

Official Title:	Aligning with Schools to Help Manage Asthma (Project ASTHMA)
NCT number:	NCT03032744
Document Type:	Parent Informed Consent
Date of the Document:	7/19/18



University at Buffalo Institutional Review Board (UBIRB)

Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Parent Permission for a Child to Participate in a Research Study

Project ASTHMA – Aligning with Schools To Help Manage Asthma

Version Date: 7-19-18

Investigator: Dr. Lucy Holmes

Why is my being invited to take part in a research study?

Your child is being invited to take part in a research study because he/she is 4-14 years old and has been diagnosed with asthma for at least 1 year.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not your child takes part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt your child, talk to the research team at 716-323-0034. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu

if:

- You have questions about your child’s rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.



Why is this research being done?

This research project is being done to find out if there are new ways we can help children with frequent asthma symptoms to have fewer symptoms and feel better.

Asthma is the most common chronic disease in children and adolescents. Children with asthma may not be able to do all of the activities that their friends can do, miss days of school, and have asthma attacks that require them to use their rescue inhaler, visit the emergency department (ED) for care, take oral steroids, and in some serious cases, be hospitalized.

Children with frequent asthma symptoms need to take medicine every day to prevent asthma attacks, also known as a controller medication. We know that remembering to take controller medications every day can be hard and not everyone remembers to take every dose of their medication all the time. Although forgetting to take their controller medicine is common, this can result in more asthma attacks in the child.

There are two different ways your child's asthma can be managed. Your child's asthma can be managed by his/her primary care provider alone, or can be managed with the assistance of the provider in the school-based health center. We want to know which way of managing asthma results in less asthma symptoms. In addition, we want to know if children who take all their preventive asthma medications at home, or children who receive some of their preventive asthma medication at school, have less asthma symptoms and less asthma attacks that require steroids.

How long will the research last?

We expect that your child will be in this research study for the remainder of the school year, from today until school ends in June.

Today's visit should take about an hour. We will call you in 1, 3, and 5 months to ask how your child's asthma is doing. At the same time we will ask your child how he/she feels his/her asthma is doing, and perform another spirometry (breathing test) on your child in the school-based health center. We ask that you return to the school-based health center in 7 months from now so we can ask you similar questions about your child's asthma. This final visit will last about 30 minutes.

How many people will be studied?

We expect about 40 students will be in this research study; 20 in the primary care provider group and 20 in the school-based health center group.

What happens if I say yes, I want my child to be in this research?

You are here today because you told us you were interested in your child taking part in this research study. Before you can start, a member of the research team will talk to you about the study. If you decide to allow your child to be in this study, you will sign this form.

The first study visit you are here for today is called an enrollment visit. We will confirm that your child meets the eligibility criteria to participate in the research study. This visit should take about 1 hour to complete. First, we will do an assessment of your child's asthma, just like your doctor would do if he/she went to the doctor's office to talk about his/her asthma. We will ask you some questions about you and your child. We will ask you questions about your child's asthma, including what

Permission to Take Part in a Human Research Study

Page 4 of 12

medication he/she currently takes for his/her asthma, how often he/she takes his/her asthma medication, and how often he/she has asthma symptoms. We will ask questions on how your child's asthma affects your and your child's quality of life. During this visit, we will also go over when and how your child should take all of his/her medicine.

Next, if your child is 6 years old or older, we will ask your child to do a breathing test called a spirometry test. For this test, your child will blow into a breathing machine to see how well his/her lungs work. Based on the frequency of your child's asthma symptoms and the spirometry test, if done, we will decide if the asthma medicine your child is using is working well enough, or if your child needs a different medicine to help his/her lungs work better. The most common names of the medicines we will recommend will be Flovent, Advair, or Symbicort. If your insurance does not cover one of these medications, we may also recommend other, similar medications, including Alvesco, ArmonAir, Asmanex, Pulmicort, Qvar, AirDuo, or Dulera. We may or may not recommend the same medicine your primary doctor prescribed for you in the past. Knowing about your child's symptoms and the results of their breathing test will help us understand how severe your child's asthma is based on the national guidelines.

