Bevacizumab Treatment for Type I Retinopathy of Prematurity (ROP4)

NCT04634578

Informed Consent Form
IRB Approval Date June 24, 2022

CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY TITLE: Bevacizumab Treatment for Type I Retinopathy of Prematurity (ROP4)

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 you as the participant if you are an adult, or 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.

- **The study is being done to look at two different dosages of bevacizumab injection into the eye for severe retinopathy of prematurity (ROP).**
- **The bevacizumab injection is not approved by the Food and Drug Administration (FDA) for ROP. For this reason, it is called experimental in this study. You will be asked to be in the study for about 1 year.**
- **The purpose of the study is to see if doses of 0.063 mg and 0.25mg are effective as treatment for severe ROP, with ROP in zone I, the very back part of the inside of the eye.**
- **The most likely risks to your infant are due to sedation. During or after the treatment, there is an increased chance that your infant's breathing may stop temporarily or his/her heart rate could slow down. During or after treatment, mild bleeding can occur. These are risks to ROP treatment whether your infant is in the study or not.**
- **As part of the study, your infant will receive treatment for ROP. Your infant's ROP may improve during the study, but it is possible that it will not improve and could worsen. Your infant may not benefit directly from this study. It is expected that there will be great potential benefit to infants in the future, by determining the safest and best treatment for severe ROP.**
- **If you do not participate, your infant may receive laser treatment, a higher dose of bevacizumab, or possibly a different medication. It is not recommended to have no treatment because that would increase the risk of retinal detachment and blindness.**

WHAT IS INFORMED CONSENT?

You are being asked to take part in this research study because your infant has severe retinopathy of prematurity (ROP). The goal of this study is to learn things that may help infants with severe ROP.

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.

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

WHO IS DOING THE STUDY?

This study is being done by the Pediatric Eye Disease Investigator Group (PEDIG). It is being paid for by the National Eye Institute (NEI) of the National Institutes of Health (NIH). The Jaeb Center for Health Research (JCHR) 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 bevacizumab in this study, then they have to tell the Jaeb Center.

WHY IS THIS STUDY BEING DONE?

Your doctor has determined that your infant has severe ROP that requires treatment. The study is being done to see if doses of 0.063 mg and 0.25mg of a medication called bevacizumab work as treatment for severe type 1 ROP. Type 1 ROP means that an eye meets criteria for treatment, based on how the blood vessels look (thickness and "wiggliness") and/or whether new blood vessels are growing in the eye that are not normal. Infants in this study have ROP in zone I, the very back part of the inside of the eye. The bevacizumab is given as an eye injection. It is not approved by the Food and Drug Administration (FDA) for ROP. For this reason, it is called experimental in this study. It has already been approved by the FDA for use in colon cancer treatment, but during this study a much smaller amount of it will be used in the eye for a purpose different from the one for which it is approved. There have been several studies of bevacizumab in the eye, and the results are promising, but there has been no large study comparing a low dose of bevacizumab to laser treatment. Bevacizumab is already being used in infants to treat ROP and in adults for other eye diseases at a much larger dose.

The standard treatment for most cases of severe ROP involves laser to the inner eye, without injecting medication into the eye. Laser has been used as treatment of ROP for about 30 years. More and more doctors are treating ROP by injecting bevacizumab, or other medications, into the eye, but we don't know if it works as well as or better than laser. There are some advantages to using bevacizumab instead of laser. The treatment takes less time. There is a lower risk of nearsightedness later. Nearsightedness means that vision is blurry when looking at far-away objects without glasses. Your

infant's side vision might be better because the blood vessels can grow in the retina after the injection. The retina is the inner lining of the back of the eye that captures images and sends them to the brain. We know that the medication gets into the bloodstream after injection. It is possible, but not known, that it could affect the growth of organs such as the brain, lungs, bones and kidneys. Most studies have said that there is little or no effect but we simply don't know. That is one of the reasons this study is being done.

The purpose of this study is to see if doses of 0.063 mg and 0.25mg of bevacizumab work well as treatment for severe type 1 ROP, with ROP and retinal vessels all in zone I. About 80 infants will enroll into this study at up to 40 sites in the North America. Visits will occur for 1 year, and are no more often than usual care visits.

WHO CAN PARTICIPATE IN THIS STUDY?

