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: PEDIATRIC UVEITIS STUDY: A Study of Uveitis in Children <18 Years of Age

STUDY DOCTOR'S INFORMATION

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

SUMMARY

In this form, when it says "you" it is referring to you as the participant in the study or to the person under your care that would be in the study if you are a legally authorized representative (LAR). For example, if a parent is reviewing this form for their child, a minor, to be in the study, "you" means "your child."

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 you have all of the information needed to decide if you want to participate in the study.

You do not have to be in this study. You can stop being in the study at any time. If you decide not to be in this study, you will not have any penalty or loss of any benefits that you normally get. You should read and discuss all of 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 a data collection study being done to collect information about children who have uveitis. Uveitis is a condition where the middle layer of the eye is inflamed. About 300 children will be in this study at about 40 sites in the United States.

- The study will collect data from you or your medical record at your regular eye doctor's visit. The most important difference between this study and your regular eye doctor's visit is there may be questionnaires given to you to ask about your uveitis.

    - The study will also ask you and your parent/child questions about how you feel about your uveitis and how it affects you and your family.

- After this visit you will be seen as part of regular care. The study will collect information from your medical record about your regular care visits 12 months later only if you are a new uveitis patient.

- Since this study is only collecting data there are few risks.
  - This study will collect some personal information like your date of birth and zip code. Plans are in place to protect that information. There is still a chance that a loss of that protection could happen. This risk would be a loss of confidentiality.
  - Questions about how you feel about your uveitis may upset you. You may skip them, take a break, or stop answering questions at any time.

- You may receive no direct benefit from being in this study. Children who take part in this study will add new knowledge that may be helpful for future trials of treatment for children with uveitis.

- You do not have to take part in this study. If you do not take part your medical care will not be affected.

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 on the first page of this form. If one of the study doctors gets money or benefits from a company involved 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 uveitis in one or both of your eyes. Uveitis is a condition where the middle layer of the eye is inflamed, which can cause blurred or loss of vision. Uveitis can be caused by an infection, by an injury to the eye, by another disease such as arthritis, or in some cases the cause is unknown. The goal of this study is to collect information to learn about your uveitis and what happens to your eyesight.

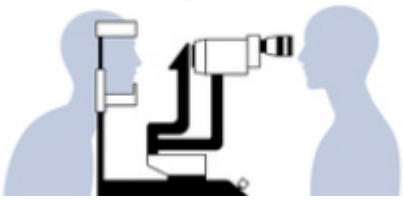
By collecting information, we hope to improve the care of future children with uveitis.

WHO CAN PARTICIPATE IN THIS STUDY?

In general, to take part in this study, you must be less than 17 years old and have uveitis in one or both of your eyes not caused by injury.

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

WHAT WILL HAPPEN IN THIS STUDY?



The study will collect data from you or your medical record at your regular eye doctor visit. This is called your enrollment visit. The most important difference between this visit and your regular eye doctor visit is that there are questionnaires that you would not answer in a regular doctor visit.

The following tests and assessments will be done as part of regular care and data collected for the study:

- Your weight will be measured as part of the study. This takes no more than 1 minute.
- The following tests are usually done as part of regular care:
    - Your visual acuity in each eye will be measured (how well you can see). This takes about 10 minutes.
    - The pressure inside each eye will be measured. This takes about 1 minute.
    - Your eye doctor will shine a light in each eye to see if there are any problems. This takes about 5 minutes.
    - Your eye doctor will use eye drops to make the pupil bigger to see further into the eye to see if there are any problems. This takes about 15 minutes.
    - Your eye doctor will evaluate how straight your eyes are, whether you need glasses, and what is your glasses prescription. These tests take about 10 minutes.
- The following may be done as part of your regular care, depending on what your doctor advises:
    - Your eye doctor may take images of one or both of your eyes as part of regular care. Images are not required for the study but if they are done as part of regular care, your eye doctor will tell us which images were taken. The study will not collect the images.
- As part of the study, the study may ask you and your parent/child questions about how you feel about your uveitis and how it affects you and your family. These questionnaires may take up to 45 minutes.

After the enrollment visit you will be seen as part of regular care.

If you are a new uveitis patient under the age of 17, the study will collect information from your medical record to learn more about your regular care visits in the twelve months since your enrollment visit.

WHAT ARE THE RISKS OF THIS STUDY?

Since this study is only collecting data there are minimal risks.

<u>Risks to Confidentiality</u>
This study will collect some personal information like your date of birth and zip code. Plans are 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.

Study Questionnaires
Answering questions about how you feel about your uveitis may upset you. You may skip them, take a break, or stop answering questions at any time.

Email Messaging
You may receive email messages from JCHR. These messages would include things like a reminder to complete your study questionnaires. You can expect to receive these messages at the enrollment visit. If you have any questions about the study or have any concerns, you should reach out directly to your study doctor. You can find the Jaeb Center's privacy policy and mobile terms of service on https://www.jaeb.org/hrpp/.

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 will not have any penalty or loss of any benefits that you normally get. You can get regular care like you normally would.

If at any time you don't want to participate in or finish a test or procedure, then tell the study doctor. It is up to you. The study doctor will tell you if you can stay in the study, or if your part in the study will be over.

The study may stop at any time and chart reviews 12 months after enrollment may not be required. You do not have to give permission for the chart reviews to stop.

ARE THERE COSTS RELATED TO THE STUDY?

This is a data collection study so it is not expected that there will be any costs related to being in this study. Any regular office visits or regular tests and procedures will be billed to you or your insurance company like they would be normally. There may be some small data charges if you allow text messages.

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 $50 for the time in office and the time required to complete the questionnaires. This payment will be made by giving you a gift card.

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.

You can choose not to get paid for your 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?

This is a data collection study and all procedures are part of your regular care. 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.

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.

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 personal Protected Health Information (PHI). 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 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:

- Name and Demographic Information (age, sex, ethnicity, address, phone number)
- Medical history / treatments
- Testing related to your eyes

You are being asked to give your permission for your 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 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 by contacting your 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, you are 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 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 withdraw.

The researchers will use a code that may have your initials or date of birth to keep your 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 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, federal agencies, and committees that monitor safety may look at your information in the study. In most cases, the information will be coded instead of having your PHI, but not always. For example, if you are 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. Only the people that need to see your information are allowed to see it.

You have the right to see your 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 will have to wait to get some information. When the study is over, you have the right to see all of your 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 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, or 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.

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 identifiable information that could be used to 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 identifiable information. The study results will also be made public. These results will not have any identifiable information either. Study results without identifiable information 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 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 not be sent to you.

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

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

Minor's Assent (13-17 years old)

NOTE: *Minor's attestation below is not required if the person obtaining consent believes that the separate simplified assent form would be better suited to obtain the written assent of the minor, or if the minor requests a separate simplified assent form (the separate IRB approved assent form may be used to document assent).*

Signing below means:

- This form and the information about the study have been reviewed with you
- You choose to be in this study

If you don't want to be in this study you do not have to sign. Being in this study is up to you, and no one will be mad at you if you don't sign, or even if you change your mind later. If you want to be in this study, please sign your name. You will get a copy of this form in case you want to read it again.

_____ _____
Sign Your Name Date

If minor's assent is **not** documented above, please indicate reason below (check one):

☐ Assent is documented on a separate IRB-approved assent form
☐ Minor is too young to provide documented assent (e.g., <7 years old)
☐ Other reason, please specify: _____

Designated Person Obtaining 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 or Designee's Printed Name	**Investigator or Designee's Signature**	**Date**