Infant Aphakia Treatment Study (IATS)

Informed Consent Form

NCT00212134

September 25, 2015

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: **Infant Aphakia Treatment Study (IATS) – Phase 3: Age 10 - 11**

Principal Investigator: **Scott R. Lambert, MD**

Sponsor: **National Institutes of Health (NIH)/ National Eye Institute (NEI)**

Investigator-Sponsor: **Scott R Lambert, MD**

Introduction

When your child was enrolled as an infant in the IATS study, the plan was to follow infants over a period of 4 years and see each child every 3 months for up to 4 years. A Teller Acuity exam gave an estimate of vision when your child was 12 months of age. Since your child was too young to speak we wanted to do a vision test when your child could talk to us. In that way we could get a better idea of what your child was seeing. An extension of the study let us continue to follow children until 5 years of age mainly to get a more accurate measurement of vision when your child was about 4 ½ years old and also to do tests to see the health of the eyes when your child was 5 years old. You are being asked to consent to one (1) visit between your child's 10th and 11th birthdays.

A description of this clinical trial is available on http://www.ClinicalTrials.gov, as required by U.S. 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 may search this Web site at any time.

What is the purpose of this study?

The purpose of this visit is to see if there have been any changes in the health of your child's eyes and to test vision by the standard research method. The doctor will do the same tests of eye health that were done when your child was 5 years old and will also take pictures of the back of the eye to help show us the health of the optic nerve and retina. At the beginning of this study some babies received a contact lens and some babies received an IOL implant. If your child was initially randomized to get a contact lens, you and your doctor may have decided that it was better for your child to have an IOL implanted after he or she turned 5 years old. The information we gather at this one visit will help us find out the health of the eye and the vision for children in each treatment group. We can also get information on children who changed from a contact lens to an IOL implant after the study was over.
There will be a short age-appropriate reading test during the visit.
The study group is also interested in how your child is doing socially and this will be covered by at-home questionnaires.

What will I be asked to do?

For this third phase of the project, the study visit will occur when your child is between 10 and 11 years of age. At this visit, you will be asked to fill out a brief questionnaire that asks about how your child did during the five years since the last study visit and you may be asked to sign a Medical Record Release if your child was seen by a non-IATS doctor. The visit will follow the same procedures that were used in the visits during the first 5 years: checking whether the glasses and/or contact lens are correct (refraction), checking for abnormal position or movement of the eyes, measuring the size of the pupil, and checking for any eye problems, especially for the onset of glaucoma or the progression of nearsightedness. A specially

trained and certified vision tester will perform a type of vision testing using a computer system that requires a response from your child. This will be similar to the single letters that were used when your child was around 4½ years of age.

At this visit, the same tests of ocular health will be performed as were done at the 5 year visit. The doctor will measure the shape and length of the eyes, the structure of the cornea, and eye movements. These tests do not require contact with the eye and so numbing drops are not needed. However, the doctor will also check the eye pressure and corneal thickness again and numbing drops will be used for these tests. At this visit the eyes will be dilated to check the health of the inside of the eye and to see if the glasses/contact prescription is correct. In addition, special photographs of the back of the eye will be taken to assess the development of the optic nerve. The camera does not touch the eye.

Another type of photograph called Optical Coherence Tomography (OCT) will show the structure of the retina in various places and assess the front part of the eye. Neither of these photographs involved touching the eye. Most of these tests are standard of care and are critical to maintaining the health and function of the eyes. Measurements from one of the photos will be done by updated special software that is not yet approved by the FDA.

If all of the tests cannot be completed in one visit, you will be asked to return the following day or within the next few days to finish the testing.

You will be given a packet of questionnaires to take home and complete. Some of them you have already seen and your child will fill out some of them. The packet will include a stamped envelope so that you can to return the questionnaires to the Coordinating Center.

What are the possible risks and discomforts?

The risks of undergoing measurements that use instruments which touch the eye include possible discomfort, infection or injury to the eye. All such instruments are disinfected before each use according to the manufacturer's recommendations and infection is very uncommon. Injury is rare and generally limited to scratching of the cornea which usually heals within a day or two. These instruments will be used by experienced practitioners and the chance of injury is very small. These instruments require the use of an anesthetic (numbing) drop that is placed in the eye prior to the use of the instrument. These drops may cause irritation and redness that lasts up to a few hours. There are no known risks associated with the questionnaire; your answers will remain confidential.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

Taking part in the extension of this research study may not benefit you or your child personally, but we (doctors, researchers and scientists) may learn new things that will help others. This information may help you to find services that may help your child in his or her everyday life.

Will I be compensated for my time and effort?

There will be no costs for your child to participate in the study extension; the costs associated with this study visit (examination, photographs, etc) will be covered by the study. You will be paid $250 for the visit to help compensate for travel and time away from work and your child will receive a $50 gift card at the completion of the visit.

If you must return for a completion visit and you live far from the study site, the study will pay for an overnight stay in a hotel near the site. The study coordinator will assist with this. If you must drive more than 150 miles round trip or choose to fly via commercial airline, those travel costs – mileage or airfare - will be reimbursed.

