MONTEFIORE MEDICAL CENTER
JACOBI MEDICAL CENTER
NORTH CENTRAL BRONX HOSPITAL
FERKAUF GRADUATE SCHOOL OF PSYCHOLOGY OF YESHIVA UNIVERSITY
ALBERT EINSTEIN COLLEGE OF MEDICINE

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child is required. When the word "you(r)" / "my" / "me" / "I" appears in this consent form, we mean the participant (you and/or your child); "we" means the research study doctors and research staff.

Introduction

You are being asked to participate in a research study called Childhood Asthma Perception Study (CAPS)**.** Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." His name is Jonathan Feldman. You can reach Dr. Feldman at:
Ferkauf Graduate School of Psychology of Yeshiva University
Van Etten Room 5C6
1300 Morris Park Avenue
Bronx, New York 10461
646-592-4379
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

Support for this research study is provided by the National Heart, Lung, and Blood Institute

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject, you may contact the IRB office at 718-430-2253 or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Why is this study being done?

The goal of this study is to learn more about asthma management and the ability to perceive asthma symptoms among Latino and Black children and adolescents. Research has shown that asthma is more common in Latino and Black children compared with Caucasian children. The purpose of this study is to test two approaches to see which is more effective in improving the ability of children to recognize asthma symptoms. The information from this study could be potentially very useful in improving the care and management of children with asthma.

Why am I being asked to participate?

You are being asked to participate in this study because you have asthma, have been prescribed controller medication for your asthma, and are either Latino or Black. If you agree to take part in this study, we will ask you some questions about your health.

You will not be eligible to participate if you are unable to read/answer the questionnaires (for example, because of a learning disability) or if you are not Latino and/or Black. You will also not be eligible if you are not prescribed daily medication for asthma or have another lung disease besides asthma (for example, cystic fibrosis).

There will be 260 caregivers and 260 children who take part in this research study at either Jacobi Medical Center, the Van Etten building on the campus of Jacobi Medical Center, or the Clinical Research Center at Einstein and Montefiore.

What will happen if I participate in the study?

-This study will involve 9 visits across 15 months. You will take home an electronic peak flow meter (a device commonly used to monitor asthma symptoms) to use on a daily basis for 13 weeks. You will enter a guess of your peak flow into the electronic peak flow meter before blowing into it. Additionally we will be reviewing your medical records.

- This intervention is not a medical treatment for asthma, and you can continue taking your usual asthma medications that you normally take for asthma.

- However, before each visit, we will ask that you do not take your rescue medication for asthma, such as albuterol, or any foods or drinks that have caffeine (soda) for at least 6 hours before the visit. We will ask that you do not take asthma medications that contain long-acting bronchodilator medication, such as Advair, Symbicort, Dulera, or Serevent, for at least 24 hours before the visit. If you need to take these asthma medications because you are having breathing problems, we will reschedule your appointment time. Due to current COVID-19 related restrictions, all study sessions will be conducted remotely. However, we may ask you to return to the research office when it is safe to do so to complete an in-person breathing test for visits #1, 4, 5, 6, 7, 8, and 9.

A) Visit #1:

- We will provide you information on asthma and its triggers, as well as medications and devices used to treat asthma.
-We will train you to use an electronic peak flow meter and to guess your peak flow.
-We will ask you to complete questionnaires about your health.
-We will attach an electronic device to your inhalers that you use for asthma treatment and to the top of a medication bottle. These devices will keep track of when you take a puff of medication or a pill. They will not change anything about the way the medications work.
-This session will last 1 ¾ hours.

-After this session, you will be asked to use the electronic peak flow meter daily in the morning and evening at home before taking asthma medications and to guess your peak flow. You will not be able to see your peak flow on this electronic peak flow meter.
-We will offer you a second peak flow meter, which can be used at any time when not guessing peak flow.

B) Visit #2: 3 weeks later
-You will be randomly assigned (like the flip of a coin) to one of two groups. In both groups, you will continue to guess your peak flow. The groups will differ in the information they receive on the electronic peak flow meter. One group will receive positive feedback messages encouraging you to use your electronic peak flow meter and the other will receive feedback by being able to see your peak flow.
-We will train you to use the newly programmed device and explain the messages that will now appear.
-You will be asked to continue using the electronic peak flow meter in the morning and evening at home before taking asthma medications and to guess your peak flow values and enter them into the device.
-This session will last approximately 20 minutes.

C) Visit #3: 3 weeks later
- Discussions will take place in both groups concerning your asthma control during the past 3 weeks.
- Both groups will play an online educational game to reinforce asthma-related information.
-This visit will last approximately 45 minutes.

