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University at Buffalo
The State University of New York
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

Assent of a 14-17 year old to Participate in a Research Study

Project ASTHMA – Aligning with Schools To Help Manage Asthma

Version Date: 6-26-18

Investigator: Dr. Lucy Holmes

Why am I being invited to take part in a research study?

You are being invited to take part in this research study because you are 14 years old and have 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 you take 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 you, 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 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.

There are two different ways your asthma can be managed. Your asthma can be managed by your 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 you will be in this research study for the remainder of the school year, from today until school ends in June.

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 to be in this research?

You are here today because you told us you were interested in 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 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 you meet 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 asthma, just like your doctor would do if you went to the doctor's office to talk about your asthma. We will ask you some questions about you & your parents. We will ask you questions about your asthma, including what medication you currently take for your asthma, how often you take your asthma medication, and how often you have asthma symptoms. We will ask questions on how your asthma affects your quality of life. During this visit, we will also go over when and how you should take all of your medicine.

Next, we will ask you to do a breathing test called a spirometry test. For this test, you will blow into a breathing machine to see how well your lungs work. Based on the frequency of your asthma symptoms and the spirometry test, if done, we will decide if the asthma medicine you are using is working well enough, or if you need a different medicine to help your 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 symptoms and the results of your spirometry test will help us understand how severe your 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 you at any of the follow-up visits, we will may ask you to come back to the school clinic another day to try the test again. Your parents do not have to come with you when you do 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 students who have persistent asthma, based on the national guidelines for asthma severity. After we complete the asthma assessment for you, we will tell you about your asthma and we will send a letter to your doctor to tell him/her the results of your asthma assessment.

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

Primary Care Provider group:
If you are in the primary care provider group, we will give your doctor the results of your asthma assessment and ask your doctor to take care of your asthma as usual. You should continue to see your doctor as usual, and keep taking all of your asthma medications at home as prescribed by your doctor. You will need to pick up your medication from the pharmacy as usual.

In about 1, 3 and 5 months from today, we will call your parent to ask you how your asthma is doing. We will also ask you how you feel your 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.

School-Based Health Center group:
If you are in the school-based health center group, the researchers will decide what controller medicine you should use to help your asthma based on your asthma assessment. The school nurse practitioner will order the controller medication for you and the research coordinator or your parent 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 doctor know about your participation in this study, the results of your asthma assessment, and the name and dosage of the controller medication you will be put on.

On school days we will ask you to come to the nurse's office in the morning and take the morning dose of your asthma controller medication. You will still be responsible for taking 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 your parent to ask you how your asthma is doing. We will also ask you how you feel your asthma is doing as well as perform another spirometry test in the school-based health center. This will help us to know how your asthma is doing, and determine if you need any changes to your asthma medication. In about 7 months from today, we will ask you and your parent to come back to the school clinic for a final asthma assessment as well as spirometry test for you. Each follow-up visit should take about 30 minutes for you.

Study Visit	Time (minutes)	Location	Eligible for the study (persistent asthma)	
			Primary Care Provider 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	✓	✓

We will also ask the school how many days of school you missed last year (2016-2017) and this year (2017-2018) to see if you were absent more or less days while you were in the study.

What are my responsibilities if I agree to take part in this research?

If you decide to take part in this research, you will be responsible to come to the school clinic for your follow-up asthma assessments.

If you are in the school-based health center group, you will be responsible for going to the nurses' office in the morning to get the morning dose of your controller medication.

For both groups, you should continue to take your asthma medication as prescribed:

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

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

Your participation in this research study is voluntary. You may choose not to enroll in this study. Instead of being in this research study, you can continue to see your doctor for all of your asthma care.

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

You can leave the research at any time and this will not be held against you.

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

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

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.

Will being in this study help me in any way?

We cannot promise any benefits to you from taking part in this research study. However, it is possible that the spirometry test will help us learn more about how severe your asthma is than we would have known without doing the test. It is also possible that by participating in the study you 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 you 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 heath care access.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your 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.

Can I be removed from the research without my OK?

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

What else do I need to know?

If you agree to take part in this research study, we will pay your parent/guardian for his/her time and effort. Your parent/guardian will receive a $30 gift card for completing today's visit. Your parent/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

Signature Block for Assent of Child

Your signature documents your permission 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.

Signature of subject _____ Date _____

Printed name of subject _____

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 _____

IRB Approval Period