To take part in this study, your infant must:

- have type 1 ROP in zone I in one or both eyes
- have a birth weight of less than 2 lb. 12.1 oz (or 1251 grams)
- live in North America
- be able to receive treatment in the next 2 days

Your infant must not:

- have had previous treatment for ROP
- have an active eye infection

WHAT WILL HAPPEN IN THIS STUDY?

If you decide to take part in this study, a computer program will be used to select whether your infant will be given doses of 0.063 mg or 0.25mg bevacizumab. This is like flipping a coin to decide which group you will be in. If both eyes need to be treated, then both eyes will receive the same treatment. If one eye qualifies to be in the study and the second eye does not, then your doctor will decide whether the second eye needs to be treated or not. If it does need to be treated, then that eye will receive the same treatment as the eye that qualifies for the study. However, if the second eye does not need treatment until a later time, and the first eye did not respond to the treatment, then your doctor would choose which treatment to use.

The injection into the eye will be performed by an eye surgeon and will be done through a small needle. The treatment setup plus injection usually takes 2-5 minutes per eye and sedation will be determined by your infant's other doctors. If the ROP is worse or no better after the injection, then your eye surgeon will give whatever non-study treatment they think is needed, which could include laser treatment, a higher dose of bevacizumab, or possibly a different medication.

You will be asked to be in the study for 1 year. Your infant will have eye exams. The exams are no more often than they would be if you do not join in the study. Pictures of the retina will be taken before treatment and one or two more times within the next several weeks. These pictures take a few minutes

and are not painful. If retinal pictures are not available at your site, then a 2nd eye exam will be done before treatment and later if the treatment is not successful. At about 6 months of age, a motor development test called "General Movements Assessment" will be done. You will record and send a short video of your awake infant at home, and an expert will review the video and grade your infant's movements. This recording will not be used for any other purpose.

Optional Blood Draw

We invite you to join in an optional part of the study too. If you agree, 4 blood samples will be collected from your infant over 4 months. The purpose of collecting blood is to see how bevacizumab effects something called vascular endothelial growth factor (VEGF). VEGF is required for normal growth of blood vessels and other organs in the body. You do not have to agree to this part of the study in order to participate in the main study.

If you are part of it, the following will occur. Before the treatment, we will collect about one-tenth of one teaspoon of blood from your infant. When possible, we will use blood that has already been collected for another reason. The blood will be sent to a laboratory to measure your infant's VEGF levels. At 2 weeks, 4 weeks, and 4 months after treatment, we will again collect about one-tenth of one teaspoon of blood from your infant, to again measure the levels of VEGF.

The samples will not identify your infant. Your infant's samples from this study will not be shared with other researchers. Your samples may be saved and possibly used for other studies conducted by PEDIG in the future to help us understand ROP.

If you decide not to let your infant's samples be used, you and your infant will not be treated differently as people, and you can still be in this study. Your regular care outside of the study will not be impacted. If you change your mind later, we will not be able to get the samples back because we won't know which samples are your infant's.

Images of Your Child's Eye

If your infant is at a site where these tests are already being done, fluorescein angiography (FA) and optical coherence tomography (OCT) will be taken. These are high-quality pictures of the eye. These would be done at the same times as pictures of the retina.

<u>Fluorescein Angiography</u>

Fluorescein angiography is a test in which pictures of your infant's retina are taken using a yellow dye. The yellow dye, called fluorescein, will be injected into a vein in your infant's arm or hand. This dye will travel in your blood vessels to the eye. The camera will then flash a blue light into your infant's eye and will take pictures of the retina. The pictures will show if any dye leaks into the retina because of blood vessels that are not normal.

<u>Optical Coherence Tomography</u>

Optical Coherence tomography (OCT) uses a dim beam of light to measure the thickness of the retina. OCT is used to help find out if your infant's retina is developing normally.

Exam Schedule
Data will be collected on the day of injection (day 0).

The exam schedule is as follows:

- 1 day after the injection
- If severe type 1 ROP is still present at day 1, then an exam will occur 4 days after the injection
- 1 week after the injection
- 2 weeks after the injection
- 3 weeks after the injection
- 4 weeks after the injection
- 2 months after the injection
- 4 months after the injection
- About 6 months of age
- About 12 months of age

WHAT ARE THE RISKS OF THIS STUDY?

