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INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES  
Connecticut Children's Medical Center

**CCMC Investigator:** PI: Jessica Hollenbach, PhD, AE-C

**Co-Investigators:** Alexander Hogan, MD; Sue Collins, MD; Catherine Wiley, MD.

**Sponsor:** Propeller Health

**Department:** Emergency and Research

**Phone:** (860) 837-5222

**Title of Research:** Feasibility and Acceptability of the Propeller Monitoring System in Children with Persistent Asthma

**In this Consent Form, “you” refers to the participant. If the participant is under the age of 18 years, “you” refers to your child. If you are a legally authorized representative, “you” refers to the participant.**

**Purpose of Research:** Asthma is a condition marked by inflammation and spasms of the breathing tubes of the lungs making it difficult to breath. While asthma cannot be cured, it can be treated with preventive and rescue inhalers. Previous research has shown that patients with asthma often do not use their inhalers as per their doctor's instructions. Propeller Health is a company that has developed the Propeller sensor, which is a sleeve type device that fits over an inhaler and uses Bluetooth connection to the smartphone. The Propeller sensor is used to remind a person with asthma to take their medication. You have been approached due to having persistent asthma and have a history of this breathing condition with a prescribed inhaler to help control it. In this study, we want to see if you like using the Propeller sensor and if you feel it helps keep your asthma under control with the reminders to take the medication (inhaler). The research team plans to enroll 100 participants at Connecticut Children's.

**Funding:** Propeller Health is providing these devices at no cost to Connecticut Children's or to participants in this study.



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**Procedures:** If you decide to take part in this research study, this is what will happen.

1. You and your parent/guardian will complete surveys/questionnaires that evaluate your asthma health and inhaler use during your visit. As part of the study, your medical records will be reviewed to obtain dates when your prescribed medications were filled over the last 6 months. If your medical records are not available to us, you will provide us with your pharmacy's contact information, and we will contact them to obtain these dates.
2. After completion of the surveys/questionnaires, you (but not your parent/guardian) will be given Propeller sensors for both your controller and rescue inhalers, access to the Propeller app for your smartphone (for you and your parent/guardian), and a Propeller subscription, all free of charge. We will help you download the Propeller Health mobile app to your smartphone. The app will run in the background on your phone and may give you a notification if the sensors on your inhalers have not linked to the phone in a while. This will help us collect the data stored on your sensor. You will keep these medication sensors until the end of the study. You will continue to use your inhalers as you normally would.
3. If the sensor has not been connected or synced to the app after receiving it, you or your parent/guardian may be contacted directly by the Support Team at Propeller Health to help with setting up the sensor to the app.
4. During the study, we will make sure the sensors are still working. If it looks like the sensors are not linking to the phone, we may contact you to see if there are any problems with the sensors.
5. As part of this study, your inhaler usage data (date, time) will be captured by a sensor and the Propeller application installed on your smartphone. When using the sensors and the application, the approximate location of your inhaler medication usage will be transferred along with the date and time of your use.
6. You agree to have your pediatrician review your Propeller data with you. You will be given a letter to bring to your pediatrician's office. This will give the pediatrician instructions for how to log on and review your Propeller data.
7. One and three months after being given the Propeller sensors, you and your parent/guardian will be contacted by phone and will again complete surveys/questionnaires; many of these are the same ones you will have completed at the time of enrollment. There will be another questionnaire that asks about your opinions of the Propeller sensor. For completion of the surveys/questionnaires one



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and three months after being given the Propeller sensors, we will need the phone numbers of both you and your parent/guardian. While it would be ideal to have both you and your parent/guardian complete the surveys/questionnaires during a single phone call (where you both would need to be present at that time), we understand that this may not be possible. For this reason, we are requesting that you and your parent/guardian provide your individual phone numbers (if you each have one) as well as the best time to contact should you and your parent/guardian need to complete the surveys/questionnaires separately. Unless you advise us otherwise, we will contact your parent/guardian first for completion of the surveys/questionnaires anticipating that you both will be present at that time.

Your participation in this study will be up to 3 months after you are given the Propeller sensor in order to collect information using the smartphone App as well as for completion of the surveys/questionnaires at the various time points. The surveys/questionnaires at each time point should take you and your parent/guardian approximately 30 minutes to complete.

**Risks and Inconveniences:** While there are no anticipated physical side effects or discomforts with participation in this study, currently unforeseeable risks may exist. Although precautions will be taken, a risk of breach of confidentiality does exist.

- Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:
  - Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research participants like you
  - Propeller Health company or designee will use the information collected to create a separate data set that does not include your name, email address or any information that can identify you attached to it. Anything that can identify you, will be kept private.
- Disclosure of identifiable information in the event of an issue with your Propeller Health device
  - Propeller Health has 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 the device, Propeller Health 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.

There is also the added inconvenience of the small amount of time needed for completing the



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surveys/questionnaires at the various time points. However, our research team and Propeller Health will take all necessary precautions to ensure that your privacy and protected health information remains protected. We ask that you take steps to protect your own confidentiality as well (no password-sharing and using a pass code to access your phone, for example).

**Benefits:** You may directly benefit from participation in this study if the Propeller sensor leads to improvement in your inhaler use and better control of your asthma. Your participation in this study may also provide valuable information on the Propeller sensor which may, in the future, benefit children and adolescents with treatment of asthma.

**Alternative Treatments:** If you do not wish to take part in, the following alternatives are available.

- You can be treated for your asthma using the medications prescribed by your doctor for routine care.
- You do not have to take part in the study at all.

