had a menstrual period or starts to menstruate during the study, she will have a urine pregnancy test at most study visits including at the time of randomization. This testing is required by the FDA for safety

reasons. If your child has a positive pregnancy test, the study doctors will tell you and your child; your child would stop the study eyedrops and continue participation in the study.

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

WHAT WILL HAPPEN IN THIS STUDY?

At the start of the study, all children will get artificial tears eyedrops. Some children will also get new regular glasses, if needed. The artificial tears have no physical effect other than moistening the eye. The purpose of artificial tears is to see how well your child can use daily eyedrops. Children will receive these eyedrops in each eye every night for 2 to 4 weeks. A parent should put in the eyedrops if the child is not able to. A parent will also need to record whether their child gets the eyedrop every night. Children will need to return to their study eye doctor for another exam after using the artificial tears eyedrops for 2 to 4 weeks.

If your child has used the artificial tear eyedrops at least 90% of the time and still meets the study criteria, your child may participate in the 2½ year study; otherwise, they will end study participation. For children who are participating in the 2½ year study, a computer program will be used to select whether your child will be given the diluted 0.05% atropine eye drop or a placebo eyedrop. A placebo eyedrop does not have any medicine in it, but it looks like the diluted 0.05% atropine eye drop. The computer program will also select whether your child will continue to wear regular lenses in the glasses, or whether your child will be given the special lenses. This selection is like pulling a name out of a hat to decide which group you will be in and is called randomization. Your child has a 75% chance of being assigned to at least one of the study treatments (atropine eyedrops, special glasses). Your child has a 25% chance of being assigned to neither study treatment, which is called the control group. Neither you nor your study doctor will know which treatments your child is receiving until the study is over. This information is available in the event of an emergency during the study.

<u>Study Eyedrop Treatment</u>

All children will receive study eyedrops. Half the children in the study will get 0.05% atropine eyedrops; the other half of children will receive placebo eyedrops (similar to artificial tears, with no medication). You, your child, and your child's eye doctor will not know which type of eyedrops your child receives.

Your child will receive one drop of study eyedrops in each eye every night for 2 years. Your child will stop the eyedrops after 2 years. Your child will have a visit with the study doctor six months after stopping the eyedrops.

<u>Study Glasses Treatment</u>

All children will receive study glasses. Half the children in the study will get special glasses; the other half of children will receive regular glasses. You, your child, and your child's eye doctor will not know which type of glasses your child receives.

Your child will receive a new pair of study glasses at randomization, 6, 12, and 18 months. Glasses should be worn all the time (i.e. at least 10 hours per day), every day for 2 years. Your child can wear sports glasses or regular glasses while playing sports or take their study glasses off for a short period time for another activity (e.g. bathing, dancing, etc.). Otherwise, the study glasses should be worn all the

time. Your child will stop using the study glasses after 2 years. At that time, your child will receive regular glasses. Your child will have a visit with the study doctor six months after stopping the study glasses and eyedrops.

All glasses will be provided at no cost to you. Your child will choose from a specific selection of glasses frames at the study doctor's office. Four weeks later, you and your child will return to the study doctor's office to have the glasses fitted and dispensed. If the study glasses are lost or broken, a replacement pair will be provided at no charge. The study glasses that your child has been wearing will be collected and exchanged for the new study glasses. Study glasses worn during the first 2 years may not be worn after the study has ended. However, your child may keep and continue to wear the regular glasses that are prescribed at 2 years.

Study Procedures

At each study eye exam visit, we will measure how well your child can see and how well your child can focus their eyes by asking them to read or match letters on charts both across the room and close to them. Your child may also have the size of their pupils measured by looking into a special machine. At each visit, eyedrops will be put into your child's eyes to dilate the pupils allowing the amount of nearsightedness to be measured using tests that are the same or very similar to those used in regular care. A special machine will be used to measure how long your child's eyes are. Your child will get an updated prescription for new glasses lenses at each study visit. If your child is female and has started her menstrual periods, she will give a urine sample for a pregnancy test at each study visit. At some visits your child will be asked to answer questions about their eyes and how easy or hard certain things are for them to see and do in everyday life. If your child needs help reading the questions, then someone will help them.

Each time new glasses are prescribed, you and your child will return four weeks later for a glasses fitting visit to obtain the new glasses.

Throughout the study, you and/or your child will use a study-provided calendar to record how often your child is using the study eyedrops and if your child is wearing their glasses at least 10 hours every day. You will also receive phone calls from the study team in between visits to check if things are going okay and to help with any problems.