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

The most likely risks to your infant are due to sedation for the procedure, which could include general anesthesia. Your doctors will decide which type of sedation is best for your infant. During or after treatment, there is an increased possibility that your infant's breathing may stop temporarily or his/her heart rate could slow down. After giving the sedation, your infant may require closer monitoring. Complications from sedation have rarely resulted in death.

A very rare complication of injection is endophthalmitis. If this occurs, it is treated by intravitreal injection of antibiotics, but there is a risk of permanent loss of vision including blindness.

It is unlikely, but possible, that the bevacizumab injection will cause or lead to bleeding in the eye, cataract, retinal detachment (the retina separating from the back of the eye), need for another surgery, blindness or loss of the eye. Tests have shown that low levels of bevacizumab can reach an infant's bloodstream after being injected into the eye. The risk of side effects involving other parts of the body is unknown. Doctors do not think bevacizumab will have any harmful side effects to an infant's organs, but since the risk is unknown, that is one of the important reasons why this study is being done. Although most studies have found no harmful effects, a few studies suggest that infants receiving bevacizumab were more likely to have delays in development, such as impaired motor skills, compared with those receiving laser. In these studies, the infants who got bevacizumab were smaller and sicker than those who got laser, so they had other reasons for delays in development. Your baby will be carefully monitored for signs of side effects. Examples of possible side effects involving the body as a whole are high blood pressure, slowed wound healing or more bleeding.

Other issues could happen, but severe injury to the eye or areas around the eye as a result of bevacizumab is rare.

Blood draws can cause pain, bruising, or redness at the sampling site. Less common things include bleeding from the sampling site, a small blood clot, swelling of the vein or area around it, or infection.

Risks of Fluorescein Angiography

After the yellow dye is injected into your infant's arm or hand, the skin may turn yellow for several hours. The yellow color will disappear as the kidneys remove the dye from the body. Because the dye passes through the kidneys, your infant's urine will turn dark orange for up to 24 hours after the exam. If the dye leaks out of your infant's vein during the injections, some the skin around the injection site may hurt or become yellow. This usually lasts a few minutes, and the yellow color goes away in a few days. An allergic reaction to the dye is rare, less than 5 in 1000. If this happens, your infant may have a rash or itching on the skin. It is very rare (fewer than 1 in one million people) for a severe allergic reaction to happen. A severe reaction can consist of breathing and/or heartbeat problems and can be life-threatening.

Unknown Risks

It is always possible that anyone receiving bevacizumab or medications used for sedation for the first time may have an allergic reaction. Also, there may be other risks that are not known. If we find out that there are any new risks, you will be told about them. You will be able to decide if you want to continue in the study based on this new information.

Risks to Confidentiality

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

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

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

Your infant needs treatment for ROP. As part of the study, your infant will receive treatment. Your infant's ROP could improve during the study, but it is possible that it will not improve and could worsen. Your infant may not benefit directly from this study. It is expected that there will be great potential benefit to infants in the future, by determining the safest and best treatment for severe ROP.

ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?

If you do not take part in this study, your infant may receive laser treatment, a higher dose of bevacizumab, or a different drug. Your study doctor will discuss these choices with you. It is not recommended that your infant have no treatment, because that would increase the risk of retinal detachment and blindness.

CAN I STOP BEING IN THE STUDY?

You can stop being in the study at any time. If you decide to stop being in this study, you and your infant or child will not be treated differently as people. Also, your child's regular care will not be impacted. Please talk to your study doctor or staff so they know why you are stopping the study and can help you do so safely.

If we find out that there is any important new information about the study, you will be told about it. You will be able to decide if you want to continue in the study based on this new information.

The study may stop or the study doctor may decide to take you out of the study at any time. You do not have to give permission for the study to stop or for the study doctor to remove you from the study. You will be told if this happens.

Some reasons why you may be removed from the study include:

- The doctors feel that it is in your best interest
- If you do not follow the study instructions
- The doctors think that being in the study may cause you harm
- You experience an injury related to the study
- You need additional or different medication

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

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

The costs of routine treatment, office visits, and tests that are part of your child's regular care will be billed to you or your insurance company like they normally would if you were not in a study.

All exams in this study are considered to be part of usual care. These exams would be needed whether your infant was in the study or not. The costs of the exams will be your or your insurance company's responsibility like they normally are.

