

HYPEROPIA TREATMENT STUDY 1 (HTS1)
Glasses Versus Observation for Moderate Hyperopia in Young Children
Informed Consent Form

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1. Introduction

You have been asked to allow your child to take part in a research study. The study is being conducted by the Pediatric Eye Disease Investigator Group. Your child's eye doctor is a member of this group. The Jaeb Center for Health Research is the coordinating center which is organizing the study. The National Eye Institute, which is part of the federal government, is providing the funding for the study. This form is part of the process to inform you about the research study. We want to make sure that you understand that the study involves research. Research is a scientific way to learn about medical conditions and/or treatments.

First, we want you to know that participation is voluntary. Refusal to take part or changing your mind later will involve no penalty or loss of benefits to which your child is otherwise entitled. Before you decide whether to have your child take part in the study, please take as much time as you need to ask any questions. You may discuss this study with your child's doctor, the medical staff, your child's primary physician, family, and/or friends. For your child to be in the study, you will need to sign this form.

2. Information about the Study

Your child has hyperopia. Hyperopia is also called farsightedness. Almost all children 1 to 6 years old are farsighted and most do not have any problems seeing clearly. Sometimes farsighted children may have a harder time focusing up close or even get headaches. Sometimes, high levels of hyperopia may cause the vision in one eye to not develop properly. This is a condition called amblyopia (also known as lazy eye). High levels of hyperopia could also cause the eyes to cross, which is called strabismus.

Some doctors feel that a child with hyperopia should have glasses before any potential vision problems develop. Other doctors feel that children should not be given glasses unless vision problems occur. It is not known if hyperopia should be treated right away or only if other problems occur. This is the reason this study is being done.

You are being asked to have your child take part in the study because he/she has hyperopia and does not wear glasses. The study will include about 700 children who, like your child, have hyperopia. Your child will be in the study for 3 years. To take part in the study, your child needs to be at least 12 months of age and less than 6 years of age and must not have ever worn glasses or contact lenses before.

You should not have your child in the study if you are planning to move out of this area in the next 3 years.

3. Study Procedures

If your child is in the study, you must be willing to follow the procedures described in this section.

Treatment Groups/Procedures: Your child's eye doctor will describe the two groups in the study.

The two study groups are:



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1. Glasses are prescribed at the start of the study
2. No Glasses at the start of the study. Glasses will be prescribed if your child develops one of the vision problems listed below.

You should not have your child take part in the study unless you are willing to have your child be in either of the two study groups.

If you decide to have your child take part in the study, a computer program will be used to decide whether or not your child will be given glasses at the start of the study. This is similar to flipping a coin to decide which approach will be followed. One group will be given glasses to wear at the start of the study. The other group will not get glasses at the start of the study. Neither you nor the doctor can choose which group your child will be in.

Children who do not get glasses at the start of the study will be prescribed glasses during the study if any of the vision problems listed below happen. Children who are given glasses at the start of the study may have their glasses changed for the same reasons. Reasons for giving new glasses to children not wearing glasses in the study (or changing glasses for children given glasses at the start of the study) include:

- Crossing of the eyes
- Distance vision becomes worse than what is normal for their age
- A large difference in vision develops between eyes
- Depth perception becomes worse than what is normal for their age
- You have concerns about your child's vision or ability to see well close up

If your child gets glasses during the study, the glasses may need to be updated as your child's eyes change. Your child's eye doctor will not change your child's glasses if they think it is better not to make the change. Your child's eye doctor may also decide that your child needs other treatments in addition to glasses, just as if your child were not part of the study.

If your child gets glasses at the start of the study, you will receive a phone call within 2 weeks from the eye doctor's office to make sure there are no problems getting the glasses and answer any questions.

Follow-up Visits:

Your child will need to return to the eye doctor for follow-up visits every 6 months for 3 years. The visits occur at 6, 12, 18, 24, 30, and 36 months after enrollment. Some children will need to come back for another visit within 2 weeks after the 6, 12, 18, 24, or 30 month visits depending on your child's condition. Some children will need to come back 4 weeks after the 36-month visit if their glasses need to be changed.

Visits at 6, 18, and 30 months after enrollment are considered study related and will be paid for by the study. If your child needs to come back within 2 weeks after the 6, 12, 18, 24, or 30 month visits or 4 weeks after the 36-month visit, these visits will also be paid for by the study.



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Your child's eye doctor may decide that more follow-up visits are needed for your child, just as if your child were not part of the study.

Your child's eyes will be tested at each visit to see if they turn in or out, and also see how well your child sees objects at distance and close up. Your child will have his/her eyes dilated with eye drops at least one time per year, and maybe more often if your child has more vision problems. These tests would be done even if your child was not part of the study. All children in the study will receive dilating eye drops during the 30- and 36-month exams.

