INFORMED CONSENT TEMPLATE

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

P.I. Name and Department
Telephone Numbers(s)
Co-P.I. Name(s)
Day Telephone Number(s)
24-Hour Emergency Number
IRB # of protocol

STUDY TITLE:

A Randomized Controlled Study of Adenotonsillectomy for Childhood Sleep Apnea

Study Key Name: CHAT

Invitation to Participate

We invite your child to take part in this research study. This form is called a consent form. The information in this consent form will tell you about what will happen during the research study and the risks and possible benefits of taking part in this research study so that you can decide with confidence whether you want your child to participate. The form also includes other important information about the research study, including the health information we will collect. Please read this information carefully before deciding whether you want to take part. If there is anything you do not understand, please ask questions. Parents or legal guardians who are giving permission for a child, please note that the word "you" in this consent form refers to either you or your child.

Being in this research study is voluntary. You do not have to have your child take part in this study if you do not want to. If your child does take part in this study, he/she can leave the study at any time.

This study is sponsored by the National Center on Sleep Disorders Research a part of the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH). This study will be conducted at the following clinical centers representing the study organization:

1. Cincinnati Children's Hospital .....Cincinnati, OH
2. Children's Hospital of Philadelphia .....Philadelphia, PA
3. Rainbow Babies and Children's Hospital.....Cleveland, OH
4. Cardnial Glennon Chiddren's Hosipta ..... St. Louis, MO
5. Montefiore Children's Hospital ..... New York, NY
6. Children's Hospital of Boston ..... Boston, MA

Overall, it is expected that 460 children will take part in this research study.

Why is your child being asked to take part in this research study?

Your child is being been invited to take part in this study because your child has enlarged tonsils and symptoms of sleep apnea, such as snoring. Sleep apnea is a condition diagnosed with an overnight sleep study that shows breathing pauses (also called “apneas”) during sleep.

The most common cause of SLEEP APNEA in children is enlarged tonsils and adenoids. Sleep Apnea can also be found in children who have a small breathing airway and normal tonsil size. Tonsils are glands located on both sides of the throat and adenoids are glands located in the back of the nose and throat.

SLEEP APNEA may cause health problems, such as poor growth, high blood pressure, behavioral problems and learning problems.

The usual treatment for children with SLEEP APNEA is surgery to remove the tonsils and adenoids. This treatment is called adenotonsillectomy surgery.

What is the purpose of this research study?

The purpose of this research study is to see if adenotonsillectomy surgery helps to reduce the sleep apnea and improve breathing during sleep. Another purpose of this research study is to find out if behavior, learning, blood sugar and blood pressure levels improve after adenotonsillectomy surgery. We also want to find out if children with sleep apnea who are overweight or of different ethnic groups are helped by the surgery.

We are doing this study because we do not know the best way to treat sleep apnea in children. Although adenotonsillectomy surgery is the usual treatment for sleep apnea in children, it has never been properly tested. For some children with sleep apnea, breathing during sleep may improve without having surgery though this has not been tested. We do not know how many children improve after surgery, and how many children continue to have problems.

How long will my child be in this research study?

This research study will last about four years. The length of time your child will take part in the research study will be one year

What is involved in this research study?

This research study involves the following: At the start of the study, all children will be evaluated for sleep apnea and will be evaluated by an ear, nose, and throat doctor. One group of children will get surgery approximately one month after they are enrolled in the study. The other group will not get surgery in a month after they are enrolled, but will wait and be re-evaluated for surgery approximately seven months after they are enrolled in the study.
All children (in both groups) will be given information about good sleep and health habits. All children will be given a salt-water nose spray to be used at bedtime as needed. All children will have their medical history reviewed by a research doctor who may make recommendations for improving health.

This research study will require your child to have overnight sleep studies at a sleep center, blood tests, and clinic visits for physical and behavioral testing. There will also be scheduled phone contacts with you between the clinic visits. You will complete forms that ask questions about your child, and

about your family medical history. Your child's schoolteacher will also be asked to complete a questionnaire about your child.

The following are the clinic visits, tests and procedures required for this study.

Screening Visit

At this first visit, we will see if your child is eligible to take part in this research study. Your child's medical chart and medical history will be reviewed. Information such as medications your child takes, past medical problems and past surgeries will be reviewed.

