Clinical Trials Cover Page
Treatment Phenotypes for Adolescents with Asthma
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Principal Investigator: Heather De Keyser, MD
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Study Title: Treatment Phenotypes For Adolescents With Asthma

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Throughout this document, whenever “you” or “your” is mentioned it is referring to the individual who will be completing the study and/or child.

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don’t understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about asthma and your medication adherence.

You are being asked to be in this research study because you are between the ages of 12-16 years old and have been diagnosed with asthma.

Other people in this study

Up to 130 people from your area will participate in the study.

What happens if I join this study?

If you join the study, you will be asked to place a medication tracker on your asthma controller and quick relief inhaler. We will enroll you in the study during a Telehealth video visit , during a standard of care clinic appointment, or while you are admitted to Children’s Hospital Colorado. After you consent to participate, we will ask you to complete a short survey and enroll you in the Propeller Health system. We will mail you the Propeller Health medication tracking devices before this video visit, or we will bring them to your clinic appointment or inpatient room. We will record how often you use your inhaler to control your asthma, as well as how often you need to use your quick relief inhaler for asthma symptoms. The study team will have access to this information, but we will not be looking at it regularly. Your doctor or provider will not know how often you are using your medications unless you tell them. Therefore, it is very important for you to continue to reach out to your provider if you have any concerns about your child’s asthma, just as you normally would.

You will be asked to download an application (app) to your phone that will allow you to see how often you are taking your medication as well. You will need to sync the sensor to your app on your phone to collect data. We will monitor your use of both of your inhaled asthma medicines for 12 months. The use of this app may have an impact on your phone's data usage.

After the 12 months, you may be asked to do an interview. This may occur over the phone or you can have a remote video interview (like Zoom).. We will record the interviews and transcribe them, but we will take out anything that can identify you from the final transcriptions.

Visit 1	Monitoring Period	Visit 2
Enrollment visit (enrolled at a clinic visit,Telehealth visit, or while admitted to CHCO)	12 months	30 min recorded semi-structured phone or remote video interview within 12 months after the end of the monitoring period
Study procedures: device activation, survey		Study procedures: taped interview
Payment: $50		Payment: $25

Propeller Health (the company that makes the sensors and app) will ask for some information from you to set up the application. This includes your name, your child's name and date of birth, mailing address, email address for you and/or your child, and phone number, as well as the types of medicines that your child takes, and what time they take them.

It is important that you sync your sensor to the app on your phone before disposing of the sensor. This will remove all information from the sensor.

You will be asked to click on "I agree" on the application after reviewing the company's user agreement.

Optional Procedures: Recruitment Database

The investigator would like your permission to include your name, contact information, and research information collected in this study to create a Recruitment Database for future studies.

1. I give my permission for my study doctor to include me in the optional Recruitment Database.

   Yes_____ No _____ _____Initials

   2. I give my permission for my study doctor (or someone he or she chooses) to contact me in the future to ask me to take part in more research.

   Yes_____ No _____ _____Initials

What are the possible discomforts or risks?

Possible risks include:

Discomforts you may experience while in this study include uneasiness when answering the survey questions.

There is a risk that a child under 2 could choke on the devices, so please keep them out of reach of small children.

There is a GPS tracking feature of the device. This means that you or your child's location could be available to the study team. If this is unacceptable to you, you can disable location tracking in your smartphone's settings.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about asthma. This study may help remind you to take your asthma medications.

This study is not designed to treat any illness or to improve your health.

Who is paying for this study?

This research is being sponsored by The National Heart, Lung and Blood Institute

Will I be paid for being in the study?

You will be paid $50 for enrolling into the study. After the 12 months of monitoring, if you are asked to take part in the recorded interview you will be paid $25 after completing the recorded interview.

This will add up to a total of $75.00 if you complete all of the visits.

If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

This study provides payment for participation. Children's Hospital Colorado uses a debit card payment system. Each time you complete the requirements for payment, the cash value will be loaded onto the card. In order to meet requirements of the Internal Revenue Service (IRS), we must report these payments as income. You will be asked to provide your social security or tax identification number to meet these IRS regulations. If by the third payment you have not provided this information, no further payments will be made for study participation.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Heather De Keyser. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. De Keyser at 720-777-4108. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. De Keyser with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on http://www.Clinical Trials.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.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- Children's Hospital Colorado (CHCO)
- Other: Barbara Davis Center

CHCO shares a medical record system with the Barbara Davis Center and PedsConnect; therefore, it is also possible that your information could be viewed by healthcare professionals at these organizations.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information, but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Heather De Keyser, MD
13123 E. 16th Avenue
B395
Aurora, Colorado
80045

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 subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study doctor and the rest of the study team.
- The NIH, who is the company paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- 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 your child will be kept private.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make *all or some* **of the following health information about you collected in this study available to:**

Propeller Health
ResMed, the parent company of Propeller Health

- **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.

- **As part of this study, your inhaler usage data (date, time) and location will be captured by a sensor and the Propeller application installed on your smartphone (unless you turn off location tracking on your smartphone).**

- **Propeller Health is interested in better understanding the management and impact of respiratory disease.** Propeller may use your PHI and "personal identifiable information (PII)" to create aggregated health information and de-identified data to improve our services and for public health purposes and to do academic research.

    - Select employees of Propeller Health and Propeller Health's parent company, ResMed, may have access to data collected during this study.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Your social security number
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, medications, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records

What happens to Data that is collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures: Recruitment Database

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I do not give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name:_____

----------Use the following only if applicable----------

Signature: _____ Date:_____
(Child Subject 13-17 years old; ***In addition*** to Parent Signature)

Print Name:_____

----------Use the following only if applicable----------

A signature of a witness is required for consent of non-reading subjects and consent using a short form.

Witness Signature: _____ Date:_____

Print Name:_____

Witness of Signature ☐
Witness of consent process ☐