You or your insurance company will be responsible for the cost of treatment procedures, complications, or additional treatment since treatment for ROP is needed whether or not your infant is in the study.

The study will pay for:

- pictures of the eyes
- blood sample testing if you choose to participate in the optional portion and blood is collected
- low-dose bevacizumab for the study injections if done as part of the study

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

You may incur cellular data usage costs when recording and sending the "General Movements Assessment" video. You may incur costs if your doctor's office communicates using text messaging.

IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will receive up to $400 for your participation. These payments will be paid as follows: $100 for the 2-month, 4-month, 6-month, and 12-month completed visits. These payments will be made by 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 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.

The use of your child's samples may result in commercial profit. You will not be compensated for the use of these samples other than what is described in this consent form. The samples collected will not be used for whole genetic research.

Because payments made to you for participating in this study may be reported to the IRS as income, you may need to provide your social security number or a Form W-9 to your study doctor's office. These will not be shared outside of your doctor's office, other than as required by the IRS.

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

If your child has an illness or injury that is related to the study, then your child can get care like you normally would. If your child has an emergency, please seek emergency care as soon as possible. Please tell the emergency doctor that you are in a research study. Please also tell your study doctor about the

emergency as soon as you can. Care will be billed to you or your insurance like it normally would. The study does not plan 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 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 CHILD'S 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)
- Biological specimen(s) and/or slide(s)
- Diagnostic imaging report relating to your eyes
- Eye exam records
- Developmental test results

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 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
- Study Laboratory
- General Movements Assessment Reading Center
- Image Reading Center

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

Results from the study will be sent to you in a study results newsletter after the study has been published. You may also receive updates and information about the study in the mail. A study logo item such as a piggy bank, tee-shirt, or stuffed animal, might also be sent to you.

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. Video calls will not be recorded.

Study Information for Future Use

Some of your identifiable study information may be stored, or used for future research by the Jaeb Center. This information includes retinal images. The types of research that may be conducted with this information include studies of retinal blood vessel growth after treatment for ROP. This study information is identifiable. If someone got this information, then they might be able to figure out that it is your child's information. The pictures of your child's eyes show the retinas. Your child's retinas are unique to your child, like a fingerprint. This means that retinas are identifiable information. It is not likely that someone could identify your child by looking at a picture of a retina, but it is possible. There are plans to protect your child's information by using a coded identification number instead of name or initials when storing the pictures on a secure network. There is still a risk that a loss of that protection could occur. This would be a loss of confidentiality.

This information may be shared with researchers outside of the Jaeb Center. The researchers may include researchers that are taking part in this study.

This information from this study may be stored indefinitely. Your child's information may be used indefinitely.

You will not be told about the specific purposes of the future research. If there is a certain kind of research study that you would not normally want to do, you will not know if a future study is like that. Also, the results from the future studies will not be shared with you.

It is not expected that your child will have any benefit by allowing this information to be used for these future research purposes. The information may help people in the future. You do not have to allow the Jaeb Center to use this information for future purposes if you don't want to.

If you decide not to let your child's information be used, you and your child will not be treated differently as people, and you can still be in the study. Also, if you decide in the future that you no longer want to allow the information from the study to be used for future research, then you can withdraw your permission. If you decide that you want to withdraw your permission for this future use, you can contact the JCHR IRB Office at 813-975-8690 or irb@jaeb.org.

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- select only one):

☐ Natural or Adoptive Parent;
☐ Legal Custodian; or
☐ Legal Guardian

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

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

_____ _____
LAR Signature Date

Permission to Notify Primary Provider About Participation

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

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

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

_____ _____
Participant or LAR Signature Date

Optional Blood Samples

The blood samples collected would not include any identifiable information about you or your child. Please choose only one of the options below:

☐ **I *do* give my permission to allow for the collection of blood samples as described above, or**

☐ **I *do not* give my permission to allow for the collection of blood samples**

_____ _____

LAR Signature **Date**

Permission for Future Use of Study Collected Information

Identifiable information is information that may be related to your child's identity. This would be like a picture of an eye because the patterns in your child's are unique to your child. We are asking to use this information for future research, but would not be giving information like your name, address, or health record number.

☐ I ***do*** give my permission to allow for the storage, maintenance, and use of the participant's information as described above, or

☐ I ***do not*** give my permission to allow for the storage, maintenance, and use of the participant's information as described above

_____ _____

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**