Sometimes, students are not able to do the spirometry test correctly on their first try. If this happens today, we will not repeat the test until the 1 month follow-up. If this happens to your child at any of the follow-up visits, we will may ask him/her to come back to the school clinic another day to try the test again. You do not have to come with your child when he/she does the spirometry test again. We will try up to 3 separate days to get an interpretable spirometry test at the follow-up visits.

This study is designed for children who have persistent asthma, based on the national guidelines for asthma severity. After we complete the asthma assessment for your child, we will tell you about your child's asthma and we will send a letter to your child's doctor to tell him/her the results of your child's asthma assessment.

If your child meets the eligibility requirements, he/she will be assigned to one of two groups: the primary care provider group, or the school-based health center group. The group he/she is put in will be chosen by chance, like flipping a coin. Neither you nor the research team can choose which group your child is put into. You will have an equal chance of being in either group. We can tell you which group your child is in after he/she has completed his/her asthma assessment, including the spirometry test.

Primary Care Provider group:

If your child is in the primary care provider group, we will give your child's doctor the results of your child's asthma assessment and ask your doctor to take care of your child's asthma as usual. You should continue to see your doctor as usual, and keep giving your child all of his/her asthma medications at home as prescribed by your child's doctor. You will need to pick up your child's medications from the pharmacy as usual.

In about 1, 3 and 5 months from today, we will call you to ask you how your child's asthma is doing. We will ask your child how he/she feels his/her asthma is doing as well as perform another spirometry test in the school-based health center.

In about 7 months from today, we will ask you to come back to the school-based health center for a final asthma assessment as well as a spirometry test for your child.

School-Based Health Center group:

If your child is in the school-based health center group, the researchers will decide what controller medicine your child should use to help his/her asthma based on your child's asthma assessment. The school nurse practitioner will order the controller medication for your child and the research coordinator or you will deliver this medication to school. You will need to pick up from your pharmacy or the school the controller medication you use at home. We will let your child's doctor know about your child's participation in this study, the results of your child's asthma assessment, and the name and dosage of the controller medication he/she will be put on.

On school days we will ask your child to come to the nurse's office in the morning and take the morning dose of his/her asthma controller medication. You will still be responsible for giving the evening dose and both doses on non-school days of the controller medication.

In about 1, 3 and 5 months from today, we will call you to ask you how your child's asthma is doing. We will ask your child how he/she feels his/her asthma is doing as well as perform another spirometry test in the school-based health center. This will help us to know how your child's asthma is doing, and determine if he/she needs any changes to his/her asthma medication. In about 7 months from today, we will ask you to come back to the school clinic for a final asthma assessment as well as spirometry test for your child. Each follow-up visit should take about 30 minutes for your child.

Study Visit	Time (minutes)	Location	Eligible for the study (persistent asthma)	
			Primary Care Provider Care Group	School-Based Health Center Group
Initial Visit	60	School clinic	✓	✓
1 Month Follow-up Visit	10 30	Parent–phone call Student–School clinic	✓	✓
3 Month Follow-up Visit	10 30	Parent–phone call Student –School clinic	✓	✓
5 Month Follow-up Visit	10 30	Parent–phone call Student –School clinic	✓	✓
Final Follow-up Visit (7 months)	30	School clinic	✓	✓

Permission to Take Part in a Human Research Study

Page 6 of 12

Regardless of which group your child is in, we want to let his/her regular doctor know about his/her participation in the study, and the results of your child's asthma assessment. We may also ask your child's doctor some questions about your child's asthma history.

In order to do this, we must know who your child's doctor is. Please provide information about your child's primary care doctor in the spaces provided below:

Child's Primary Care Doctor:

Doctor's Name: _____

Practice Name: _____

Phone Number: _____

Parent Signature: _____

Some children with asthma also see another doctor, usually an Allergy & Immunology Specialist, or a Pulmonologist (Lung Specialist), for their asthma treatment. If your child sees a specialist for their asthma, we want to let his/her specialist know about his/her participation in the study, and the results of your child's asthma assessment. We may also ask your child's specialist doctor some questions about your child's asthma history.