**Voluntariness and Right to Withdraw:** Your decision for participation is voluntary. You may refuse to participate, and you may withdraw your consent or assent and discontinue your enrollment in the study at any time. Your decision whether or not to take part will not affect your future medical care at Connecticut Children's Medical Center or at Community Health Center or any other benefits to which you are entitled.

**Questions:** The Principal Investigator, Dr. Jessica Hollenbach, is willing to answer any questions you may have about the study, or address any concerns, complaints, or other occurrences and may be reached at (860) 837-5333. Future concerns or questions about this study may also be directed to Mrs. Sigrid Almeida and can be reached at (860) 837-5343. If you have questions about your rights as a research subject, or if you would like to discuss problems, concerns, or questions, obtain information, or offer input about a particular research study, you may call the Institutional Review Board Office at Connecticut Children's Medical Center at (860) 545-9980.

**ClinicalTrials.gov:** 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.

**Confidentiality:** To help maintain the confidentiality of your records we will not use any identifiers as part of your unique study identification number. The study identification number will



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be used to link your name and medical record number by a code that only Dr. Hollenbach and her research staff will have access to. The research study database will be password protected. All study related documents will be stored in locked file cabinets.

As part of the study, we will ask your pediatrician to evaluate the data located in the Propeller application and review it with you during your regular visits.

Name and phone number for primary care physician: \_\_\_\_\_

As part of the study, we will review your medical records to obtain dates when your prescribed medications were filled over the last 6 months. If your medical records do not include dates when prescriptions were filled, we will contact your pharmacy for this information.

Name and phone number for pharmacy: \_\_\_\_\_

You may request that your records be released to your personal physician. However, no information that would reveal your identity will be released or published without your permission. The sponsor of the study (Propeller Health) as well as Connecticut Children's Medical Center Institutional Review Board and a research monitor for Connecticut Children's Medical Center may view the study related medical records.

**Economic Considerations:** You will be responsible for any charges associated with your standard of care visits or any other visits associated with your asthma condition. These may be covered by your medical insurance, but you will be responsible for charges associated with these medications or procedures.

There is no cost with the Propeller sensor(s) given to you as part of this research study.

**Compensation:** You will receive a \$10 Target gift card at the time of enrollment. You will receive another \$20 Target gift card for completion of the phone visits at both one and three months after being given the Propeller sensor, but only a \$10 Target gift card for completion of the phone visit at either one or three months after being given the Propeller sensor.



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**In Case of Injury:** If you have an injury or health problem that is directly related to taking part in this study, please contact the Principal Investigator immediately at (860) 837-5222.

Treatment for injuries or health problems related to this study is available at Connecticut Children's Medical Center. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance, unless specified otherwise below. This does not prevent you from seeking payment for injury related to malpractice or negligence. You do not give up any of your legal rights by signing this consent form.

Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

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

**Consent to Take Part in this Research Study:** Based on the information provided, you are indicating that you have had your questions answered and you agree to take part in the research study. For participants that are under the age of 18 years, you confirm that you are legally authorized to consent to your child's participation. Upon signing, you will receive a copy of this form.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Signature of Participant (if 18 years old)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Parent/Legal Guardian/Legally Authorized Representative (if participant is under 18 years old)

\_\_\_\_\_  
Signature of Parent/Legal Guardian/Legally Authorized Representative (if participant is under 18 years old)

\_\_\_\_\_  
Date



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I have fully explained to the parent/guardian or subject if 18 years of age or older, 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.

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Investigator/Person Obtaining Consent

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Date

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Witness (*where required*)

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Date



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### **Assent**

Your doctor and parents have talked to you about being part of a study that includes children and adolescents who have come to Connecticut Children's Medical Center or CHC because your asthma has made it hard to breathe. Because you have a history of this breathing problem and also use an inhaler to help, you can take part in this study so long as you also have a smartphone. This study is looking at a sleeve type device (called the Propeller sensor) that fits over an inhaler and uses Bluetooth connection to a cell phone. The Propeller sensor reminds you to take your medication. In this study, we want to see if you like using the Propeller sensor and if you feel it helps keep your asthma under control with the reminders to take the medication (inhaler).

You are being asked to take part in this study. If you agree to take part in this study, this is what will happen:

1. You and your parent/guardian will complete surveys/questionnaires that evaluate your asthma health and inhaler use.
2. After completion of the surveys/questionnaires, you (but not your parent/guardian) will be given Propeller sensors for your inhalers, an App for your smartphone, and a Propeller subscription.
3. Your doctor review your Propeller data with you. You and your parent/guardian will be given a letter to bring to your doctor's office which has instructions for how to log on and review your Propeller data.
4. One and three months after being given the Propeller sensors, you and your parent/guardian will be contacted by phone and will again complete several surveys/questionnaires; many of these are the same ones you will have completed when you first entered the study. There will be another questionnaire that asks you how you feel about the Propeller sensor.

The researchers in this study do not expect that you will have any physical side effects or discomforts. The researchers will also do everything possible to keep your personal information private.

You may ask questions about this study at any time.

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

Whatever you decide to do, your doctor will not be angry with you and will continue to treat you as his/her patient.

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Participant's Assent

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Date



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Reason why Participant did not sign: \_\_\_\_\_

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**Documentation that Assent Was Sought**

I am satisfied that Dr. \_\_\_\_\_ has discussed these procedures with my child in a manner and to an extent that is appropriate for his/her capacity to understand at the present time. My child has been informed of the procedures that will be performed, the reason for such treatment, and the associated risks. In addition, all of the alternative procedures have been described.

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Parent/Guardian

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Date