Visit Schedule

All children in the study will have **an eye exam** with their study eye doctor at:

- Enrollment
- 2 to 4 weeks after enrollment (randomization visit)
- 6 months after randomization
- 12 months after randomization
- 18 months after randomization
- 24 months after randomization
- 30 months after randomization

In addition, all children in the study will have a **glasses fitting visit** at their eye doctor's office at

- 4 weeks after randomization
- 4 weeks after 6-month eye exam
- 4 weeks after 12-month eye exam
- 4 weeks after 18-month eye exam
- 4 weeks after 24-month eye exam

In addition, parents will have a phone call from their study eye doctor's office at:

- 3 months after randomization
- 9 months after randomization
- 15 months after randomization
- 21 months after randomization
- 27 months after randomization

The table that follows shows what will happen at each study visit or interaction:

	Enrollment Visit	Randomization Visit	6-Month Visit	12-Month Visit	18-Month Visit	24-Month Visit	30-Month Visit	Glasses Fitting Visits (5)	Phone Calls
Informed Consent and Assent* (assent for children 7 years or older)	X								
Medical History	X		X	X	X	X	X		
Discuss how well your child is using treatments Time: approximately 2 minutes			X	X	X	X	X		X
Discuss any side effects of treatment Time: approximately 2 minutes			X	X	X	X	X		X
Demographics	X								
Answering Questions (parent and child) Testing time: approximately 5-7 minutes			X			X			
Measurement of pupil size Testing time: approximately 3 minutes		X	X	X	X	X	X		
Vision at distance and near Testing time: approximately 8-13 minutes		X	X	X	X	X	X		
Measure eye focusing (right eye only) Testing time: approximately 3 minutes		X	X	X	X	X	X		
Dilating eyedrops Time to fully dilate: approximately 35 minutes	X	X†	X	X	X	X	X		
Measure level of nearsightedness Testing time: approximately 2-4 minutes	X	X†	X	X	X	X	X		
Measure eye length Testing time: approximately 5-10 minutes	X	X†	X	X	X	X	X		
Determine glasses prescription Testing time: approximately 5-10 minutes	X	X†	X	X	X	X	X		
Urine pregnancy test (for individuals who have had a menstrual period)		X	X	X	X	X			

	Enrollment Visit	Randomization Visit	6-Month Visit	12-Month Visit	18-Month Visit	24-Month Visit	30-Month Visit	Glasses Fitting Visits (5)	Phone Calls
Receive artificial tears eyedrops to use until randomization visit Time: approximately 2 minutes	X								
Have new study glasses fitted and adjusted Time: approximately 5-10 minutes								X	
Have previous study glasses collected (when new glasses are dispensed) Time: approximately 1 minute								X	
Receive study eyedrops Time: approximately 2 minutes			X	X	X	X		X	
Have unused study eyedrops collected Time: approximately 1 minute			X	X	X	X			

†Measurements repeated at the Randomization Visit only if has been more than 28 days since Enrollment. Study eyedrops are first given out at the glasses fitting visit 4 weeks after randomization. After that, study eyedrops are dispensed at the 6-, 12-, and 18-month Eye Exam Visits. Note that study eyedrops are not used between 24 to 30 months.

WHAT ARE THE RISKS OF THIS STUDY?

If you decide to let your child take part in the study, your child will be at risk for the side effects listed below.

Eye Examinations

The risks and discomforts for the eye examinations will be the same whether or not your child is taking part in the study.

Study Eyedrops

- One possible side effect of study eyedrops is enlarged pupils, the black opening in the eye that allows light to enter. Enlarged pupils can cause sensitivity to light. If this is very bothersome, then clip-on sunglasses can be prescribed. In other studies, this occurred in up to one third of patients.

- It is very common (about 70%-80%) for the eyedrops to cause eye irritation (e.g. stinging, burning) when they are first administered. Normally the irritation goes away within a few seconds to a few minutes.

- The eyedrops can also cause the eye to be less able to focus on nearby objects. As a result, your child may experience blurry vision when they look at things up close. In other studies, this was mild and occurred in 1% of patients.

- Another risk is allergic conjunctivitis, which may cause itchy eyes and may be seasonal. In a recent study, this occurred in 10% of patients over 2 years. It is also possible that your child could have an allergic reaction to the study medication, although this is reported to occur less commonly. If your child has a confirmed allergic reaction to the eye drops, your child would need to stop the study eye drops, but would continue in the study.

- Another possible risk is reduced tear production, which may cause eyes to feel dry after using study medication. If this occurs, artificial tears may be used 10 minutes after the study medication eyedrop to moisturize the eyes.