4. Risks

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

Glasses: The risks associated with glasses are the same whether your child receives glasses as part of the study or not. Some children experience temporary discomfort or blurred vision when adjusting to new glasses. There are no known serious or long-lasting risks.

Amblyopia or Strabismus: Some children with hyperopia may develop amblyopia (decreased vision in one or both eyes) or strabismus (crossing of eyes). Amblyopia or strabismus may develop even if a child is already wearing glasses. Some doctors think there may be a higher risk of developing amblyopia or strabismus in children with hyperopia who are not wearing glasses. Other doctors do not think that there is greater risk of developing amblyopia or strabismus in children with hyperopia who are not prescribed glasses right away. If amblyopia or strabismus develops, additional treatment may be needed. Treatment will start with prescribing new glasses or changing the glasses the child is currently wearing. Many cases of amblyopia and strabismus can be corrected with glasses alone. If needed, amblyopia may be treated with patching one eye, putting drops in one eye to blur vision, or by wearing a blurring filter over the good eye. If needed, strabismus may be treated several different ways, including prism, bifocals, vision therapy or surgery.

Unknown Risks: Although we have tried to list all possible risks and discomforts, there may be others that we do not know about at this time. However, these unknown risks would be the same whether your child received treatment as part of this study or not.

5. Benefits of Participation

If the study requires that your child needs to wear glasses or a lens change during the study, those glasses or new lenses will be provided at no cost.

Your child may not directly benefit from taking part in this study. However, the results of this study will be very important for doctors treating children with hyperopia in the future.



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6. Alternative Procedures or Treatments

You do not have to allow your child to take part in this research study in order to receive treatment. Your child may receive treatment for hyperopia outside of this study if you want. Your child could receive other treatments not offered by the study.

7. Costs and Compensation

The National Eye Institute will provide funds for services specific to the research study, but will not cover patient services considered to be routine patient care.

Visits at 6, 18, and 30 months are considered study-related visits and will be paid for by the study. If your child needs to come back within 2 weeks after the 6, 12, 18, 24, or 30 month visits or 4 weeks after the 36-month visit, these visits will also be paid for by the study.

All glasses prescribed or changed as part of the study will be paid for by the study. Glasses needing replacement because of damage will also be paid for by the study. If your doctor makes changes to your glasses that are not required by the study, the cost of changing will not be paid for by the study. The additional cost of prisms or bifocals will not be paid for by the study if your doctor prescribes them.

Visits at 12, 24, and 36 months are considered part of usual care. Because these visits would be needed whether your child was in the study or not, their cost will be your or your insurance company's responsibility.

In addition, you will be given \$40 (by check or by merchandise or money-card) after completing each study visit (not including enrollment) for a possible total of \$480 if all 6 visits are completed and your child is required to come back within 2 weeks of every visit. This payment is meant to compensate for your time and for any travel expenses involved with coming to the study visits. If your child is required to come back for any additional study visits, you will be given an additional \$40 each visit. You will receive payment for completed study visits even if your child leaves before the end of the study. If your expenses exceed \$40 per study visit and you will be unable to complete a study visit without additional funds, please discuss this with the study staff. Additional funds may be available.

8. Research-Related Injuries

It is not likely that some physical injury might happen because your child is part of this research study. However, if this were to happen, medical treatment is available, but you or your insurance company must pay for the treatment. There are no payments for lost wages and/or direct or indirect losses. If your child suffers an injury related to this study, the medical care will not be covered. You can get more information about research-related injuries from the Jaeb Center Institutional Review Board (toll-free at 888-797-3344).

Further information about research-related injuries is available from your child's eye doctor (see contact information on the last page) or from the coordinating center staff at the Jaeb Center (toll-free at 888-797-3344).



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9. Withdrawal from the Study

It is up to you whether your child takes part in this study. You can withdraw your child from the study at any time by contacting your child's eye doctor and by letting him/her know in writing that you are withdrawing your child (see contact information on the last page).

During the study, you will be told of any new scientific findings that might affect your willingness to have your child stay in this study.

Your child's doctor or persons in charge of this study may stop your child's participation in the study for reasons such as:

- It is determined that your child was not eligible for the study.
- Your child's doctor decides that continued participation would be harmful to your child.
- The study is stopped.
- There are unanticipated circumstances.

If your child leaves the study early for any reason, those data which were already collected will still be used in evaluation of the study results.

If you have any questions about the study at any time, you should speak with your child's eye doctor or one of his/her staff. If you have questions about your child's rights as a research subject, you should contact the Institutional Review Board office at 888-797-3344. You may also call the coordinating center staff toll-free at 888-797-3344 should you have any questions at any time.

