Consent form for protocol # 20-0883

Version date: March 29, 2023

(Submitted for IRB review and approved on June 9, 2023 – the delay in dates is simply because the consent was not needed yet so it was submitted with the next amendment)

IRB approval date: June 9, 2023

Principal investigator: Stanley Szefler, MD

Consent and Authorization Form

Principal Investigator: Stanley Szefler, MD COMIRB
No: 20-0883
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Study Title: Reducing Asthma Attacks in Disadvantaged School Children with Asthma

You and your child are being asked to be in a research study. because the child with asthma has poorly controlled asthma and is more at-risk to miss school and need medical care for worsening asthma or a flare-up in the future. This form provides you with information about the study. "You" as used in this consent form means "you" or "your child" if you are consenting on behalf of your child. A member of the team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?
Asthma is one of our nation's most common and costly conditions. In children, asthma is a leading cause of missed school days and urgent health services use. The purpose of this study is to help students, families, health care providers and school personnel improve asthma management through a comprehensive asthma education, case management and care coordination program that also addresses common barriers to successful asthma management and control.

You are being asked to be in this research study because you are either a child with asthma between the ages of 5-12 years old or you are a parent/caregiver of a child with asthma between 5-12 years old participating in this research.

Other people in this study
Up to 500 students and their parents/caregivers from various Colorado schools will participate in this study.

What happens if I join this study?
If you join the study, you will be assigned to one of three groups. The group you will be assigned to depends on what school you/your child attends. You will not know which group you were assigned. Schools/school nurses were randomly assigned to one of the three groups. Random means that the research/study team or schools were not involved in the decision of which schools received what grouping and that each had an equal chance of being assigned to Group 1, Group 2 or Group 3. See Figure 1: Group Assignment for Study below for more detail.

Study-related activities will include completing the Colorado Department of Education's Asthma Intake Form, surveys, interviews, education and practicing proper technique of asthma inhaler. This study does not involve any physical exams, painful procedures or drug administration. Some online study visits may be audio recorded for quality purposes that you can ask to stop recording at any time or decline the recording initially. Prior to recording the session you will be informed and asked for your permission to record. If you do not want the session recorded just inform the team member or asthma navigator leading the session and it will not be recorded. All study-related activities will be conducted by trained study team members and asthma navigators.

While you participate in this study, some information may be shared with your school nurse and your primary care provider, and asthma specialist, if you have one.

Group 1 – Usual Practice Asthma Care in Schools Comparison:

Participants in Group 1 will complete/answer questions from the Colorado Department of Education's Asthma Intake Form at the beginning and end of the school year and will receive usual asthma care in schools.

- At the end of the year, if the asthma is still not under good control, you/your child will be placed or re-assigned into a group that receives more intense care, support and education in your second year of study involvement. Re-assignment could occur to Group 2 or Group 3. See below additional details.

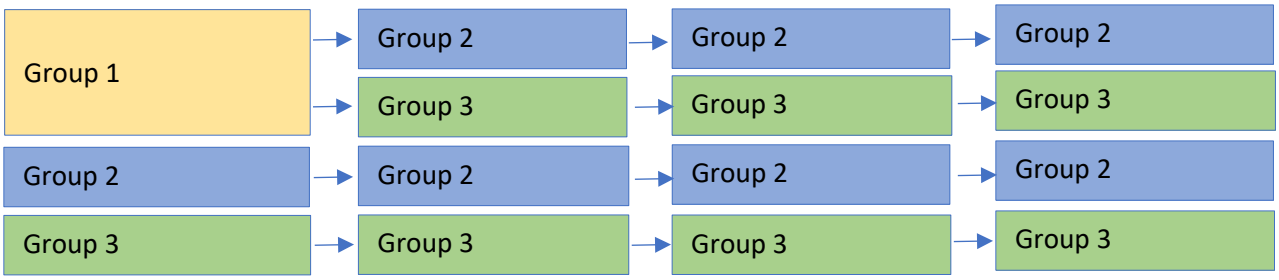
Group 2 – Better Asthma Control for Kids (BACK) - Standard (BACK-S):

Participants in Group 2 will complete/answer questions from the Colorado Department of Education's Asthma Intake Form at the beginning and end of the school year and will complete at least 3 visits with an Asthma Navigator for both your child with asthma and you. During these visits, an Asthma Navigator will complete an asthma assessment questionnaire and a child's physical activity questionnaire, assess and discuss social determinants of health challenges (access to meds and a health care provider, transportation, food insecurity), provide asthma education including accurate inhaler technique, and will send your primary care provider a follow-up letter regarding the visit. Separate visits by the Asthma Navigator will be provided to the parent/guardian/caregiver and the child with asthma. Visits for the child with asthma will occur at school. Visits for parent/guardian/caregiver can occur by phone, zoom or in person at the school, given the best format for parent/guardian/caregiver.