- If the study eyedrops do slow your child's myopia progression, it is possible that the benefit may go away after the study eyedrops are discontinued.

- Potential systemic side effects include dry skin and mouth, tachycardia, fever, flushing and irritability. Of these specific systemic effects, tachychardia occurred once (with 0.02% atropine) among several studies of 0.05% and lower atropine eyedrop concentrations.

Special Glasses
Your child may experience blurriness in their side (i.e. peripheral) vision from the glasses.

It typically takes a short period of time for a child to adapt to the glasses. It may be a week or so, but we don't know for sure. During this time, your child should use caution doing things that could potentially injure them, like riding a bike or skateboard, climbing walls, or playing sports.

Risk to Nearsightedness
Your child's nearsightedness (myopia) would normally be expected to increase over the next 2½ years. The atropine eyedrops and/or special glasses may or may not help the myopia progression. If your child receives placebo eyedrops and regular glasses, they will not be receiving active treatment for myopia progression.

This study also includes 6 months of monitoring your child after stopping study eyedrops and glasses at 2 years. Your child will just continue the study wearing regular glasses during that time. The time without study treatment may make your child's nearsightedness increase.

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

Risks for Unborn Babies
The risks of this study on an unborn baby or breastfeeding baby are unknown. For this reason, anyone who is pregnant or breastfeeding cannot be in this study. Anyone who becomes pregnant during the study will have to stop using the study eyedrops but will stay in the study. Urine pregnancy tests are done as part of this study for anyone that is considered able to get pregnant.

If you are not comfortable with any of the following, then you should not allow your child to participate:

- Your child getting information about pregnancy
- Your child discussing pregnancy with you and the study doctor
- Your child having pregnancy tests

Risks to Confidentiality
This study will be collecting some information about your child like identifiable, personal information. An example is your child's date of birth. The study has plans in place to protect that information. There is still a chance that a loss of that protection could happen. This would be a loss of confidentiality. Please see the "How will my information be protected and kept confidential" section below for more information. Also, if any questions upset your child, then they can refuse to answer. Your child can decide to take a break from the study or stop taking part in the study at any time.

Study Questionnaires/Surveys
This study will involve asking your child some questions about your child's eyes and how easy or hard it is to do everyday things such as reading. It is not a test and there are no right or wrong answers. Your

child's answers will not be shared with anyone unless there is a concern about their safety or their ability to do things.

Shipping Supplies

The study team maybe sending study supplies to you using a shipping account that belongs to the Jaeb Center for Health Research. This means that the Jaeb Center for Health Research may have access to your contact information through the shipper, like FedEx. Your shipping information will not be used for any other purpose.

Text or Email Messaging

You will be offered the option to receive text messages from the Jaeb Center to remind you about study appointments. The text messages are called secure because there are steps in place to help keep people from seeing these messages that are not supposed to. It is possible that someone else may see the text messages on your phone. If they do, they might know that you are in a study or see a detail about the study. You would receive text messages a few times a year in relation to upcoming study appointments. The company that manages the system that sends the texts will see your phone number. They use this information to send the text messages. They are not allowed to share your phone number with anyone. Please ask the study team if you would like a copy of the company's privacy policy.

The study doctor and staff may use your contact information to call, text or email you during the study. They are not allowed to send you private information by text or regular email because it is not secure. This means that there is a risk that a message may be seen by someone that is not supposed to see it, like when an email gets hacked. Your email, phone number and your 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.

CAN I STOP BEING IN THE STUDY?

Your child can stop being in the study at any time. If your child decides to stop being in this study, your child will not have any penalty or loss of any benefits that your child would normally get. Your child can get regular care, but they will not be able to keep using the special lenses or study eyedrops.

Also, if at any time your child doesn't want to participate in or finish a test or procedure, then tell the study doctor. It is up to your child. The study doctor will tell you if your child can stay in the study without the tests or procedures, or if it means that your child's part in the study will be over. For example, if there is a question that your child does not want to answer, then it might be fine for your child to stay in the study.

You and your child can even tell the study doctor if you want to stop study treatment but want to keep giving information to the study. Information can only keep being collected this way if you and your

child say that it is okay in writing, like with a letter or an email. You and your child can also use the JCHR IRB Withdraw Letter found on our website at www.jaeb.org/research-participants.

If we find out that there is any important new information, you and your child will be told about it. You and your child 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 your child out of the study at any time too. You and your child do not have to give permission for the study to stop or for the study doctor to remove your child from the study. You and your child will be told if this happens. Some reasons why your child may be removed from the study include:

- The doctors feel that it is in your child's best interest
- Your child does not follow the study instructions

ARE THERE COSTS RELATED TO THE STUDY?