D) Visit #4: 3 weeks later
- Electronic peak flow meters will be reprogrammed and you will continue to guess your peak flow over the next month. Now there will no longer be any messages on the electronic peak flow meter. If you do not return the electronic peak flow meter OR do not use the electronic peak flow meter enough OR do not use the electronic peak flow meter properly, you will receive half of the payment for this session.
- We will continue attaching electronic devices to your medications for asthma.
- We will ask you to complete questionnaires about your health.
- You will be asked to continue using the electronic peak flow meter in the morning and evening at home before taking asthma medications and to guess your peak flow values and enter them into the device.
- This visit will last approximately 1 ½ hours.

E) Visit # 5: 4 weeks later
- Your electronic peak flow meter will be returned at this time.
If you do not return the electronic peak flow meter OR do not use the electronic peak flow meter enough OR do not use the electronic peak flow meter properly, you will receive half of the payment for this session.

- We will continue attaching electronic devices to your medications for asthma.
- We will ask you to complete questionnaires about your health.
- This visit will last approximately 45 minutes.

F) Visits 6-9: every 3 months
-Every 3 months you will be asked to come back for a visit to complete questionnaires, and to continue attaching electronic devices to your medications for asthma; we will also make monthly phone contact in between these visits.

-We will ask you to use the electronic peak flow meter two more times a day over the next year. You may return it by mail using an envelope we will send you with pre-paid postage. If you do not return the electronic peak flow meter OR do not use the electronic peak flow meter enough OR do not use the electronic peak flow meter properly, you will receive half of the payment for these sessions.
-Each visit will last approximately 45 minutes.

Will there be audio and/or video recording?
-Your sessions will be audiotaped.
-Your name will not be used on the recording and you will be identified by a subject number.
-Audiotapes will be listened to by trained project staff. The purpose is to make sure the proper procedures are being followed. All computer files will be stored on password-protected computers in a secured manner, and only include a code in the file name.
-Recordings will be stored for 5 years after the completion of the study and destroyed after that time period.

Will I be paid for being in this research study?
Yes, we will provide financial compensation for your participation to recognize the time and transportation costs involved in the study.

Your family will receive a total of $340 for completing the entire study: $30 for Visit 1, $10 for Visit 2, $20 for visit 3, $50 for Visit 4, and $50 for Visit 5 if you return the electronic peak flow meter and electronic devices that were attached to the asthma medications. You will be paid $30 for Visit 6, $40 for Visit 7, $50 for Visit 8, and $60 for Visit 9. If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed. If you do not return the electronic peak flow meter OR do not use the electronic peak flow meter enough OR do not use the electronic peak flow meter properly, you will receive half of the payment for this session.

When we return to in-person research procedures, you will also be given Metro Cards to reimburse you for your travel expenses.

Will it cost me anything to participate in this study?
There will be no cost to you to participate in the study.

Are there any risks to me?
No

Confidentiality
We will keep your information confidential; however, a risk of taking part in this study is that your confidential information might be shared accidentally with someone who is not on the study team and is not supposed to see or know about your information. This is very unlikely, because the study team takes confidentiality of your information seriously. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information will be kept as long as they are useful for this research.

The only people who can see your research records are:
- the research team and staff who work with them

- the organization that funded the research: National Heart, Lung, and Blood Institute
- organizations and institutions involved in this research: Yeshiva University, Montefiore Medical Center-Albert Einstein College of Medicine, and Ohio State University
- groups that review research: the Einstein IRB and the Office for Human Research Protections

These people who receive your health information may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Are there any times you would not keep my data confidential?
If you give us information that suggests that you your child or any other child is being abused, we are required by law to report that information to the Administration for Children's Services (ACS). Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities.

If you give us information that you may hurt yourself or someone else, we are required by law to report this information and may take steps to protect you. This may involve a member of the research team reporting information of intent to harm to the individual at risk, a family member, the police, and/or other health care providers.

Certificate of Confidentiality
To help protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation for Federally funded projects or for information that must be disclosed in order to meet the requirements of the Federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your Involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Exceptions:
A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent in incidents such as child abuse, and intent to harm yourself or others.

Other Risks
-There are no expected serious risks in this study. The breathing test conducted in our office/clinic for this research study may reveal if you are having significant problems with the functioning of your lungs. If this happens we will inform you of these findings and encourage you to follow your existing asthma management plan.
- It is possible that you might delay seeking medical attention if you mistakenly think this research study is replacing your medical care. Test results from this study will not be part of

your medical record, and information collected at home on peak flow and medication use will not affect your treatment by your health care providers.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. By participating in this study, you may be more likely to recognize asthma symptoms.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed.

Can the study end my participation early?

We will not let you participate in the study anymore if you are unable to perform the required breathing tests after considerable teaching. If the electronic peak flow meter given to you is not used regularly, lost, or damaged upon its return, we may choose to take you out of the study before you complete it. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant (not applicable for participants under age 13)	Date
Printed name of guardian or family member (when applicable)	Signature of guardian or family member (when applicable)	Date
Printed name of the person conducting the consent process	Signature	Date