CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER

INFORMED CONSENT/PARENTAL PERMISSION FOR PARTICIPATION IN A RESEARCH STUDY

STUDY TITLE: Phase 4: Improving Asthma Outcomes By Facilitating Patient-Centered Care At School (Asthma-Free School)

STUDY NUMBER: 2015-6747

FUNDING ORGANIZATION: Luther Foundation and Verizon Foundation

Theresa Guilbert, MD
Name of Principal Investigator

513-636-6771 After office hours, ask the operator to page the Pulmonary Fellow on call.
Telephone Number

ABOUT THIS CONSENT FORM

If you are 18 years and older: This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of this form for your records.

Parents/Guardians: You have the option of having your child or teen join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records.
The word **"you" or "I"** in this form refers to your child/teen.

INTRODUCTION

We are asking you to be in a research study so that we can learn new information that may help others. If you decide not to be in this study, we will still take good care of you. If you decide to be in this study, you may change your mind at any time during the study and you can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to be in the study. You can ask questions at any time.

1. WHY ARE WE DOING THIS RESEARCH?

In this research study we want to learn more about a better way to help treat children with asthma in schools.

We are asking you and other people with asthma to be in the research, because you:

1) Are between the ages of 10 to 17 years old
2) Have a history of asthma diagnosed by your doctor
3) Are attending a participating school

How many people will take part in the study?

About 30 people (children) will participate in this study that is being done by Cincinnati Children's Hospital (CCHMC), your school and the school nurses with the Cincinnati Health Department.

2. WHO IS IN CHARGE OF THE RESEARCH?

Dr. Theresa Guilbert is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that is in charge of this study. CCHMC is being paid by the Luther Foundation and the Verizon Foundation to do this study.

3. WHO SHOULD NOT BE IN THE STUDY

You cannot be in this study if you have any of the following:

- A chronic illness other than asthma or allergies
- Plans to change schools during the school year

The study doctor will review your medical records with the full list of reasons (in addition to those listed above) and decide if you might not be allowed to participate in this study. **The study doctor can remove you from the study at any time if he decides it is in the best interest of you or the study.**

The study doctor may also remove you from the study for any of the following reasons:

- Four or more severe asthma exacerbations as determined by the study doctor during the medical exam at each study visit.

4. WHAT WILL HAPPEN IN THE STUDY?

The research staff will explain each visit to you. You will be able to ask questions to make sure that you understand what will happen.

You will have 2 kinds of visits in this study, a medical visit called a Study Visit and a visit to help keep you motivated called a Self-Management Visit. On all the visits while you are at school we will use a computer to talk to a doctor or motivation team member that is at CCHMC. We might do this computer visit (sometimes called Skyping or telehealth) in your

home, at CCHMC or school. We will try to schedule the school visits at lunch, after school, during a study hall or a non-core class to keep to a minimum the interruption to your school day. We will provide a meal or snack for you to eat during the visits. If you are scheduled for a visit with the school nurse, we may combine the study visit with your school clinic visit.

During this study the asthma doctor will see if your asthma is under control and might change the asthma medicines that you take to help make your asthma better. We will put a cap on the asthma inhalers that will send information through your phone to the study team to tell both you and the asthma doctor how often you use your asthma medicines. To do this, we will give you a phone to use during the research study.

Other things you will be asked to do in this study include:

- You will answer questions about your asthma symptoms at the visits. One of the questionnaires is done on a computer and is called TreatSmart.
- There will be a short medical checkup where the research team member at the school or school nurse will use a stethoscope on your chest so the doctor can listen to your lungs during the computer visit.
- On some visits (Visit 2 and 6), you (the student) will get an e-mail (either to you or through your parent's e-mail address) a few days after the visit to ask you to do an online survey. This will be part of the research and you will need to go through the link in your e-mail to answer the questions. For your parent, they will get an e-mail and be asked to do the online survey after Visit 1 and 6. Every time you complete the survey, you will get $10 added to your ClinCard debit card. Your parent will also get $10 on their ClinCard when they complete their survey.

