Children's Hospital of Philadelphia

Informed Consent Form and HIPAA Authorization

Study Title: The Tailored Adherence Incentives for Childhood Asthma Medications Trial

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You and your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff. The word "you" refers to the child's parent or legal guardian.

Why are you being asked to take part in this study?

You and your child are being asked to take part in this research study because your child has had an asthma flare and has a prescription for daily asthma controller medicine.

What is the purpose of this research study?

The purpose of this research study is to see which of several strategies can help families better manage their child's asthma.

How many people will take part?

About 125 families will take part in this study.

What is involved in the study?

If you choose to take part in this study, you will be assigned to one of three groups.

For the first month, all subjects will have access to the inhaler sensor app and will receive electronic monitoring of asthma medication use. You will also be asked to respond to at least one of 4 text messages. If no data is transmitted or you don't respond to any of the 4 text messages in the first two weeks of the study, you will not be randomized and or complete additional study tasks, but data from your medical record may still continue to be collected unless you withdraw. Your child will be given $10 for their participation.

After the first month, if any inhaler use data is transmitted to the study and you reply to at least one text message in the first two weeks of the study, you will be randomized (like flipping a coin) to one of three groups. Some of the groups will receive reminders and

feedback about medication use. You can earn up to $100 for participating and your child can earn up to $70 and may have the opportunity to earn more. Neither you nor the study doctor will get to choose which group you are in. You will not know how much other participants are paid.

You will also complete surveys and use the app that works with the sensor. You may be asked to participate in an interview, which will be audio-recorded.

How long will you be in this study?

If you agree to take part, your participation will last for up to 13 months and will involve 5 study visits.

What are the study procedures?

Your child will continue to use their inhalers as directed by their doctor.

Electronic Monitoring: An electronic monitoring device will be installed that attaches to your child's inhalers. The device counts the number of puffs and records the time of the puffs. This information will sync with an application on your mobile device. We will also ask you to download the app onto your mobile device. This will allow both you and the study team can see how and when your child takes their asthma medications.

Surveys: You will complete surveys throughout the study. Each survey will take approximately 15 minutes to complete and will ask you questions about family make up, asthma medications, and asthma care in your family.

Interview: We may ask you and your child a few questions about the medication reminders, feedback, and rewards for your child. This will take about 45 minutes. The interview will be audio-recorded and then transcribed.

Medication Reminder and Feedback Messages: Two of the three groups include reminder messages. If you are randomized into one of these two groups, we will also send you daily medication reminder messages. You will also receive messages that give you feedback on your child's medication use in every week for part of the study.

Review of Medical Records: We will look at your child's medical record to collect information about their medical history, current health, diagnosis, treatments, medications, and results of clinical tests.

Visit Schedule

The table below provides a brief description of the purpose and duration of each study visit.

Visit	Purpose	Main Procedures	Duration
Visit 1	Study Sign Up and Beginning of Study	Consent form, first survey, electronic monitoring device and study instructions (clinic or phone)	30 minutes
Randomization			
Visit 2, month 2	Check asthma behaviors and control	Follow-up survey (clinic/home or phone)	15 minutes
Visit 3, month 4	Check asthma behaviors and control	Follow-up survey & interview (clinic/home or phone)	60-75 minutes
Visit 4, month 7	Check asthma behaviors and control	Follow-up survey (clinic/home or phone)	15 minutes
Visit 5, month 12	Complete study	Follow-up survey (clinic/home or phone)	15 minutes

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your child's regular doctor.

While in this study, you are at risk for the following:

Risks associated with surveys and interview: There are no physical risks but you might experience momentary embarrassment or discomfort because of the nature of the questions. You do not have to answer any questions that make you feel too uncomfortable.

Risks associated with medical record review, electronic monitoring, and mobile app: As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

At the time of participation, each participating family will be assigned a study identification number. This number will be used on data collection forms, and in the database instead of names and other private information. A separate list will be

maintained that will link each participating family's name to the study identification number.

Are there any benefits to taking part in this study?

The best strategy to improve medication usage is not known. Your child might benefit if the text messages or the financial rewards help to better manage childhood asthma. However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study.

Findings from this study will help to inform the design of future studies to improve daily medication use in children with asthma.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record. Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order for your child to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you and your child are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

What choices do you have other than this study?

There are options for you other than this study including:

- Mobile apps and other similar technologies that will help you with taking your asthma controller medicine on time
- Not participation in this study.
- You may discuss other options available to you with your doctor.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about your child will be collected. This will include information from medical records. Information related to your medical care at CHOP will go in your medical record. Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your child’s personal information private and confidential.

However, we cannot guarantee absolute confidentiality. You or your child's personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep you and your child's identities private in any publication or presentation.

Several people and organizations may review or receive you or your child's identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP;
- Developers at the University of Pennsylvania who will send out textmessages through the Way to Health program;
- Propeller Health who will send out push notification reminders through the Propeller app and track your adherence;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.

By law, CHOP is required to protect your child's health information. The research staff will only allow access to your child's health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your child's health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

The identifiable information from this study will be destroyed 6 years after the study is completed. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done. In the event where you do not respond to the first 4 text or have data recorded and are not randomized, we may use your child's data from the electronic health record at CHOP unless you take back this permission by withdrawing from the study.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your data could be shared for other scientific research.

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institute of Health may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.

The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your child's health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Chén Kenyon
Children's Hospital of Philadelphia
34th Street and Civic Center Blvd
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your child's health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your child's personal health information, you and your child will be withdrawn from the study.

Financial Information

While you are in this study, the cost of your child's usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

The cell phone application for this study will use about 200 megabytes of data over the course of the study. You will also receive text messages throughout the study. You will be responsible for costs associated with running the app and text messaging.

Will you be paid for taking part in this study?

You will receive $20 for each study visit that you complete, with a total possible compensation of $100. You will receive this on a debit card. Your child can earn up to $70 with an opportunity to earn more. If your child is not randomized, they will receive $10 total.

If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

Who is funding this research study?

Children's Hospital of Philadelphia and the National Institutes of Health are providing funding for this study.

What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Kenyon at 267-426-6339. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

A description of this clinical trial will be 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 can search this Web site at any time.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part and to allow your child to take part in this research study, and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share the health information that will be collected for this study, as explained above. If you don't agree to the collection, use, and sharing of health information, you and your child cannot participate in this study.

NOTE: *A foster parent is not legally authorized to consent for a foster child's participation.*

Consent for Child's Participation

Name of Subject	
Name of Authorized Representative	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

Consent for Parent or Legal Guardian's Participation

Name of Adult Participant	
Signature of Adult Participant	Date

Child Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to_____in terms he/she could understand and that he/she freely assented to take part in this study.

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

This study has been explained to me and I agree to take part.

_____ _____
Signature of Subject (optional) Date

For children unable to assent:

I certify that_____was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

_____
Person Responsible for Obtaining Assent

_____ _____
Signature of Person Responsible Date