Study Title: Evaluation of the Asthma Management Program to Promote Activity for Students in Schools (Asthma-PASS)

NCT Number: NCT04576442
IRB Protocol ID: 2019-10930
IRB Approval Date: 05/08/2025

ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT
PARENT/GUARDIAN CONSENT

EVALUATION OF THE ASTHMA MANAGEMENT PROGRAM TO PROMOTE ACTIVITY FOR STUDENTS IN SCHOOLS (ASTHMA-PASS)

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 may be required. When the word "you(r)" / "my" / "me" / "I" appears in this consent form, we mean the participant (you or your child); "we" means the research study doctors and research staff.

Introduction

You are being asked to participate in a research study called "Evaluation of the Asthma management program to Promote Activity for Students in Schools (Asthma-PASS)". 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 started the study. If you say "no," your decision will not affect any of your rights, benefits, or your access to care.

The researcher in charge of this project is called the "Principal Investigator." Her name is Marina Reznik MD, MS. You can reach Dr. Reznik at:
Montefiore Medical Center
111 East 210th Street, Bronx, NY 10467
Telephone #:718-741-2494
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

Montefiore Medical Center is receiving payment from the National Institutes of Health, including the Heart, Lung, and Blood Institute for conducting this research.

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, by e-mail at irb@einstein.yu.edu, 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?

Asthma is an epidemic in the Bronx, NY. Exercise and other forms of physical activity are important for students with asthma and have been linked to fewer symptoms and better quality of life. School children, and especially students with asthma, may not be getting enough exercise. We have identified barriers to physical activity in students with asthma in Bronx schools and developed a program to address these barriers. This study's goal is to improve asthma, exercise, and other forms of physical activity in students with asthma.

Why am I being asked to participate?

You are being asked to participate in this research study because you are a parent/guardian of a child with asthma. There will be approximately 500 children and their caregivers participating

in this study. This study is being conducted in about 60 schools in NYC (primarily in the Bronx) and adjacent neighborhoods (e.g. Yonkers) by Montefiore Medical Center.

What will happen if I participate in the study?

If you choose to participate:

- You and your child will be one of approximately 500 parent/child pairs from about 60 schools who will participate in this study lasting 12 months.
- We will ask you to complete a baseline survey about your child's asthma, asthma medicines, environmental triggers, asthma symptoms with exercise, how much your child exercises, his/her feelings towards exercise, and your family's background. This should take about 60 minutes to complete.
- You will be contacted by telephone approximately 3 months, 6 months, 9 months, and 12 months after today's survey to complete follow-up surveys with you about your child's asthma symptoms and medicines. These surveys will be completed over the phone and should take about 40 minutes to complete. If we are not able to reach you on the phone numbers you have provided, we will ask your child's school if they have updated phone numbers for you, as well as ask your child's doctor for updated contact information.
- While assessments will be completed within 12 months, we may contact all participants again within 5 years to collect additional outcome measures about your child's asthma symptoms, medications, and visits to the doctor.

• Your child's school will be selected randomly (like by a flip of a coin) to receive either Program A or Program B.

– Program A includes:
  - A school-wide asthma awareness week.
  - An asthma workshop for the school staff.
  - Collaboration with your child's doctor to make sure that your child is receiving appropriate medications based on how severe their asthma is and if they have symptoms with exercise, as well as, ensure a Medication Administration Form (MAF 504) is filed with the school.
  - A community health worker who will follow up with your child's doctor as needed, work with pharmacies to have medication delivered to schools and homes, provide two 20-minute asthma educational lessons, 3-4 weeks apart, with your child, and speak with you after each lesson to highlight key points reviewed with your child, and answer any questions you may have.
  - A community health worker will be there to assist you with scheduling visits with your child's physician, link to care if needed, troubleshoot medication-related issues, and refer to community resources (for example, for smoking cessation and pest control).

– Program B includes:
  - Notification of your child's doctor about your child's asthma severity and the need to re-evaluate the asthma treatment plan.
  - A community health worker will also provide two general asthma education sessions for your child and speak with you after each session to review key points from the child's asthma education sessions and answer any questions you may have.

• Regardless if your child's school is selected to receive Program A or Program B, all participating students will be asked to wear a small physical activity monitor on their waist for seven consecutive days (one week) at four different times during the one-year study period (at

baseline, 3 months, 6 months and 9 months). This monitor records all movements the person makes during a week, and this information is later transferred to a computer. These monitors have been used before in children, they are light, about the size of a beeper, and do not interfere with people's daily activities. We will ask you to help your child record the time he/she puts the monitor on in the morning, the time he/she takes it off at night, and what kind of physical activity he/she participated in each day that week. You and your child will be given instructions on how to use the monitor. This monitor must be returned to the research staff after 7 days. If there is not enough data recorded on the monitor, we may ask your child to wear it for 1-2 extra days.

Information Banking (Future Use and Storage)

We will destroy the information about you when the study is complete.

Will I be paid for being in this research study?

To thank you for participating, you will receive $20 after the initial survey is completed today. You will receive $15 after finishing each of the 3, 6, and 9 months follow-up telephone surveys. After completion of the final 12-month telephone survey, you will receive $35 for completing this study. These payments will be placed on a ClinCard after completion of each survey. The ClinCard, produced by Greenphire, is an automated, reloadable payment card which can be used like a credit card for in-store and online purchases, or cash advances. If you choose to withdraw from the study before all surveys are completed, you will be paid only for the surveys you completed.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

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?

There is a potential risk that there will be a loss of privacy if the information collected were to be released. You may refuse to answer any questions for any reason and may also choose to withdraw from the study at any time.

Confidentiality

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.

Are there any times you would not keep my data confidential?

If you give us information that suggests that 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 hurt someone else, we can break confidentiality and refer you to someone who can help you.

Certificate of Confidentiality

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, 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.

Are there possible benefits to me?

The possible benefits of taking part in this study include improved care and management of your child's asthma and his/her asthma symptoms may improve, which may lead to your child participating in more physical activities.

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 child's care by his/her doctor. However, some of the information may have already been entered into the study and that will not be removed.

To revoke (take back) your consent, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and she will stop collecting new information about you. If you take back your consent, you will not be allowed to continue to participate in this research study.

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 providing a verbal consent. I will be given a copy of this consent form.

_____

Printed Name of Parent or Guardian participant

_____	_____	_____
Printed name of the person conducting the consent process	Signature	Date