INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES

Connecticut Children's Medical Center

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Title of Research: **"A prospective, randomized, multi-center controlled study to assess medication adherence in children with asthma managed on BreatheSmart and feedback"**

Purpose of Research: Children with asthma often do not take their controller medication everyday as prescribed. This results in overuse of rescue medication, increased asthma symptoms, more frequent Asthma attacks, and increased emergency room visits and hospital admissions. Currently, doctors have to rely on patient-self report of medication adherence (following scheduling instructions correctly) to support their decision making, which is not always accurate.
Many studies using electronic devices to measure adherence only provide reminders for patients to take their medication. This study evaluates whether electronic devices used to measure adherence in combination with a reminder system and patient education can prove to be effective in increasing adherence rates and can be used by your doctor to improve your child's asthma control and outcomes. The objectives of this study are to determine if the addition of the BreatheSmart platform, which includes electronic devices for your child's asthma medications and an app that provides education and reminders if your child did not take his/her medication, improves medication adherence and health outcomes in children with persistent asthma who are prescribed an inhaled corticosteroid by their doctor.

Procedures: This study will enroll children who are 8 to 17 years of age and have been diagnosed with persistent asthma. We plan to recruit 75 children from CT Children's Medical Center Pulmonary Clinic as well as our Primary care offices in East and West Hartford . A computer program will place you in one of the study groups (intervention or control). Neither you nor your doctor can choose the group you will be in. You will have a one in three chance of being placed in the control group. Participants randomized to the control group are reminded to adhere to the prescribed standard of care therapy provided by their clinician. 50 children will receive the intervention and 25 children will receive the standard of care. All participants will be seen at screening/baseline, 90 and 180 days' post randomization.

During the screening visit the following assessments will be performed:

1. An interview of you and your child during the screening assessment where the study staff will document the following: type of mobile device and version number of the operating system in use, email address, age/gender/ethnicity, parent income level/education level/medical insurance type, date of asthma diagnosis, other comorbidities, use of inhaled corticosteroids and other inhaled therapies for asthma, use and timing of oral systemic corticosteroids and use of other concomitant medications
2. Review of pharmacy records to collect information about your child's medication refill information

During all three visits the following assessments will be performed:

1. Measurement of lung function including FEV1, FEV1/FVC ratio, FEF25-75, FeNO will be assessed by the clinician at each study visit (standard clinic measurement at he Pulmonary clinics only)
2. A survey, which asks questions about your child's asthma control called the Asthma Control Test
3. A survey, which asks questions about missed school days, medication changes/refills and exacerbation of asthma episodes requiring courses of oral steroids, doctor visits outside of standard of care, Emergency Room visits and hospitalizations
4. A survey for both you and your child which asks questions about your child's quality of life called the PedsQL asthma module
5. A survey, which asks questions about your child's medication adherence called the Test of Adherence to Inhalers (TAI)

In addition, active participants (intervention arm) will be continuously monitored via the CoheroConnect dashboard which allows the Investigator to monitor the child's medication adherence in real time. To ensure proper placement of the sensor device on the appropriate inhalers, we will call you 24 hours after your initial

study visit. You will receive a phone call or text appointment reminders the day prior to your 3 and 6 month follow up appointments. At the follow-up visit, these data will be reviewed with you and your child. The adherence rate and barriers identified will be discussed and, if necessary, personalized strategies for improvement will be devised. Study personnel are notified of any excessive albuterol use which may indicate an asthma exacerbation, and will inform your provider who may call you to better understand the excessive use.

The visit will take approximately 1 hour. Results of the breathing tests for your child with asthma will be discussed with you by your clinician in the Pulmonary Clinic

Once the data is obtained from the surveys and chart extraction, it will then be entered into a password protected database. Upon enrollment, subjects will be designated a study number. Once data is entered in the database, they will only be identified by study number. Protected Health Information (PHI) will not be entered into the database. Original source documents will be kept in a locked filing cabinet in a locked office until data analysis is complete.