The research team will not collect any information from your school record. We will ask the school nurse if you have had any asthma visits at the nurse office or clinic.

Because this is a long-term study it is important for us to remain in contact with you for the duration of the study. Therefore, we will ask you to provide some information that will help us find you in case you move or change your phone number (e.g. your demographic information, social security number and/or the names of 2 people who might know where you have moved). Please know that this information will not be shared with anyone without your authorization, and will only be used to allow us to re-contact you in case we lose contact with you during the course of the research.

How long does the study last?

If you qualify and decide you want to be in the study, you will come to your school nurse's office or your school health clinic 12 times over the next 6 to 7 months.

Study timeline:

Visits	Study Visit 1	Study Visit 2	Self Management Visit 1	Study Visit 3	Self Management Visit 2	Self Management Visit 3	Study Visit 4	Self Management Visit 4	Self Management Visit 5	Study Visit 5	Study Visit 6	Study Visit 7
When	Day 1	Week 4	Week 6	Month 2	Month 2	Month 2 1/2	Month 3	Month 3	Month 3 1/2	Month 4	Month 5	Month 6
How long: (about)	1.5 hour	20 min	20 min	20 min	20 min	20 min	20 min	20 min	20 min	20 min	20 min	1 hour

Here is what will happen at each visit:

Study Visit 1- Baseline Visit
This visit could occur at your home, Cincinnati Children's Hospital Medical Center (CCHMC), your school nurse office, or your school-based health clinic.

Before we do anything, we will explain the study to you and your parent or guardian and make sure all your questions are answered. If you agree to be in this study, the consent form and assent form will be signed and then we will start the study visit.

These are the things that will happen during this visit:

- You will be provided with some education about asthma
- You will answer a questionnaire about your asthma medicines
- You will complete an Asthma Control Test (ACT)
- You will be given a smart phone with a data plan so that you can use an app that will monitor your asthma medications while you are in the study.
- If you do not change your asthma medicines at the first visit, a Propeller Health monitoring cap will be placed on your inhalers. This cap sends information to the smart phone app on how often you use your asthma inhalers.
- If you need a change to your asthma medicines, we will arrange to meet with you on a different day for you to pick up your new medicines. The new inhalers will have the Propeller Health monitoring cap on them.

Study Visit 2- Study Visit 7
These visits could occur at your home, school nurse office or your school-based health clinic. Your parent or guardian will not need to be present for these visits.

These are the things that will happen during this visit:
- You will answer a questionnaire about your asthma medicines.
- You will complete an Asthma Control Test (ACT)
- The coordinator will help you complete the TreatSmart program at Visits 6 and 7.
- The study coordinator will go over the information from the Propeller Health monitoring cap. You will be able to look at your inhaler use on the Propeller Health app.
- You will meet with an asthma doctor through the computer and review the TreatSmart recommendations at Visits 6 and 7. The doctor will decide with you if your medicines need to be changed.

Self- Management Visits 1-5
Self-Management visits will start at week 6 and occur every 2 weeks for ten weeks; 5 self-management visits total.

This is what will happen during the adherence visits:
- You will meet with a CCHMC motivational team member (Health Psychologist) to talk about how well you are doing with the study. You will meet with this team member over the computer and the study coordinator will set it up for you.
- The study coordinator will go over the information from the Propeller Health monitoring cap.

5. WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?
We hope that this study will help you feel better or help to control your asthma, but we don't know if it will. When we finish the research, we expect that we will know more about school programs to help children with asthma. This may help other people with asthma later on.

6. WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?
There are minimal risks for participants in this study. You may expect the following possible risks:
- Missed school classroom time. We will try to schedule study visits during your lunch period, after school, or during a study hall period. If we cannot schedule during those times, we might schedule some visits during non-core classes or combine with a planned school clinic visit.
- Asthma Questionnaires: There is small inconvenience of filling out the questionnaires.
- There is a slight risk that someone outside of the study may find out some of your personal information.

