Consent to Participate in a Research Study
A Prospective Observational Study of Adult Strabismus

Today, you are being asked to take part in this **research** study because you have strabismus, which is a misalignment of the eyes. Research is a study that is done to answer a question. Participation in this study is voluntary. You can decide not to take part in this study at any time. Your study doctor will be talking with you regarding this document. However, any of the study doctors from the practice may take care of you during the study if you decide to participate. If you do not clearly understand information in this document, please ask your study doctor to explain.

The Pediatric Eye Disease Investigator Group is doing this study to learn how well treatments for strabismus work. Your eye doctor is a member of this group.

Before you decide to take part in this research study, we encourage you to speak with friends and family members. Take your time making a decision. Carefully read this document. Your decision will not affect your regular medical care. If you are taking part in another research study, please tell your study doctor.

Important information about this study is found in this consent form. This form is part of the process to inform you about the research study.

Your doctor(s) and/or clinic staff will carry out this study; see their names in the last page. Funding for the study is being provided by the National Eye Institute. The institute is part of the federal government. This funding will be used by the Jaeb Center for Health Research to organize the research study and will be paid to your doctor's office for conducting the study.

WHY ARE WE DOING THIS STUDY?

The purpose of this study is to learn about treatments for strabismus in adults. We will collect information about many adults who receive treatment for this problem. By getting this information, we hope to improve the care of adults with strabismus.

There are several different treatment options for strabismus. Sometimes these conditions are treated with special glasses that help to align the eyes (prism) or with exercises that help the eyes work together. Sometimes these conditions are treated with surgery or botox injection to straighten the eyes. You and your eye doctor will decide which treatment you feel is the best option for you. We encourage you to talk with your eye doctor about your treatment.

You and your eye doctor will decide the best treatment option for you. We encourage you to talk with your eye doctor about your treatment.

HOW MANY PEOPLE ARE WE EXPECTING TAKE PART IN THIS STUDY?

Up to 650 people will take part in this study at several different locations throughout North America.

WHAT HAPPENS IF I AGREE TO TAKE PART IN THIS STUDY?

To take part in the study, you will need to carefully read and sign this document. Your participation is VOLUNTARY. You can decide not to take part in this study. You can decide to stop your participation in this study at any time. You may continue to receive medical care not related to this study. No penalty or loss of medical care will result from your decision.

To take part in this study, you must have one of the following types of strabismus:

- **Convergence insufficiency** – the eyes do not turn in enough to focus together on close objects.
- **Divergence insufficiency** – the eyes align at near, but cross slightly when viewing distant objects.
- **Small-angle hypertropia** – one eye points slightly higher or lower than the other eye.

To take part in this study, you and your eye doctor must be ready to initiate treatment. Treatment can be prism, eye exercises, botox injection, or surgery.

There are some other criteria that are necessary for you to be part of the study. Your study doctor will check if you have these or not.

If you take part in the study, you must be willing to follow the procedures described below.

The study involves collecting information from your medical record. This will include the type of strabismus you have, how it is being treated, how well your eyes move and are aligned, and how well you are able to see. We will also collect information about symptoms you may have because of your strabismus and how it affects you.

You will see your doctor at 10 weeks and 1 year after starting treatment for strabismus. Your doctor may also decide that he/she will see you at other times as well. If your doctor changes

you to a different treatment, you may see your doctor again at 10 weeks and 1 year after starting the new treatment.

In the following table you will find what will be done at each visit:

Test	Description
Diplopia Questionnaire	Evaluates how often and where you see double
Adult Strabismus 20 (AS-20) Questionnaire	Evaluates how well your eyes feel
Distance Visual Acuity	Evaluates how well you see in each eye
Ocular Alignment	Evaluates how well your eyes line up with each other
Fusion with Prism in Space	Evaluates how your eyes align together using prisms

Additional tests depend on your strabismus type.