The study will pay for your child's glasses (frames and lenses), and for the eyedrops. At the glasses fitting visits that occur 4 weeks following the 6-, 12-, and 18-month visits, the study glasses that your child has been wearing will be collected and exchanged for the new study glasses. At the glasses fitting visit after the 24 month visit, or if your child withdraws from the study, you must return the study glasses to the study doctor, but your child will be provided with regular glasses that your child can keep to wear after the study ends.

Any regular office visits or additional tests and procedures will be billed to you or your insurance company like they would normally. You will be responsible for any data charges from text messaging and for fees related to transportation and parking.

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

IS THERE PAYMENT FROM THE STUDY?

If you take part in the study, you will receive up to $700 for your participation. These payments will be paid to the parent/LAR as follows:

- $100 for each completed **eye examination** up to 7 visits.
- **Glasses fitting visits** to receive study glasses are not paid.

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

The study may reimburse you or your study doctor's office for your extra direct and reasonable travel expenses to attend study visits or to pick up study supplies. If you would like reimbursement for these travel expenses, then please tell the study doctor's office. Direct and reasonable travel expenses are the actual costs of the most sensible travel option to and from the required study visits. If you drive in a personal vehicle more than 50 miles round trip, mileage reimbursement will be made based on the

current standard federal mileage rate for mileage over the first 50 miles. If you take a taxi or ride-share service, then the actual cost noted on your receipt will be reimbursed. The distance traveled will be verified by your study doctor's office. You will be asked to provide receipts or proof of mileage.

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

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

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

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

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

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

If your child has an illness or injury related to 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 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.

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

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

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

If you have questions, comments or suggestions about the research or your rights as a participant you can contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

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

- Medical history / treatments
- Testing relating to your child's eyes

You are being asked to give your permission for your child's PHI to be shared from your doctors, clinics, and hospitals to the researchers doing this study. This is called giving your Authorization. The PHI is needed to do the study, so you will have to give your Authorization for your child to be in the study. If you do not want to give Authorization, then your child 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 by contacting your child's study doctor's office in writing, or the JCHR IRB Office at 813-975-8690 or irb@jaeb.org. When you fully cancel your Authorization, your child is no longer part of the study. No new PHI will be collected for the study, except if there is a safety concern. If there is a safety concern, you may be asked for more information, or your child's entire medical record may need to be reviewed. The researchers will have all the information collected up to the time that you canceled your Authorization. Any information that has been received will remain in the study database after you and your child withdraw.

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

- your child's treating healthcare providers and their staff
- associated healthcare institutions and hospitals where your child receives care
- Jaeb Center for Health Research

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

You have the right to see your child's records too. During the study, you may not be able to see or get copies of everything. The study doctor will be able to tell you if you and your child will have to wait to get some information. When the study is over, you have the right to see all of your child's study 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 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, or local court, or public agency. If your child needs 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 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 your child; and
- if your study doctor or research team learn that your child plans to harm themself 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 your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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 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 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 child's name, address, identifying pictures, or medical record numbers. Any researcher would need to sign an agreement to protect your child's PHI before getting this dataset as required by law.

Overall study results will be sent to you and your child after the study ends. You should talk to your child's regular doctors about these results and any future treatment options.

Social Media
We would like to ask you and your child 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 confidentiality. This is also important because the products being used in this study may not be available outside of this study. You and your child do have the right to discuss the study with others to help you decide if you and your child 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 (i.e., phone number and address). Also, if your child's study doctor's office is not able to locate you when they try to schedule your child's follow-up visit, a third-party search service may be used to try to contact you.

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

Contact from the Jaeb Center for Health Research

With your permission, the Jaeb Center would like to send you secure text messages to remind you about your study appointments. Please **sign your initials** next to one of the following choices to confirm whether you give permission for the Jaeb Center to send you these reminders.

_____ (sign initials) I ***do*** give my permission to for the Jaeb Center to send these reminders, or

_____ (sign initials) I ***do not*** give my permission for the Jaeb Center to send these reminders

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

I, _____ (print name of adult) attest that I am one of the following individuals authorized to provide consent for the child named above as I am one of the following LARs (checkbox):

☐ Natural or Adoptive Parent; or if not the parent, then
☐Legal Custodian; or
☐ Legal Guardian

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

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

_____ _____
LAR Signature Date

If the Informed Consent was presented orally to the LAR, the LAR is only required to sign the short form. Check "N/A" here and skip this section – N/A ☐

Investigator's Consent Certification

I certify that to the best of my knowledge:

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

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

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