There may also be some concerns about the use of the cell phones for this study. We ask that participants use this phone the same as they would use their own cell phone and use this cell phone as their only cell phone during the study. Parents or care givers will be provided with a list of apps installed on the phone and be given information on these apps. Parents or care givers will also receive an instruction sheet on how to use the phone so that they may remove apps if they need to.

There may be other risks that we do not know about yet.

7. WHAT ARE THE REPRODUCTION RISKS?

There are no known risks for pregnancy with this study.

8. WHAT OTHER CHOICES ARE THERE?

Instead of being in this study, you can choose not to be in it.

9. HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE?

Making sure that information about you remains private is important to us. To protect your privacy in this research study:

- We will keep records identifying you in locked areas with access restricted to people who are working on this research study.
- Your study information will be coded with your study ID and not your name.
- The unique code number will be used if we share your research information with anyone outside of the study team. The key to this code will be kept in a locked file or a password-protected computer file in the study team's locked office.
- In the event of any publication regarding this study, there will be no information specific enough to identify you.
- Electronic data is stored on secure networks.

Because this research study involves payment for participation we are required by federal Internal Revenue Service (IRS) rules to collect and use your social security or tax ID number (SSN) in order to track the amount of money that we pay you. Unless you have given specific permission for another use of your SSN related to this research we will only use your SSN to keep track of how much money we pay you and your SSN will not be used as part of this research.

A copy of this consent form will be included in your medical and research record. You will be registered in the Cincinnati Children's Hospital Medical Center's computer system as a research subject.

By signing this consent form you are giving permission for representatives of the Cincinnati Children's Hospital Medical Center ("CCHMC"), the Investigator and CCHMC employees

involved with the research study including the Institutional Review Board and the Office for Research Compliance and Regulatory Affairs, and any sponsoring company or their appointed agent to be allowed to inspect sections of your medical and research records related to this study.

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 study results. You can search this website at any time.

10. WHAT IF WE LEARN NEW INFORMATION DURING THE RESEARCH?

The study doctor will tell you if they find out about new information from this or other studies that may affect your health, safety or willingness to stay in this study.

11. WILL IT COST YOU ANYTHING EXTRA TO BE IN THE RESEARCH STUDY?

There is no cost to you for the phone, data plan, Propeller caps or for medical care received as part of the study visits.
The cost of prescriptions and sick visits will be the responsibility of you and your insurance.

12. WILL YOU BE PAID TO BE IN THIS RESEARCH STUDY?

Reimbursement for participating will be paid on the following schedule:

Visits	Amount
V1	$100
V2	$20
V3	$25
V4	$30
V5	$35
V6	$40
V7	$150

Self Management Only Visits	Amount
1 ½ month Visit	$30
2 month Visit	$30
2 ½ month Visit	$30
3 month Visit	$30
3 ½ month Visit	$30

We will give you your payment in the form of a reloadable debit card (ClinCard) and you will receive a handout that will explain how to use the card. We will provide you with a card and we will load money onto your card after each visit that you complete based on the schedule listed above.

Caregivers will receive $20 for completing questionnaires at the baseline visit.

For the Study Visit 2-7: Participants will get a meal or snack from a local restaurant such as Subway, Chipotle or McDonald's. You may choose an incentive worth approximately $10 OR an additional $10 will be added to your ClinCard if Propeller caps are returned each month to place on new inhalers.

For the Self- Management visits: Participants will get a meal or snack from a local restaurant such as Subway, Chipotle or McDonald's.

For Study Visit 7: Participants will be given the cell phone used in the study to keep but the data plan will be stopped and reset to factory settings.

For Post-Visit Surveys:
There will be $10 onto your ClinCard for each time the Post Visit (online) survey is completed by you.
There will be $10 onto your parent's ClinCard for each time the Post Visit (online) survey is completed by your parent.