10. CONFIDENTIALITY AND YOUR PROTECTED HEALTH INFORMATION (PHI)
(Section Required by the HIPAA Privacy Rule – 45 CFR 164.508)

Note: If applicable, this section refers to your child's participation in the study and your child's protected health information.

A. Purpose of Authorization

The HIPAA Privacy Rule is a federal law about privacy (45 CFR Part 160 and Subparts A and E of Part 164). It explains how to guard the privacy of your protected health information, also called PHI. This authorization defines who can use and disclose your PHI for the study and why.

You must sign 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 PHI for the study. If you do not give this authorization you will not be able to be in the study.

B. Use and Disclosure of the Protected Health Information (PHI)

As part of the study, you will have testing and examinations and/or will answer questions. 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.



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There are other people in the study. They are from this doctor's office and/or from other doctors' offices. Their study results will also be given to the Jaeb Center. A code number will go with the study results instead of the study participant name, address, telephone number, or social security number.

This doctor's office will not disclose study results that have a direct personal identifier except as explained later in this authorization or when required by law. Name, address, telephone number, and social security number are examples of direct personal identifiers. The Jaeb Center and this doctor's office will guard the privacy of your study PHI.

Study results may appear in medical journals and be shared at scientific meetings. No one will disclose the identity of a study participant in a medical journal or at a scientific meeting. Your records will be confidential. They will be kept according to the requirements of federal and state law.

It is very important that your study doctor's office has your current contact information. You will be informed of the study results when they are made public.

C. Authorized Recipients and Users

The following people may receive, see, use, and disclose your study PHI:

1. The people who work for this doctor's office
2. The people who work for the Jaeb Center
3. The scientific investigators who help run the study
4. Any review board that oversees human investigations rules for your doctor's office
5. Any federal agency that oversees clinical trials

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 and the above persons or people outside the doctor's office who assist in your care may have access to your study PHI. For example, they may need to see it if you have an adverse (unfavorable) event that is related to the study. If it is reviewed by any of these people, they may need to review your whole medical record.

Other Considerations

We will send the information about your child's eyes to a central computer. The computer is located at the Jaeb Center for Health Research in Tampa, Florida. The Jaeb Center for Health Research is the coordinating center which is organizing the study.

In addition, separately from your child's research data, the Jaeb Center for Health Research will be provided with information on how to contact you.

- If your child receives glasses you will receive a call from the eye doctor's office within 2 weeks to ask if there are any problems getting the glasses and ask if you have any questions.



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- During the study, you may receive calls from the coordinating center to help schedule an office visit for your child. If we are not able to reach you when we try to schedule your child's follow-up visit, we will try to contact you through the other information you have given us. If this is not successful, we may use the information you have given us to try to locate you through the use of a third-party search service.
- You can call the coordinating center toll-free at 888-797-3344 if you have any questions at any time.
- You may also receive updates and information about the study in the mail.
- The data collected in the study may be put in public domain in a format that will have no identifying information.

Your child may receive a pair of glasses as part of the study. LensCrafters has agreed to provide the study with a discount on eyeglasses. Your child's eye doctor may send you to LensCrafters or another contracted optician to get new eyeglasses. In order to provide your child with new eyeglasses, the optician or LensCrafters will receive information on your child. Your child's name, birth date, and study identification number will be given to the optician who is making the eyeglasses. If your child is to receive study-paid eyeglasses through LensCrafters, this information will be given to LensCrafters by the Jaeb Center, via the EyeMed/Eye Care Plan of America website, to help process the making of your child's eyeglasses.

D. Reasons for Access and Use

The people named above (see section C) may receive, see, use, and disclose your study PHI. They need it to help run the study and to analyze the results. They may also need it to meet the requirements of federal or state law.

This doctor's office will provide the study PHI to the Jaeb Center and to the other people named above as needed and/or requested by them. The study PHI will typically be provided to them via the Jaeb Center, because it is the coordinating center.

E. Potential for Redisclosure

The HIPAA Privacy Rule may not require the people named above (see section C) to guard the privacy of your study PHI. It is possible that they may give it out again.

F. Cancellation of authorization

You may stop 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.



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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.

G. 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 end of the study is when no one has to monitor the study anymore, the funding agency data analyses are done, and the primary articles are accepted for publication.

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.



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Note: If we are inviting you to have your child take part in this study, please see **all** the text in parentheses.

Subject's Name *printed* _____

Description of Representative's Authority to Act for the Subject: _____

Protected Health Information Authorization

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

Signature

Date

Study Enrollment

By signing, you agree to (have your child) 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 (have your child) participate.*

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Signature

Date

I certify that to the best of my knowledge the subject (parent/guardian) understands the nature, demands, risks, and benefits involved in his/her (child's) participation in this study.

Investigator's Signature

Date

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



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Investigator Contact Information

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

Address:

Telephone:

Sample Only
Replace this page with list of
investigators at your site