Test	Description
If you have convergence insufficiency:	
CI Symptom Survey	Evaluates if you have symptoms of CI
Positive Fusional Vergence	Measures how well your eyes move towards each other horizontally
Near Point of Convergence	Measures how well your eyes work together up close
If you have divergence insufficiency	
Negative Fusional Vergence	Measures how well your eyes move away from each other horizontally
If you have small angle-hypertropia:	
Vertical Fusional Amplitudes	Measures how well your eye move towards each other vertically
Double Maddox Rod Testing	Determines how much your eyes are tilted with respect to each other

If you decide not to take part in this study and do not sign this document, you may continue receiving medical care unrelated to this study. You can decide to stop being in the study at any time. No penalty or loss of medical care will result if you decide not to take part in this study.

ARE THERE RISKS IN THIS STUDY?

If you decide to be part of the study, a possible risk is the chance that an unauthorized person outside of the research team will see your health information. This is unlikely to happen. The study will take special efforts to make sure this does not happen.

This form does not list risks related to your normal medical care. This form does not list risks to the treatment that you and your doctor have selected. We encourage you to discuss these with your study doctor, your primary care provider, or another health care professional.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?
You may receive no direct benefit from being in the study. People who take part in this research study will add to new knowledge that may help other people with the same problems.

WHAT ALTERNATIVE PROCEDURES OR TREATMENT ARE AVAILABLE IF I DO NOT TAKE PART IN THIS STUDY?
You do not need to be in this study to get treatment for strabismus. We suggest you discuss your options with your study doctor, your primary care physician, or another health care professional.

WHAT IF I WANT TO WITHDRAW FROM THE STUDY, OR I AM ASKED TO WITHDRAW FROM THE STUDY?
You can stop participating in this study at any time. You may continue to receive medical care not related to this study. No penalty or loss of medical care will result from your decision. However, we encourage you to talk to a member of the research group so that they know why you are leaving the study. If there are any new findings during the study that may affect whether you want to continue participating, you will be told about them.

Your participation can be stopped by your doctor. The study can be stopped by federal regulatory agencies or the sponsor. Your permission is not required for this. Some possible reasons for this include poor recruitment or unexpected circumstances.

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?
As required by law, study related records with identifying information will be kept confidential. Safeguards for authorized access, security, and privacy of your information have been put in place by the Federal Privacy Regulations. Unless the law requires it, your name, address, social security number, telephone number, or any other direct identifying information will not be used to identify you.

A. Purpose of Authorization
We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your information. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

You must sign the **Protected Health Information Authorization** at the end of this form if you want to be in the study. When you sign the form, you give permission for the use and disclosure

of your Protected Health Information (PHI) for the study. PHI is health information that identifies you. Your authorization is beneficial and important for the study. Without your authorization, you will not be able to be in it.

B. Use and Disclosure of the PHI

Your study doctor will collect information about you. This information includes things learned from procedures listed and described in this form as well as your name, address, date of birth, and information from your medical records. Your name, address, telephone number, and social security number are examples of identifiable information.

A code number will go with your study results instead of your name, address, telephone number, or social security number. Your study results will be given to the Jaeb Center for Health Research. The Jaeb Center is the coordinating center for the study. It is located in Tampa, Florida.

This doctor's office will not disclose study results that have your identifiable information except as explained in Section C. or when required by law. The Jaeb Center and this doctor's office will guard the privacy of your study PHI.

Study results without your protected information may appear in medical journals and be shared at scientific meetings. Your records will be kept confidential. No one will disclose your identity in a medical journal or at a scientific meeting.

C. Authorized Recipients and Users

People outside of this doctor's office and the Jaeb Center may need to see or receive your information from this study. Some examples include: government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study, and companies that sponsor the study.

In most cases the information will have a code number with it instead of your name, address, telephone number, or social security number.

There are some situations where the information will not have a code number with it. If so, people outside this doctor's office who assist in your care may see your study PHI. They may not be covered by the federal Privacy Rule. We try to make sure that everyone who needs to see

your information keeps it confidential – but we cannot guarantee that your information will not be disclosed.

Other Considerations

The data collected in the study may be provided to other researchers to use; however, the data that are provided will not contain any information that could identify you.

When the results are made public, all of the study data collected may also be made public. However, no identifying information will be included.

Separately from your research data, the Jaeb Center for Health Research in Tampa, Florida will be provided with information on how to contact you.

- Before your study visits you may receive a phone call from a staff member at the Jaeb Center to check on your condition and to see if you have any questions. You will be called at a time that you indicate is most convenient for you. If you are not available at the time of the call and prefer to call the coordinating center yourself, you can call the coordinating center toll-free at 1-888-797-3344.

