OMB Number: 0925-0593
Expiration Date: July 31, 2013

Permission/Consent to Take Part
In a Study Conducted at St. Christopher's Hospital for Children

Child's Name: _____

Parent/Guardian's Name: _____

Title of Research: Tools for screening of pulmonary function in children 1-8 years of age - a vanguard study for the National Children's Study

Investigator's Name: Robyn T. Cohen, MD, MPH

Research Entity:
This research study is being done by a member of the Philadelphia Health & Education Corporation (doing business as Drexel University College of Medicine) teaching faculty, who is based at St. Christopher's Hospital for Children. Note, both Drexel University and St. Christopher's Hospital for Children are corporations separate and distinct from Philadelphia Health & Education Corporation, which is the entity responsible for this research study.

Consenting for the Research Study:
This is a long and an important document. If you sign it, you will be authorizing St. Christopher's Hospital for Children and its researchers to perform research studies on you and your child. You should take your time and carefully read it. You can also take a copy of this consent form to discuss it with your family member, physician, attorney or anyone else you would like before you sign it. Do not sign it unless you are comfortable in participating in this study.

YOUR RIGHT TO PRIVACY AND CONFIDENTIALITY.
Very specific information on your right to privacy and the confidentiality of the use and disclosure of your personal health information can be found at the end of this consent form. We need your authorization to use and disclose the health information that we may collect about you during this research study. To be in this research study you must read and sign the authorization at the end of this consent form.

PURPOSE OF RESEARCH:
You and your child are being asked to participate in a research study. The purpose of this study is to find out if young children can do simple breathing tests that will help doctors and nurses learn about their lung function. We are asking you and your child to be in our study because we want to learn about the breathing tests in generally healthy children who are between 1 and 8

years of age. We hope to enroll approximately 450 children altogether, including 80 subjects here at St. Christopher's Hospital for Children. If your child was born prematurely (less than 34 weeks), or has been diagnosed with asthma, cystic fibrosis, or another chronic breathing problem, he/she is not eligible to participate in our study. If your child has had a respiratory illness (cold, cough, etc) any time in the past 2 weeks, your child cannot participate until this illness has resolved for 14 days. Participation in our study is completely voluntary and will not affect the care your child and family receive at St. Christopher's Hospital for Children. You can withdraw your child from the study at any time.

PROCEDURES AND DURATION:
You understand that the following things will be done with you and your child:

<u>At the first visit</u>, you and your child will come to our Pulmonary Function Test laboratory for a visit that will take about 20-30 minutes. You will be asked to fill out a questionnaire about your child's medical history, breathing symptoms, and some demographic information.

We will attempt 2 or 3 simple breathing tests with your child.
The first, called Airway Resistance, will involve your child breathing into a mask or mouthpiece for 30 seconds.

The second, called Exhaled Nitric Oxide, will involve your child breathing into a mask or mouthpiece for 10 seconds.

The third, called spirometry, will only be attempted if your child is 4 years of age or older and seems able to follow specific directions. It involves taking a big breath and then blowing out hard into a mouthpiece for several seconds.

<u>At the second visit</u> (approximately 1 week after the first visit), a brief health screener will be administered, and the breathing tests your child did at the first visit will be repeated. This visit should be shorter than the first visit, approximately 15-20 minutes.

<u>At the third visit</u> (approximately 1 month after the second visit), a brief health screener will be administered, and the same breathing tests will be repeated. You will be asked to fill out a survey about how easy/difficult, etc. the breathing tests were for you and your child. This visit should take approximately 15-20 minutes.

RISKS AND DISCOMFORTS/CONSTRAINTS:
Spirometry and other breathing tests can sometimes cause temporary fatigue, dizziness or lightheadedness that is relieved by rest. In order to minimize risks from the lung function tests, the tests will be performed by a licensed respiratory therapist. If your child develops wheezing or coughing as a result of doing the breathing tests, Albuterol (an inhaled medication) may be administered by a physician or the respiratory therapist in consultation with the doctor in charge of the study. Answering questions can sometimes cause mental discomfort.

UNFORESEEN RISKS:
Participation in the study may involve unforeseen risks. You/your child will be told in a timely manner of any new risks that become known that may affect

your/your child's willingness to continue in the study. If unforeseen risks become known, they will be reported to the Office of Regulatory Research Compliance.

BENEFITS:
Potential benefits from participating in this study include your child having breathing tests at no cost to you. We may discover abnormal results on the breathing tests and, therefore, these results may assist with early identification of potential breathing problems such as asthma. There are no other direct benefits to your child from participating in this study, but this study will provide information about whether these breathing tests will be useful to doctors and patients in the future.

ALTERNATIVE PROCEDURES/TREATMENT:
The alternative is not to participate in this study. If you/your child choose(s) not to participate in this study, your/your child's care will not be affected in any way.

REASONS FOR REMOVAL FROM STUDY:
You may be required to stop the study before the end for any of the following reasons:

- **Change in medical condition;**
- **If all or part of the study is discontinued for any reason by the sponsor, investigator, university authorities, or government agencies; or**
- **Other reasons, including new information available to the investigator or harmful unforeseen reactions experienced by the subject or other subjects in this study.**

VOLUNTARY PARTICIPATION:

You understand that being in this study is voluntary. Your health care will not be affected in any way if you decline to be in or later withdraw from the study.