In order to do this, we must know who your child's asthma specialist is. If your child does see a specialist for his/her asthma, please provide information about your child's asthma specialist in the spaces provided below:

Child's Asthma Specialist:

Not applicable, my child does not see a specialist for his/her asthma

Asthma Specialist's Name: _____

Specialty: _____

Practice Name: _____

Phone Number: _____

Parent Signature: _____

Children with asthma sometimes miss school because of their asthma. We would like to know if being in our study changes the number of days your child misses school. The Buffalo Public Schools have agreed to tell us how many days of school your child missed last year (2017-2018) and the number of

days of school your children missed this year (2018-2019), so that we can see if they missed more or less school days while they were in this research study than when they were not.

What are my / my child's responsibilities if I agree for my child to take part in this research?

If you decide to let your child take part in this research, you will be responsible to answer, by phone, questions about your child's asthma in about 1, 3 and 5 months from today. You will also be responsible to come to the school-based health center for your child's final asthma assessment in 7 months.

If your child is in the school-based health center group, your child will be responsible for going to the nurses' office in the morning to get the morning dose of his/her controller medication.

For both groups, you should continue to give your child his/her asthma medication as prescribed:

- 1) Primary Care Provider group: if your child is in the primary care provider group, you should continue to give him/her all of the doses of his/her controller medication at home as prescribed by his/her doctor.
- 2) School-Based Health Center group: if your child is in this group, he/she will get his/her morning dose of his/her controller medication at school on school days. You should continue to give your child his/her controller medication at home every night on school days, and twice a day on all non-school days.

We will also ask you to let us know if your child moves to another school during the school year. If your child is in the primary care provider group, we will still ask him/her to come for all his/her follow-up asthma assessments in about 1, 3, 5, and 7 months from now, at his/her original school at the time of enrollment.

If your child is in the school-based health center group, and he/she moves to another school that is participating in the research study, your child can continue in this group at the new school. If your child moves to a school that is not participating in the study, then he/she cannot be in the study any more.

What happens if I do not want my child to be in this research?

You and your child's participation in this research study is voluntary. You may choose not to enroll your child in this study. Instead of being in this research study, you can continue to see your child's doctor for all of his/her asthma care.

What happens if I say yes, but I change my mind later?

Your child can leave the research study at any time and this will not be held against you or your child.

If you decide to leave the research study, contact the research coordinator so that we can let your child's doctor know that your child is no longer in the study. You should keep going to your regular doctor to take care of your asthma.

If you stop being in the research study, data that has already been collected may not be removed from the study database. You will be asked whether the investigator can still collect follow-up data about

Permission to Take Part in a Human Research Study

Page 8 of 12

your child's asthma from his/her medical records. If you agree, this data will be treated the same as research data.

If we are unable to contact you for any of the follow-up visits, we will continue to review your child's medical records to collect data about your child's asthma.

Is there any way being in this study could be bad for my child?

There are minimal risks associated with participating in this research study.

Students who have a spirometry test must breathe hard and fast into the machine for 3 to 6 seconds. Most students experience no discomfort from performing this test. A small number of students may experience shortness of breath for a few minutes after the test.

During this study, we will collect private, identifiable health information about your child. Special precautions are taken to ensure that the information is protected. However, there is always a very small risk of loss of confidentiality during unanticipated situations. We will do everything we can to make sure that the data is protected.

Taking part in this research study may lead to added costs to you for transportation to and from your child's school for the study visits. However, we will provide payment for your visits to help cover these costs.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. This includes any co-pays for the medications. There will be no charge for your child's asthma assessments and spirometry tests since these are being performed for study purposes.

There may be risks that we do not know about at this time. We will notify you of any new information that may affect your willingness to continue your child's participation in this study.