Your child will receive an examination by a doctor who specializes in ear, nose, and throat problems. This is called an ear, nose, and throat evaluation and requires the doctor to look inside your child's throat, ears, and nose with a small flashlight. This ear, nose, and throat evaluation may occur at the screening visit or may be scheduled as a separate visit at an Ear, Nose, and Throat Clinic. If your child has received an ear, nose, and throat evaluation within 3 months before entered into the study the results of that evaluation will be reviewed to see if your child is eligible to participate in the research study.

Your child will also be scheduled for an overnight sleep study at a Sleep Center. If your child has had an overnight sleep study less than two months before being entered into the study then the results of that sleep study will be evaluated to see if your child is eligible to participate in the research study.

Sleep Study Visit

A sleep study is a routine clinical test that will tell us if your child has sleep apnea or not. The sleep study is done overnight at the sleep center. Before going to sleep for the night at the sleep center, a number of small patches will be placed on the skin of your child's head, face, chest and legs and a patch will be taped around your child's finger or toe. These patches will be connected by wires to machines in a separate room where your child's breathing, heart rate, leg movements, and sleep will be monitored. Your child will wear stretchy belts that are placed around the chest and belly to measure breathing. Small plastic tubes will be placed in the nose to measure your child's breathing. A video recording of your child is made while they are sleeping to monitor the testing. You will sleep in the same room as your child during the testing.

In order to be eligible for the research study, the results of your child's sleep study must be abnormal and show that your child has sleep apnea. If the sleep study is very abnormal and shows a severe condition of sleep apnea, your child will not be enrolled in the research study as we think it may not be safe to wait for surgery if a child has a severe condition of sleep apnea.

Randomization

If your child is eligible to be in the research study, they will be randomly assigned to one of the two treatment groups talked about below. "Randomly Assigned" means being put into a group by chance. It is like flipping a coin. Your child will have an equal chance of being in either group. A computer will choose which group your child will be in. The main research study doctor will not know which group your child is in.

Appendix B: Informed Consent Template

One treatment group will have early adenotonsillectomy surgery that will be scheduled within one month after being enrolled in the study. This is called the *Early Adenotonsillectomy Surgery* group.

The second treatment group will be re-evaluated for surgery by the ear, nose, and throat doctor about 7 months after being enrolled in the study. If the ear, nose, and throat doctor finds that surgery is needed, then surgery will be scheduled by the ENT's office to occur within one month of the 7month visit. This is called the *Watchful Waiting with Supportive Care* group.

Children in both groups will be given sleep and health information, a salt-water nose spray to use as needed at night, and will have their medical history reviewed to make sure all medical problems are well addressed.

Baseline Visit

During this visit, you will have a number of tests done. These tests will take about 4 hours and must be done in the morning. There will be breaks scheduled during the tests so that your child doesn't get tired. Your child cannot eat for 10 hours before the blood test, but will be able to eat breakfast as soon as the blood sample is taken. The following are the tests that will be done:

1. Blood will be taken from your child to test your child's blood sugar, insulin, lipids (fat and cholesterol) and C-reactive protein (a test of inflammation). This requires that a vein in your child's arm to be pricked with a sterile needle and approximately 2 tablespoons of blood will be collected into a tube. Because a needle stick can be painful for your child, the doctor may order a medicine cream that is used to numb the skin so that your child will not feel the needle as it goes in. Before your child is scheduled for the blood test, you will receive instructions on how to apply the cream to your child's skin.

   We would like to store a sample of this blood for future genetic testing to help us research the cause of sleep apnea and the health problems related to it. You will be asked to sign a separate consent form for collecting and storing a genetic blood sample from your child.

2. A brief physical examination will be done. This will include height, weight, blood pressure, and measurements of the neck, waist and hips. A research doctor will also look into your child's mouth with a flashlight, and do a brief physical examination as is usually done in a doctor's office.

3. Behavior and learning tests will be done. A trained research assistant will give your child tests that examine memory, intelligence, behavior and mood. You will be in a different room and will fill out questionnaires about your child's health and behavior while your child is being tested.

4. A Teacher Questionnaire. With your permission, we will mail to your child's teacher two brief questionnaires to fill out. These are questions about how your child is doing in school. We will ask you to tell us the name of the teacher that knows your child best, and to sign a form giving the teacher permission to fill out the questionnaires. We will then mail the teacher a letter. If you prefer, you can give the teacher the letter yourself.