Risks and Inconveniences:

1. 90 and 180 post randomization follow up appointments: Can be inconvenient but will be coordinated with the patient's routine pulmonary clinic follow up (+/-20 days).
2. Breach of confidentiality: There is chance that your child's confidentiality could be compromised; however, we are taking precautions to minimize this risk.

Breathing tests will only be conducted for the participants who are seen at the Pulmonary Clinicsby a doctor, nurse or licensed clinician who has experience doing these tests.

Benefits: There is a potential benefit that your child will experience increased adherence to his/her asthma medications if enrolled in the intervention arm of this study. There is an indirect benefit of participating in this study as it is possible that the doctors will learn more about the asthma medication adherence. In the future, it could help them better treat their patients with asthma.

Your child will learn about the importance of taking his/her asthma medications and about the functioning of their lungs.

The education we provide may help your child manage his/her asthma.

Voluntary Participation: Your decision to allow your child to participate is voluntary. You may refuse to allow your child to participate and/or withdraw your consent and discontinue your child's participation in the project at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to allow your child to participate will not affect your child's future medical care at Connecticut Children's Medical Center. You will be informed about any medical consequences of withdrawing early from the study and you will be told about any new information that may influence your willingness to continue your child's participation in the research.

Questions: The investigator is willing to answer any questions you may have concerning the procedures described in this form. All of the questions you have at this time have been answered. Future questions about this study may be directed to Dr. Jessica Hollenbach at 860-837-5333. If you have questions about you or your child's rights as a research subject, you may call the Research Office at Connecticut Children's Medical Center at (860) 545-9980.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, *as required by U.S. Law.* This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Compensation: You will receive a $35 gift card after the 180 day study visit, for the time and inconvenience of this study. No other compensation is provided for participating in this study.

Confidentiality: The confidentiality of your child's records will be maintained in accordance with the state and federal laws that apply to medical records. The research data will be store on a password protected computer and on a cloud-based HIPAA-compliant server (CoheroConnect™) with access limited to doctors and study staff. You may request your child's records to be released to your personal physician. However, no information that would reveal your child's identity will be released or published.

Costs: There will be no cost to you for participating in this study.

Please read the above information carefully and discuss this study with the principal investigator, Dr. Hollenbach and her staff. You may obtain information about the results of this study when it is completed, by contacting the principal investigator, Dr. Hollenbach .

Based on the information provided, I agree to allow my child to participate in this study. Upon signing, I will receive a copy of this form. All the questions I have at this time have been answered.

As the parent/guardian, I have legal responsibility for the care and custody of:_____. I willingly agree to allow my child,_____, to participate in this investigation, "A prospective, randomized, multi-center controlled study to assess medication adherence in children with asthma managed on BreatheSmart and feedback." I understand the purpose, procedures, and length of my child's involvement, as stated above:

_____
Printed Name of Parent/Legal Guardian/Legally Authorized Representative

_____ _____
Signature of Parent/Legal Guardian/Authorized Representative Date

_____ _____
Witness Date

I have fully explained to the parents the nature and purpose of the above described research and the risks involved in its performance. I have answered and will answer all questions to the best of my ability. I will inform the participant of any changes in the procedure or the risks and benefits, if any should occur during or after the course of this study.

_____ _____

Investigator/Person Obtaining Consent Date

Assent for the child (8years of age and older)

My doctor and parents have talked to me about being part of a study about taking my asthma medications.

I understand the reason for the study and why I am being asked to take part in it. I have been told that as a subject in the study I will:

1. Answer questions about my asthma and asthma medications
2. Do some breathing tests
3. Answer some questions about my asthma control and my life with asthma
4. Potentially download and use a mobile application on my phone/device or my parent's phone/device and put a sensor on my asthma medications so the staff knows when I take my medications

I understand that these procedures may cause:

1. Inconvenience for me

I know that I can ask questions about this study at any time.

I also know that I can decide not to be in this study, or after entering the study I can decide that I want to be taken out of it.

Whatever I decide to do, I know my doctor will not be angry with me and will continue to treat me as his/her patient.

_____ _____

Participant/Patient Date

Reason why Participant/Patient did not sign:_____