Title of research study: **Using Technology-Assisted Stepped Care Intervention to Improve Adherence in Adolescents with Asthma**

Investigator: **Rachelle R. Ramsey, Ph.D.**

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Parental Permission/Assent: If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this form, we mean you or your child; "we" means the study doctor and other staff.

Reason for the study:

The main reason for this research study is to learn more about how well an intervention program delivered using technology works to help improve your medication adherence (how often you take your medicine) and your asthma symptoms. We are asking you to be in this study because you have been diagnosed with asthma, are currently taking an inhaled controller medication, and are between the ages of 12 and 18 years. We plan to enroll up to 70 patients in this study.

Procedures:

We expect that you will be in this research study for 6 months. You will be asked to complete 6 study visits that occur monthly via phone. The first visit is in person in which you will complete questionnaires and be randomized to one of two intervention conditions. The first visit will take about 30 to 45 minutes and the remaining visits will each take about 10 to 15 minutes. More detailed information about the study procedures can be found under ***"Detailed Procedures."***

Risks to Participate:

This is a minimal risk study, meaning we do not foresee anything bad happening to you during the study. You may feel uncomfortable answering some of the study questionnaires, but you can refuse to answer them at any time.

As with any research there may be other risks that we do not know about yet.

Benefits to Participate:

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improved adherence to your asthma medication and improved communication about managing asthma treatments. In addition, the

information that researchers hope to learn from this study could allow health care providers and those diagnosed with asthma to have a better understanding of inhaler adherence and treatment management.

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive.

Your alternative to participating in this research study is to not participate.

Cost to Participate:

There are no costs to you for participating in this research study. We are only asking for your time and participation. There is no cost for the Propeller or FindAir sensors (caps), however, data charges may apply when using your own phone or device. In addition, you will continue to be responsible for the usual costs of your medical care.

Payment:

You may receive up to $320 for your time and effort associated with participation in this research study, depending on which study visits you receive. You will receive $50 for the baseline visit, $20 at the end of month 1, $20 at the end of month 2, $25 at the end of month 3, $30 at the end of month 4, $40 at the end of month 5, and $75 at the end of the study. If in the intervention group, participants will be paid $10 a week for syncing their Propeller or FindAir caps in conjunction with the Step 2 texting intervention if indicated, allowing the interventionists to obtain the data needed to complete the intervention. Participants who qualify for behavioral intervention sessions will be paid $15 per session for up to four sessions. Payment will be given in the form of a reloadable debit card (ClinCard) for which you will receive a handout explaining how to use the card. Each family will receive one ClinCard and compensation will be loaded once after each study visit is completed.

Because you (your child) are being paid for your participation, Cincinnati Children's is required by the Internal Revenue Service (IRS) to collect and use your (your child's) social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your child's Social Security number. This form will be given to the Cincinnati Children's business office. It will not be kept as part of your child's study chart. If you move, you will need to complete another W-9 with an updated address.

If I have Questions or would like to know about:

What…	You can call …	At …
• General study questions • Emergencies • Research-related injuries • Any research concerns or complaints	**Krishna Unadkat, M.S.**	Phone: 513-708-0601
• Emergencies • Research-related injuries • Any research concerns or complaints	**Rachelle R. Ramsey, Ph.D.**	Phone: 513-803-8348
• Your child's rights as a research participant	**Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: (513) 636-8039

Detailed Procedures:

At the first visit you will fill out a series of questionnaires and you will receive two trackers that will go on top of your daily and rescue inhaler. The tracker connects to the Propeller Health or FindAir app and records how many times you use your inhaler. Study staff will be able to see how often you are taking your medication through this app. Also, you will be given a mobile spirometer to assess your lung function, which you will be asked to use during the monthly visits over the phone. At this visit, you will also be "randomized" to either the TASC Intervention **OR** the treatment as usual group, which are described below. Randomization means that you will be put into a study group completely by chance, like flipping a coin. You will have an equal chance of being in each condition.

Intervention Assignments:

Both the TASC Intervention group and treatment as usual group will have phone calls with the study coordinator once a month to complete questionnaires and a spirometry test.

Treatment as usual: The treatment as usual condition includes 6 study visits over the phone with the study coordinator each month to complete questionnaires. These visits will each take about 10 minutes.

TASC Intervention: The TASC Intervention condition also includes 6 study visits over the phone with the study coordinator each month to complete questionnaires and 3 possible interventions. After your first month in the study, you will complete questionnaires with the study coordinator over the phone. After your second month in the study, you will complete your next visit over the phone. During this visit you will complete 2 questionnaires and begin using an intervention through an app with educational materials and medication strategies. This visit will take about 10 to 15 minutes. The rest of the monthly visits for the study will be conducted over the phone and will also take approximately 10 to 15 minutes. During these visits we will review your adherence and determine whether you will continue to receive the educational materials or if you will receive the text messaging intervention or the behavioral intervention for the next month. In the text messaging intervention, a study team member will send you brief personalized text messages 1-2 times a week to help you set goals related to your asthma and improve your adherence. The behavioral intervention includes four 20-30 minute sessions via video conference focused on problem solving to improve your adherence with a trained clinician. After each month, study staff will call you to get your feedback on the interventions and have you fill out 2 to 5 questionnaires.

Change of Mind/Study Withdrawal:

You can leave the research at any time; it will not be held against you.

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include abuse of CCHMC device privileges (see cell phone contract).

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

Privacy:

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Data collected from the sensor caps on your inhalers include the time, date, and approximate location of inhaler medication use. Location is determined using latitude/

longitude data collected from your smartphone should those smartphone permissions be enabled.

Samples and/or data collected for or generated from this study could be shared and used for future research. Samples and /or data may be shared with other collaborators at Cincinnati Children's and possibly with outside collaborators, who may be at another institution or for-profit company.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential. In addition, Propeller Health and FindAir have a legal obligation to maintain records regarding complaints and incidents related to their device which includes both the sensor and the application. In the event that you have a complaint or there is an incident related to your device, Propeller Health or FindAir may collect identifiable information regarding the complaint or incident for their records. This information can include your name, contact information, device ID, and information related to the complaint or incident.

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.

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?

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) will need to use and share your PHI as part of this study. This PHI will come from:

- Your Cincinnati Children's 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 Cincinnati Children's)
- 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.
- Propeller Health or FindAir may use your personal identifiable information (PHI) to create aggregated health information and de-identified data to improve their services and for public health.
- The members of the Cincinnati Children's 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.

Will your child's other medical care be impacted?

By signing this document, you / your child agree to participate in this research study and give permission to Cincinnati Children's to use and share you/your child's PHI for the purpose of this research study. If you refuse to sign this document you/your child will not be able to participate in the study. However, you/your child's rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

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/your child should participate in this research, you will document your permission by signature below.

You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent or Assent — Date

_____ _____
Signature of Parent or Legally Authorized Representative* — Date

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* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____
Signature of Individual Obtaining Consent — Date