5. Sleep diary. You will be asked to fill out a 5-day sleep diary showing what time your child gets up in the morning and what time your child goes to sleep at night and some general questions about beverages you child drinks and your child's activity level.

Treatment

If your child is randomized to the Early Adenotonsillectomy Surgery group, your child will receive adenotonsillectomy surgery within one month of completing the baseline tests. You will be given a supply of salt water nasal spray for your child to use at bedtime if needed, to help with nasal dryness. You will be given information about good sleep habits. Your child's medical history will be reviewed by the research doctor who may make recommendations to you or your child's other doctors on ways to improve your child's health

If your child is randomized to the Watchful Waiting with Supportive Care group, your child will be re-evaluated for surgery by the ear, nose, and throat doctor about 7 months after completing the baseline tests. If the ear, nose, and throat doctor finds that surgery is needed, it will be scheduled. You will be given a supply of salt water nasal spray for your child to use at bedtime if needed, to help with nasal dryness. You will be given information about good sleep habits. Your child's medical history will be reviewed by the research doctor who may make recommendations to you or your child's other doctors on ways to improve your child's health.

As a measure of surgical quality control in this research study, photographs of the inside of the throat will be taken on every 10th child. Your child may be selected. A photograph of the inside of the throat will be taken before and after the tonsils and adenoids are removed. These photographs will add less than a minute to the time for surgery. Your child will not be identified as the photos are only of the inside of the mouth.

Follow-up phone calls

You will get a phone call from the study staff 2 times during the 7 month study period to see how things are going and whether there are any problems (for example, questions about new illnesses, health or behavioral concerns, unscheduled doctor visits, medications).

3-Month Clinic Visit

This is a research clinic visit that occurs three months after enrollment in the study. Your child will have height, weight and blood pressure measured again at this visit. This visit will last about 30 minutes.

6-Month Sleep Study

Your child will have another overnight sleep study at the sleep center 6 months after entering the study. The same sleep study procedures will be done just like they were done for the first sleep study. Also like the first sleep study, you will sleep in the same room as your child during the testing. You will also be given another sleep journal to record your child's sleep patterns again for 5 nights. The study staff will ask you to return the completed journal at the 7 month visit.

7-Month Clinic Visit and Testing

Your child will return to the research clinic where all the tests that were given at the baseline visit will be repeated. (Please see baseline visit on pages 4 & 5 for details of the tests). These tests will take about 4 hours all together, and must be done in the morning.

The tests include the blood sample (your child cannot eat for 12 hours before the blood sample is taken), physical exam, behavior and learning tests, teacher questionnaire., and sleep diary.

If your child is in the Watch Waiting with Supportive Care group, they will be seen again by the ear, nose, and throat doctor who will decide whether your child should have adenotonsillectomy surgery. If surgery is recommended, then the surgery will be scheduled to be done within approximately one month of this visit.

What are the risks of taking part in this research study?

Taking part in a research study involves risks or "side effects." You should talk about these risks or side effects with the study doctor, the ear, nose, and throat doctor, or your child's regular doctor. There may be risks or side effects we do not know about yet.

While in this study, your child is at risk for the following side effects:

Side Effects of later or delayed surgical treatment of sleep apnea:

The possible side effects of untreated sleep apnea may include behavioral, learning, blood pressure, blood sugar and growth problems. For children randomized to *the Watchful Waiting with Supportive Care* group, we believe the 7-month wait or delay period before surgery is within a safe range and waiting for surgery is not a danger to your child. We will closely follow your child's condition during this period. If your child develops symptoms of severe sleep apnea during this wait period, immediate surgical treatment will be needed. If your child develops new health or behavior problems during the study like high blood pressure, prompt surgery also may be recommended.

Side Effects of adenotonsillectomy surgery and general anesthesia:

Common side effects of adenotonsillectomy surgery are temporary sore throat with painful swallowing and minimal blood loss that can be expected to last up to 7-10 days after surgery. Less common side effects can occur such as dehydration, a larger than expected blood loss, infection, trauma or burns to teeth or the throat, temporary difficulty with swallowing or speech or regrowth of tonsil or adenoid tissue. These problems may require blood transfusions, speech therapy or additional surgery. Very rare complications of surgery include scarring of the airway, serious infections, and death.