13. WHAT HAPPENS IF YOU ARE INJURED FROM BEING IN THIS STUDY?

If you believe that you have been injured as a result of this research you should contact Dr. Theresa Guilbert at 513-636-6771 as soon as possible to discuss the concerns. Treatment for injuries is available at CCHMC. If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in a research study. If possible, you should give them a copy of this consent form.

CCHMC follows a policy of making all decisions about compensation for the medical treatment of physical injuries that happened during or were caused by research on an individual basis.

14. WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document. If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

Request Permission for Future Contact

1. May we contact you for future undetermined studies conducted by Dr. Guilbert or the CCHMC Asthma Center? If yes, we will need to look at your child's Protected Health Information (PHI) in the CCHMC medical records to check for study eligibility.	**___ Yes**	**___ No**
3. May other CCHMC physicians conducting research on asthma or allergies contact you? If yes, your child's PHI may be shared with other physicians.	**___ Yes**	**___ No**

Taking part in future studies is optional. You can ask us at any time to take your child off our contact list.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH
To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?
CCHMC will need to use and share your PHI as part of this study. This PHI will come from:
- Your CCHMC medical records
- Your research records

The types of information that will be used and shared from these records include:
- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your protected health information in this study?
- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?
People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be

required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?
You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?
Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your other medical care be impacted?
By signing this document you are agree to participate in this research study and give permission to CCHMC to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

ABOUT TELEHEALTH VISITS:
This information is about telehealth visits (doctor visits over the computer). You will need to agree to having telehealth visits to be in this study.

1. I am choosing to participate in a Telehealth examination as part of these study visits.
2. I understand that the CCHMC study provider may not have important information that is usually obtained through an in-person physical examination. The physical exam the participant is receiving is limited and provisional (part of this research). The CCHMC study provider may choose to discontinue service at any time if the condition cannot be treated using Telehealth. The study team may recommend an in-person evaluation by another provider.
3. Telehealth videoconferencing technology is currently in use at CCHMC for clinical medical visits that take place at locations outside of CCHMC. Telehealth technology will be used on the study laptop to connect the study coordinator, the participant and for the first visit, the parent/ guardian, with the CCHMC study provider, a lung specialist. The lung specialist will review the asthma symptoms, medication needs, and do a limited physical exam using a stethoscope to listen to the heart and lungs. This will be done while the participant is at home or school. The study Telehealth visits are not the same as a full medical evaluation or an in-person visit with a provider because the participant is not in the same room as the provider. Telehealth technology will also be used for the Adherence/motivational interview visits with the CCHMC Adherence Health Psychology study team investigators.
4. Technical problems are rare. I understand that there is a risk to using the technology, including but not limited to, interruptions, unauthorized access, and other technical difficulties. I understand that the study team can discontinue the Telehealth visit at any time if it is felt that the technology is not adequate. I do not hold CCHMC responsible for technical failures.
5. CCHMC will provide a record of the site where the visit took place in the CCHMC medical record.
6. I understand that others may have access to the participant's healthcare information including the study team and providers, the Cincinnati Public School nurse, and the participant's primary care physician. All involved mentioned individuals are bound to maintain confidentiality of information obtained. The participant will be informed of anyone's presence during a video interaction.
7. I understand that the video and technology used during the study visits are encrypted to protect the participant's privacy.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your consent by signature below.

By signing this form, you have read and agreed to the Telehealth visits that are part of this research study. You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
If research participant is 18 years and older Date
Signature of Research Participant Indicating Consent

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If research participant is younger than 18 years:

_____
Printed Name of Legally Authorized Representative (Parent or Guardian)

_____ _____
Signature of Legally Authorized Representative Date

_____
If signed by a Legally Authorized Representative, a description of such representative's authority must be provided

_____ _____
Signature of Individual Obtaining Consent Date