- If we are not able to locate you when we try to schedule your follow-up visit, the Jaeb Center may try to contact you through the alternative contact information you have given us. If this is not successful, the Jaeb Center may use the information you have given us to try to locate you through the use of a third-party search service.

D. Cancellation of Authorization

You may cancel your permission for the use and disclosure of your study PHI at any time. You need to contact your study doctor and give him/her a notice of cancellation in writing. When you cancel your permission or when you withdraw from the study directly, you are no longer part of the study. No new information about you will be gathered for the study except when it is on an adverse (unfavorable) event that is related or potentially related to the study. If one happens, your entire medical record may need to be reviewed.

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

E. 50 Year Expiration Date and Indefinite Expiration Date

Some of your study PHI does not have a code number with it. Your permission for the use and disclosure of this PHI lasts 50 years from the date of your signature or until the end of the study, whichever is sooner.

The rest of your study PHI does have a code number with it. When it is collected, it becomes a research report. Your permission for the use and disclosure of these coded data will never end. These coded data do not have your name, address, telephone number, or social security number. *The above supports the HIPAA Privacy Rule – 45 CFR 164.508*

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

The study will pay for visits that are done just for the research study. The study will not pay for usual care visits. Usual care visits are those that would occur whether or not you are in the study. The cost of usual care visits will be your or your insurance company's responsibility.

The study will not pay for any costs associated with treatment. These will be your or your insurance company's responsibility.

IS THERE COMPENSATION FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will receive $25 for each 10-week visit and $50 for each 12-month visit (by money card). The maximum amount you will receive will be $150. The money card is being given to you to cover the cost of travel and other visit related costs. You will not receive any money for extra visits your doctor believes are needed for your usual care.

If you have travel expenses that make it difficult for you to return for study visits, let your doctor know. Additional funds may be available.

WHAT HAPPENS IF I EXPERIENCE A RESEARCH RELATED INJURY?

If you have a research-related injury, medical care is available. In case of an emergency, you can get emergency care. If possible, you should tell the emergency care medical staff that you are in a research study. You should also tell your study doctor about the emergency as soon as possible.

The study will not provide costs for medical expenses or any other costs for research-related injuries. The costs of care are your or your insurance company's responsibility. Money for lost wages and/or direct or indirect losses is not available. You are not precluded from seeking to get

compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

If you have questions about the study or research-related injuries, contact your eye doctor or one of his/her staff (see contact information on the last page). You may also contact the PEDIG Coordinating Center staff at the Jaeb Center (toll-free at 888-797-3344).

WHO SHOULD I CONTACT, IF I SHOULD EXPERIENCE ANY PROBLEMS OR HAVE ANY QUESTIONS?

Please contact your eye doctor or one of his/her staff (see contact information on the last page) if you:

- Have questions about this study
- Have questions about research-related injury
- Have concerns or suggestions

You may also contact the PEDIG Coordinating Center staff at the Jaeb Center (toll-free at 888-797-3344).

Please contact the Jaeb Center for Health Research Institutional Review (IRB) Office at 813-975-8690 or at irb@jaeb.org if you:

- Have questions about your rights as a research participant
- Wish to talk about your concerns or suggestions linked to the research study
- Want additional information about the research
- Want to provide comments about the research.

WITHDRAWAL BY INVESTIGATOR, PHYSICIAN, OR FUNDING SOURCE

The investigators, physicians or funding source may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

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Your Full Name (printed) _____

Description of Representative's Authority to Act for the Subject

_____ (if applicable)

Protected Health Information Authorization

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

Signature _____ Date _____

Study Enrollment

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

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

Name of Study: A Prospective Observational Study of Adult Strabismus

_____ _____
Signature Date

I certify that to the best of my knowledge the participant understands the nature, demands, risks, and benefits involved in his/her participation in this study.

Investigator's Printed Name Investigator's Signature Date

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

FULL REVIEW – APPROVED
AUG 10, 2015

Investigator Contact Information

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

_____
_____
_____
_____

Address: _____
_____

Telephone: _____

Sample Only this page with list of investigators at your site