Adenotonsillectomy surgery is done under general anesthesia. General anesthesia affects the entire body and makes the person unconscious. Although general anesthesia involves some risk, major side effects and complications from anesthesia are uncommon.

Common side effects of general anesthesia include nausea, vomiting, and sore or painful throat following surgery. Serious general anesthesia-related complications, though rare, can include breathing difficulties, drug reactions, changes in blood pressure or heart rate or rhythm, heart attack, or stroke. Death or serious illness or injury due to anesthesia is very rare.

Before undergoing surgery, the surgeon and anesthesiologist will meet with you to discuss any questions you or your child may have about surgery and anesthesia. Additional details related to adenotonsillectomy surgery and general anesthesia will be discussed at this time. You will be asked to sign a separate surgical consent form before your child receives surgery.

Side Effects of Blood Tests: Taking blood may cause some discomfort or pain, bleeding or bruising at the spot where the needle pokes through the skin. Rare Side Effects: Taking blood may cause nausea, lightheadedness, or fainting or infection at the area where blood is taken.

Side Effects of Numbing Cream: The medicine cream used to numb the skin before the blood test my cause some redness, swelling, itching, or rash on the skin where the medicine is applied.

Side Effects of Sleep study: The sleep patches for the overnight sleep study are attached with paste and tape and may cause some irritation of the skin. Sleeping overnight away from home can be distressing for some children, however, you or another family member will sleep in the same room with your child during the sleep study.

Side Effects of behavior and learning tests: Some children may find taking the behavior and learning tests to be mildly stressful. If a particular question makes your child uncomfortable, they will not be required to answer the question.

Are there any benefits to taking part in this research study?

There may or may not be a direct medical benefit to your child if he/she takes part in this research study. Your child may be identified during this study as having a medical problem you did not know about like high blood pressure, diabetes, or high cholesterol, which would benefit from early treatment. At the end of the study, you will also receive the results of your child's behavior and learning tests, and be referred for further evaluation if these tests are abnormal. In the unlikely event that the behavior tests show severe depression or suicidal intent, your family will be notified and you will be referred for further help.

Do you need to give your consent to get treatment?

Yes, you need to give consent for your child to be in this research study. If you do not give consent, your child can still get clinical treatment without being in this research study.

What happens if you decide not to have your child take part in this research study?

If you decide not to have your child take part in this research study, your child's current and future medical care at *(Insert name of Institution)* will not be affected and your child will receive the same standard of heath care given for sleep apnea.

What if you want to have your child leave the research study after he/she begins?

Being in this research study is voluntary. You may choose to have your child leave the study at any time.

This research study is expected to end after all participants have completed all visits, and all information has been collected. The study doctor may have your child leave the study at any time without your consent for the following reasons:

- Your child's condition worsens
- Your child cannot meet all the requirements of the research study
- You decide to take back the permission you gave for us to collect, use or share your child's health information
- New information suggests that taking part in the research study may not be in your child's best interests
- The research study is stopped by the study doctor or the study sponsor

Will confidential health information be collected as part of this study?

Yes. We need to collect your health information to conduct this study and we will keep it confidential as required by law. Every effort will be made to keep your child's health information private. Your child's study information will be given a unique code. Your child will never be tracked through the study by name, medical record number, or other personal identifiers. The key to this unique code will be kept in a locked file or a password-protected computer file in the study team's locked office.

The University of Pennsylvania serves as the Data Coordinating Center for this research study. All the study information from all the research centers, after being stripped of your child's identifying information, will be stored in secure electronic files at the University of Pennsylvania. All study data will be sent to the Data Coordinating Center by secured internet connection. Quality control measures for the sleep and blood pressure studies with be directed by Harvard. . Quality control measures for surgery, and the behavioral and learning studies will be directed by the University of Michigan. Only authorized members of the research study will have permission to see the study data. Authorized representatives of the Sponsor, the National Center on Sleep Disorders Research a part of the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), the Institutional Review Board *(insert name of institution)*, may have access to an may copy medical or research records that identify your child by name. This step is necessary to insure the accuracy of the research findings and your safety and welfare.

The results of this study may be shown at meetings or published in journals so other doctors and health professionals know about the study. Your child will not be identified by name or other personal identifier in any publication or presentation about the study.