Will being in this study help my child in any way?

We cannot promise any benefits to you or your child from taking part in this research study. However, it is possible that the spirometry test will help us learn more about how severe your child's asthma is than we would have known without doing the test. It is also possible that by participating in the study your child will have less asthma symptoms as well as improved asthma outcomes such as less asthma exacerbations, ED visits, and hospitalizations.

We cannot promise any benefits to others from your child taking part in this research. However, we hope that the information learned from this study will help us better understand the best way to improve asthma outcomes within a population with known difficulties with health care access.

What happens to the information collected for the research?

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

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.

Permission to Take Part in a Human Research Study

Page 9 of 12

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Can my child be removed from the research without my OK?

The principal investigator of the study can remove your child from the research study without your approval. Possible reasons for removal include: if your child's doctor does not want him/her to be in the research study, or if your child moves to a new school that is not participating in Project ASTHMA.

What else do I need to know?

If you need medical care because of taking part in this research study, contact the investigator and your child's primary doctor. Generally, this care will be billed to you, your insurance, or other third party. The University at Buffalo has no program to pay for medical care for research-related injury.

If you agree to take part in this research study, we will pay you for your time and effort. All parents/guardians of study participants will receive a \$30 gift card for completing today's visit. Parents/guardian will receive another \$30 gift card at the final 7 month follow-up visit.

Study Visit	Not eligible for the study today	Eligible for the study today (persistent asthma)	
		Primary Care Provider Group	School-based Health Center Group
1 (Initial Visit)	\$30	\$30	\$30
2 (7 Month Final Visit)	X	\$30	\$30
Total	\$30	\$60	\$60

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about your child and your child's health that will be obtained by the researchers when he/she participates in the research study. Health information is considered "protected health information" when it may directly identify your child as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about your child as part of this research study?

- ✓ Information from your child's full medical records that is related to his/her asthma such as the medications your child is currently taking, how often you filled a prescription for a preventive asthma medication, the number of times your child was in the hospital for asthma, the school medication logs, etc.

- New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.
- Insurance provider claims data to determine medication compliance and health care utilization.

B. Who is authorized to provide or collect this information?

- KALEIDA Health, Buffalo NY
- Catholic Health, Buffalo NY
- University Pediatric Associates, Buffalo, NY
- Principal Investigator or designee
- Your child's Primary Care Doctor (as listed in the space provided, above)
- Your child's Asthma Specialist (as listed in the space provided, above, if applicable)
- Your child's insurance provider
- Your child's pharmacy

C. With whom may my child's protected health information be shared?

Your child's health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

- Clinical staff not involved in this research study who may become involved in your child's care if it is potentially relevant to your treatment
- Your child's Primary Care Doctor (as listed in the space provided, above)
- Your child's Asthma Specialist (as listed in the space provided, above, if applicable)
- Your child's insurance provider: if your child's insurance provider requires a prior authorization to release 3 inhalers at 1 time so your child will have enough medicine for home and school use for 3 months, we will have to tell your child's insurance provider that you will be getting the medication at school and at home.

Your child's information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your child's information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your child's individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your child's protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

- ✓ This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about your child unless you revoke this authorization in writing.
- ✓ Your child's protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about your child will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Dr. Lucy Holmes
1001 Main Street, 5th Floor
Buffalo, NY 14203

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care your child receives at this institution and will not cause any penalty or loss of benefits to which your child is otherwise entitled. If you decide not to sign this authorization, your child will not be able to participate in the research study.

Permission to Take Part in a Human Research Study

Page 12 of 12

Signature Block for Parental Permission

Your signature documents your permission for the named child to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

Printed name of parent or individual legally authorized to consent to the child's general medical care

- Parent
- Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Assent Process

- Child is birth-6 yrs. old - Assent is not required
- Child is 7-17 yrs. old – A separate Assent Document is to be signed by the child
- Assent will be obtained Verbally
- Assent has been waived by the IRB

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent

Date

Printed name of person obtaining consent