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University at Buffalo Institutional Review Board (UBIRB)

Office of Research Compliance | Clinical and Translational Research Center Room 5018
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Project ASTHMA – Aligning with Schools To Help Manage Asthma

Assent to be in a Research Study - (for Children 7-13 yrs of age)

Version date: 6-26-18

Who are we?

My name is _____ and I am part of the Project ASTHMA research team at the University of Buffalo.

Why are we meeting with you?

We want to tell you about a study that involves children like yourself who have asthma. We want to ask if you would like to be in this study.

Why are we doing this study?

We are doing this study to see if children with asthma have less asthma symptoms when they get all their asthma medication at home or get the morning dose of their preventive asthma medication at school.

What will happen to you if you are in the study?

Before you can start, someone from the research team will talk to you about the study. If you decide to be in this research study, we will ask you and your parents about your asthma to see how you are doing. Then, we will do a breathing test called a spirometry test. For this test you blow into a breathing machine to see how well your lungs work. Based on how often you have asthma symptoms and the results of your breathing test, we will decide what is the best medicine & dose 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.

If you still want to be in this study, you will be put into one of two groups. A computer will decide by chance (like flipping a coin), which group you will be in. When we do research, we use two groups to help us know if what we are doing is making a difference.

If you are in the primary care provider group, we will tell your doctor what we think about your asthma and ask him/her to take care of your asthma just like he/she usually would. You should keep using your asthma medications at home just like your doctor tells you to. In about 1, 3, 5 and 7 months from today, we will ask you to come back to the school clinic to ask you questions about your asthma and do the breathing test again.

If you are in the school-based health center group, on school days we will ask you to come to the nurse's office in the morning and take the morning dose of your controller asthma medication at school. We will ask you to come back to the school clinic to tell us about your asthma and do the breathing test again in about 1, 3, 5 and 7 months from now.



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What are the good things and bad things that may happen to you if you are in the study?

Every person who is in this research study will get the spirometry breathing test which helps us better understand how your lungs are working and helps make sure you are on the right medication to make your asthma better. This may mean that you feel better and have less problems with your asthma. If we are watching your asthma more closely, or we know you are getting your medication every day in school, it is possible that your asthma will get better.

You may feel a little short of breath after doing the breathing test but if this happens it will only last a few minutes.

Do you have to be in the study?

No you don't. No one will get angry or upset with you if you don't want to do this. Just tell us if you don't want to be in the study. And remember, you can change your mind later if you decide you don't want to be in the study anymore.

Do you have any questions?

You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study. You can call:

Dr. Lucy Holmes
716-323-0034

Now take your time and think if you want to be in the study. Signing your name below means that you agree to be in this study.

I will be in this study No, I don't want to do this

Signature Block for Assent of Child

Your signature documents your permission to take part in this 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