The information collected about your child as part of this study will be retained for at least seven (7) years or until the study is completed, whichever is longer. At that time, the research information will either be destroyed or all the information that identifies your child will be removed from the study results and the key destroyed.

Use of your child's information in future studies

Your child's information may be useful for other studies. We can only use your child's information again if special committees, called the Institutional Review Boards, let us. These committees may want us to talk to you again before we do another study using your child's information, or the committees may also let us do research without talking to you again if we keep your child's health information private. You may also tell us that you do not want us to use your child's information in future studies.

What happens to the health information if you want your child to leave the study?

You do not have to have your child take part in this study if you do not want to. You can have your child leave the study at any time or ask that your child's health information not be used. If you ask that we no longer collect your child's health information, then your child will have to leave the study.

If you chose to have your child leave the study, but will let the researchers use or share your child's personal health information, you will be asked to fill out a form, called the "Withdrawal from Study" form.

If you do not want us to collect, use or share your health information anymore, you must send a letter to the study doctor. In the letter, you must say you changed your mind and that you will not allow us to use and share your child's health information anymore. We will then ask you to fill out a form, called a "Withdrawal of Study Participation and Consent/Authorization" form.

Even if you take back your permission for us to use your child's information, we may still use the information about your child that we collected before you left the study. We do this because we need to know what happens to everyone who starts a research study.

What will we do with the blood we collect from your child?

As part of the study, we will collect blood samples. Information that can identify your child will not be placed on the samples. The blood samples will be shipped to the University of Vermont Research Biochemistry Laboratory, where they will be analyzed and permanently stored.

If you have your child leave the study, you can ask that your child's blood samples be destroyed.

What will it cost you to have your child participate?

The cost for the following research procedures will be paid for by the research study funds:
Physical examinations, blood tests, behavioral and learning tests.

The cost of the first research sleep study to determine if your child meets criteria to participate in this study will be paid for by the research study *if your child's doctor did not order a sleep study and you have consented to participate in this study*

However, if your child's doctor has already ordered a sleep study as part of routine care for your child, then the cost of clinical care sleep study that your doctor has ordered is the responsibility of you and your insurance company.

The costs of the second research sleep study will be paid for by the research study funds.

Costs related to surgery: You and/or your insurance company, Medicare or Medicaid will be responsible for the costs of the adenotonsillectomy surgery that your child receives during this study. Since surgery is the usual treatment for sleep apnea, these are costs that are considered medically reasonable and necessary and will be part of the care your child receives if they do not take part in this study.

Will you be paid for taking part in this research study?

For taking part in this research study, you will be paid *(Customize per clinical center - specific participant payment information should be itemized)*

Who is funding this research study?

This research study is supported by grants from the National Heart Lung and Blood Institute, and the General Clinical Research Center, which are part of the National Institutes of Health. The National Institutes of Health is a part of the federal government. It conducts and funds medical research. The results of the study will be reported to the National Institutes of Health.

What if you have questions about the study?

The (*Insert your Institution's name)* has a committee called the Institutional Review Board. It is their responsibility to make sure that the research being conducted is safe and that people in the study are informed about risks and benefits of the research study. If you would like more information or have

questions about your child's rights as a research subject, you can contact the Office of Regulatory Affairs (*insert appropriate information for your clinical site IRB)*

What happens if your child is injured during the study?

Your child will not get free care, payment or special services from (*insert name of institution)* or the study sponsor if your child is injured while taking part in this study. Doctors at these hospitals can arrange for emergency medical care if your child is hurt or gets sick from something that is done as part of this study. You will not pay for this emergency care if your injury is caused by the experimental part of this study. Otherwise, treatment for your injuries will be paid for the same way you usually pay (for example, through your insurance)

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to have your child participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your child's participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

_____

Printed Name of Participant

_____ Date_____ _____

Parent or Legal Guardian signature Relationship to Child

_____Date_____ _____

Signature of Person Obtaining Consent Printed Name, Person Obtaining Consent

(Must be study investigator or individual who has been designated in the Checklist to obtain consent.)

_____Date_____ _____

Signature of Principal Investigator Printed Name of Principal Investigator

(Affirming subject eligibility for the study and that informed consent has been obtained.)