STIPEND/REIMBURSEMENT (include only if appropriate):

As compensation for participating in our study, you will receive the following:
1. $25 Target Gift Card + $10 transportation/parking reimbursement.
2. $25 Target Gift Card + $10 transportation/parking reimbursement.
3. $25 Target Gift Card, a book for your child + $10 transportation/parking reimbursement.

RESPONSIBILITY FOR COST
There is no cost to you/your child for participating in this study. The clinic visit, laboratory testing and pulmonary function testing will be free of charge.

IN CASE OF INJURY:
If you/your child have/has any questions or believe you/your child have/has been injured in any way by being in this research study, you should contact Dr. Cohen at (215) 427-5183. If you/your child are/is injured by the research activity as outlined in section 8 above, medical care including hospitalization is available to you/your child at St. Christopher's Hospital for Children. This

agreement to care for you/your child does not include treatment for any injury that is not a result of the research activity. No other payments will be made. If you/your child are/is injured or have/has an adverse reaction, you should also contact the Office of Regulatory Research Compliance at (215) 255-7857.

CONFIDENTIALITY AND PRIVACY:
This section gives more specific information about the privacy and confidentiality of your health information. It explains what health information about you will be collected during this research study and who may use, give out and receive your health information. It also describes your right to inspect your medical records and how you can revoke this authorization after you sign it.

By signing this form, you agree that your health information may be used and disclosed during this research study. Your health information may be disclosed or transmitted electronically. We will only collect information that is needed for the research study. Your health information will only be used and given out as explained in this consent form or as permitted by law.

In any publication or presentation of research results, your identity will be kept confidential.

Health Information that will be collected
The following personal health information about you will be collected and used during the research study and may be given out to others only for scientific purposes related to this study:

- **Personal and family medical history;**
- **Information from procedures described in this consent form.**
- **Information learned during telephone calls, surveys, questionnaires and office visits done as part of this research study;**
- **Information in medical records located in your doctor's office or at other medical facilities you may have received treatment.**

Your name, address, and telephone number will be kept separate from your responses to questionnaires and health measurements. An ID number will be assigned to your records. Only approved persons will have access to your name and contact information. Your contact information will only be used for project management and follow up with you in relation to this research project.

Who will see and use your health information within St. Christopher's Hospital for Children.
The research study investigator and other authorized individuals involved in the research study at St. Christopher's Hospital for Children will see your health information and may give out your health information during the research study. These include the research investigator and the research staff, the institutional review board and their staff, legal counsel, research office and compliance staff, officers of the organization and other people who need to see the information in order to conduct the research study or make sure it is being done properly.

Who else may see and use your health information.

Other persons and organizations outside of St. Christopher's Hospital for Children may see and use your health information during this research study. These include:

- **Governmental entities that have the right to see or review your health information, such as the Office of Human Research Protections and the Food and Drug Administration**

- **Doctors and staff at the hospital where this research study will take place.**

- **Doctors and staff at other places that are participating in the research study. This includes the Study Staff at the University of Miami School of Medicine.**

- **The sponsor of this research study and persons that the sponsor may hire to work on the research study. The name of the sponsor is the National Institutes of Health.**

- **An outside institutional review board.**

If your health information is given to someone not required by law to keep it confidential, then that information may no longer be protected, and may be used or given out without your permission.

Why your health information will be used and given out.
This study is originating at the University of Miami Medical Center, so their study staff will be using the information we collect for this study. Your health information will be used and given out to carry out the research study and to evaluate the results of the study.

Your information may also be used to meet the reporting requirements of governmental agencies.

If you do not want to give authorization to use your health information.
You do not have to give your authorization to use or give out your health information. However, if you do not give authorization, you cannot participate in this research study.

How to cancel your authorization.
At any time you may cancel your authorization to allow your health information to be used or given out by sending a written notice to the Office of Regulatory Research Compliance, 1601 Cherry Street, 3 Parkway Bldg., Mail Stop 10-444, Philadelphia, Pennsylvania, 19102. If you leave this research study, no new health information about you will be gathered after you leave. However, information gathered before that date may be used or given out if it is needed for the research study or any follow-up.

When your authorization ends
Your authorization to use and give out health information will continue until you withdraw or cancel your authorization.

After the research study is finished, your health information will be maintained in a research database. St. Christopher's Hospital for Children shall not re-use or re-disclose the health information in this database for other purposes unless

you give written authorization to do so. However, the Drexel University College of Medicine Institutional Review Board may permit other researchers to see and use your health information under adequate privacy safeguards.

Your right to inspect your medical and research records.
You have the right to look at your medical records at any time during this research study. However, the investigator does not have to release research information to you if it is not part of your medical record.

OTHER CONSIDERATIONS:
If you wish further information regarding your rights as a research subject or if you have problems with a research-related injury, for medical problems please contact the Institution's Office of Regulatory Research Compliance by telephoning 215-255-7857.

CONSENT:

I have been informed of the reasons for this study.

I have had the study explained to me.

I have had all of my questions answered.

I have carefully read this consent form, have initialed each page, and have received a signed copy.

I authorize the use and disclosure of my personal health information as explained in this consent form.

I give consent voluntarily.

_____ _____
Subject or Legally Authorized Representative Date

_____ _____
Investigator or Individual Obtaining this Consent/Permission Date

_____ _____
Witness to Signature Date

List of Individuals Authorized to Obtain Consent/Permission

Name	Title	Day Phone #	24 Hr Phone #
Robyn T. Cohen, MD, MPH		215-427-5183	215-427-5000
Mark E. Dovey, MD,		215-427-5183	215-427-5000
Marsha D. Simmons, B.S.		215-427-3797	