

Person in Charge of the Study: Stanley Szeffler,
MD COMIRB No: 20-0883
Version Date: February 14, 2023

Assent Form for: Reducing Asthma Attacks in Disadvantaged School Children with Asthma

What is this study about?

This study is being done to learn the best way for schools to help children with asthma.

Why are you asking me?

We are asking you to be involved in the study because you are an elementary student with asthma.

What Do I Have to Do or What Will Happen to Me?

At the beginning of the study, you will be randomly assigned (like a flip of coin) to one of three groups:

- Group 1 – you will receive the usual asthma care from your school nurse and your health care provider. If at the end of your first year in the study, your asthma is not under good control (such as you miss school because of asthma, you have a hard time breathing playing sports or during recess most of the time, or have to go to the ER or hospital for asthma) then you will either join group 2 or group 3 for the next school year.
- Group 2 - you will answer questions about your asthma, meet with your Asthma Navigator 3 times during the school year to learn about asthma and how to manage it so you can do the activities you want to do, and get help with things that can make it harder to control your asthma.
- Group 3 - you will do the same things described in group 2, but your Asthma Navigator will work with your school nurse, health care providers and community partners/organizations to get additional help.

If you are in Group 1 at the end of your first year, it is likely that you will be moved to Group 2 or 3 for the next year.

If you start out in Group 2 or 3, there is a chance that you may change groups. For instance, you could move to Group 1 if your asthma control is good. If your asthma has not changed, you would stay in your first group, Group 2 or Group 3.

This study will happen over four years in elementary schools. If you join the study in year 1, you can participate in this study for up to 4 years. If you leave your elementary school, a study team member will contact your family once a year to see how you and your asthma are doing.

Being in this study means that you will be asked questions about your asthma. If you don't want to answer them, you don't have to. You don't have to answer any questions

that you don't want to, and you can stop the visit or being in the study at any time, just tell your school nurse or your family or the Asthma Navigator.

Will this Hurt?

Answering questions can sometimes be uncomfortable and/or boring.

Can I ask Questions?

You can ask any questions that you have about the study or your asthma now or at any time. You can ask the Asthma Navigator, your school nurse, or your family. If you have a question for the person leading the study, you can call Dr. Szefler at 720-777-0985 to get your question answered.

Do I Have to Do This?

You do not have to be in this study. No one will be mad at you if you say no. You can choose to stop at any time. Just tell the researcher if you want to stop.

Do you want to be in the study at this time? (Check one box)

☐ Yes ☐ No

You will get a copy of this form to keep.

Child's Signature: _____ **Date:** _____

Child's Printed Name: _____

Consent form explained by: _____
(Print name)

I have explained the research at a level that is understandable by the child and believe that the child understands what is expected during this study.

Signature of Person Obtaining Assent: _____

Date: _____