What are my other options*?*

If you decide not to enter your child in this study, there is care available outside of this research study. The study doctor will discuss these with you. Your child does not have to be in this study to be treated for a condition related to the original surgery.

How will you protect my child's private information that you collect in this study?

Emory will keep any research records that it creates private to the extent that this is required to do so by law. Whenever possible, a study number, rather than your child's name, will be used on study records. Your child's name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

As you know, people other than those doing the study, such as the medical monitor, may look at both medical charts and study records. Agencies and Emory departments and committees that make rules and policy about how research is done have the right to review these records, as do the companies and agencies that pay for the study. The government agencies and units within Emory that are responsible for making sure that studies are conducted and handled correctly may look at the study records in order to do this job; they include the Food and Drug Administration, the Office for Human Research Protections, the National eye Institute (NEI) of the National Institutes of Health (NIH), the Emory University Institutional Review Board (IRB), the Emory Office of Research Compliance, and the Clinical Trials Office. In addition, records can be opened by court order or produced in response to a subpoena or a request for production of documents. We will keep any records that we produce private to the extent we are required to do so by law. We will continue to use a study number rather than your child's name on study records where we can. Your child's name and other facts that might point to him or her will not appear when we present this study or publish its results.

The Emory IRB has the ultimate responsibility for deciding what information and documents regarding a research subject's participation should be kept in the subject's medical record. In making these decisions, the Emory IRB will take into account subject safety and confidentiality considerations, as well as any requirements imposed by applicable laws, regulations, and accreditation standards.

Medical Record

If your child has been an Emory Healthcare patient before, then s/he already has an Emory Healthcare medical record. If your child has never been an Emory Healthcare patient, s/he does not have one. An Emory Healthcare medical record will be made for her/him if an Emory provider or facility provides any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record your child has now or any time during the study.

Emory Healthcare may create study information about your child that can help with his/her care. For example, the results of study tests or procedures. These study results will be put in his/her Emory Healthcare medical record. Anyone who has access to the medical records will be able to have access to all the study information placed there. The confidentiality of the study information in the medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your child's medical record. For this study, those items include:

Tests and procedures done at non-Emory places may not become part of the Emory medical record. Also, if you decide to have your child be in this study, it is up to you to let your other health providers know.

In Case of Injury

If your child gets ill or injured from being in the study, Emory will help to get medical treatment. Emory and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that the injury or illness is directly caused by the negligence of an Emory or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe your child has been injured by this research, you should contact Dr. Lambert (phone 404-778-4417). You should also let any health care provider who treats your child know that s/he is in a research study.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. Your child's participation is completely voluntary and you have the right to refuse to allow your child to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your child's current or future medical care or any other benefits to which s/he is otherwise entitled.

The study doctor, investigator and/or sponsor may stop your child from taking part in this study at any time if they decide it is in his or her best interest, or if you do not follow study instructions.

Authorization to Use and Disclose Protected Health Information

The privacy of your child's health information is important to us. We call the health information that identifies your child, his/her "protected health information" or "PHI." To protect the PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your child's PHI for the study.

PHI that WILL be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about your child including medical history and present/past medications.
- Results of exams, procedures and tests your child has before and during the study.

Purposes for Which Your Child's PHI Will be Used/Disclosed:

We will use and share your child's PHI for the conduct and oversight of the research study. We will use and share the PHI to provide you with study related treatment and for payment for such treatment. We will also use and share the PHI to conduct normal business operations. We may share the PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If your child leaves the study, we may use the PHI to determine health, vital status or contact information. We will use and disclose the PHI for the administration and payment of any costs relating to subject injury from the study.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your child's PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose the PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your child's PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your child's PHI. If you do not sign this form, then your child may not participate in the research study or receive research-related treatment. She or he may still receive non-research related treatment.

People Who Will Use/Disclose Your PHI:
The following people and groups will use and disclose your child's PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose the PHI to conduct the study and give your child study related treatment.
- Emory may use and disclose the PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share the PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The National Institutes of Health/National Eye Institute the Sponsor of the study. The Sponsor may use and disclose the PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose the PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The research team and the Sponsor may use and disclose the PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your child's PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: [Office for Human Research Protections; Food and Drug Administration].
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

Expiration of Your Authorization
Your child's PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your child's information. If you want to do this, you must contact Marla Shainberg at 404-778-2928

At that point, the researchers would not collect any more of your child's PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization s/he will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your child's information to people who are not covered by the Privacy Rules, including HIPAA, then the information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to the PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your child's PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about your child. If it is necessary for your child's health care, the health information will be provided to your doctor.

We may remove identifying information from your child's PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Please call the coordinator, Marla Shainberg, at 404-778-2928 or Scott Lambert, MD, at 404-778-4417

- if you have any questions about this study or your child's part in it,
- if you feel your child has had a research-related injury, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your child's rights as a research participant, or
- if you have questions, concerns or complaints about the research,
- You may also let the IRB know about your child's experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

Please print your name and sign below if you agree to allow your child to be in this study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed consent to keep.

_____ _____

Name of Subject Name of Parent/Legal Representative

_____ _____

Signature of Parent/Legally Authorized Representative Date Time

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion Date Time