Group 3 – Better Asthma Control for Kids (BACK)- Expanded (BACK-E):

Group 3 will complete all of the items explained in Group 2. In addition, Group 3, will include additional strategies to engage the school and community in the program.

This study will occur over four years, 2023-2027. Refer to Figure 1: Group Assignment for Study for a layout of group assignment.



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 subsequent 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 child's asthma control is good. If your child's asthma has not changed you would stay in Group 2 or Group 3 as you were assigned.

As mentioned, 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 things are going for your family and your child's asthma.

What are the possible discomforts or risks?
Discomforts you may experience while in this study related to the above activities:

Asthma/physical activity Questionnaires: Other than the inconvenience associated with completing the questionnaires, we do not expect any risks or discomfort to be involved. Asthma control may change over time and that is why regular monitoring is important.

Social Determinants of Health Screening Tool: Five questions will be asked to parent/guardian/caregiver about things that can make it hard to take care of your child's asthma. We will try to find community resources to help you with needs that you identify.

Asthma Navigator visits: The visits may bring inconvenience and will require a minimum of 3 hours of your time and 1 hour of your child's time. These visits are meant to provide you with understanding of asthma and skills for better asthma control.

Information may not stay confidential: As part of the project, we will share and work with your school and health providers to provide effective asthma management to achieve asthma control. There is a risk that people outside of the study team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed. All records (paper and electronic) will be kept in a secure area and only study personnel will have access to the records. Computerized/electronic data will be password protected with double authentication and with access limited to the study personnel. On

paper forms (except the informed consent and informed assent) and electronic study records you/your child will be identified by a code, and no personal information from your records will be released without your written permission. You will not be identified in any reports, presentations or publications.

What are the possible benefits of the study?
This study is designed for the study team to learn more about the best ways to improve asthma care within a school system that involves children and their families, school teams and health care providers.

If you agree to take part in this study, there may or may not be direct benefits to you. The expected benefit of this study is improved asthma control and asthma management through your gained skills and understanding so that there is a decrease in the number of asthma worsenings or flare-ups, urgent health care use and school absences due to asthma. Additional benefits include improved asthma awareness in schools, free asthma education for children and their families, and improved asthma care at school by close communication between the family, school and health care provider.

Are there alternative treatments?
There may be other ways of managing asthma. These other ways include receiving the standard of care for children with asthma offered at your school or health care clinic. You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave/quit this study and still have these other choices available to you. The care provided by your school nurse or health care provider will not be impacted if you decide not to participate.

Who is paying for this study?
This study is being funded by the National Heart, Lung and Blood Institute of the National Institute of Health (NIH).

Will I be paid for being in the study?
Parents/guardians/caregivers will be paid a $20 gift card per visit for keeping records about your child's asthma symptoms and emergency doctor's visits. Parents/guardians/caregivers can indicate whether they prefer a physical or electronic gift card and chose between Walmart or Amazon. An electronic gift card will be emailed or sent via text message to their phone. A physical gift card will be mailed using USPS. Your family will receive an asthma tool kit (spacers for home and school, educational materials, swag bag at a retail value of $50.00). Additionally, small incentives will be provided during school visits with children, such as school supplies and healthy snacks.

If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits completed.

Will I have to pay for anything?
It will not cost you anything to be in the study.

Is my participation voluntary?
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you don't take part or decide to withdraw/stop later, you will not lose any benefits or rights to which you are entitled. If you quit or leave the study or decide not to participate, we encourage you to talk to a study team member so that they understand your decisions and reasons. This could be important and suggest possible areas for the study team to improve. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them. If you leave this study, you will still receive your normal care at school and health care clinics. The only care that you will lose is the asthma care you are getting as part of this study. You might be able to get that same kind of care outside of the study. Talk to the study doctor, Dr. Stanley Szefler, (contact information provided below) if you have concerns or questions about this.

Can I be removed from this study?
The study doctor may decide to stop your participation without your permission if there are repeated missed visits, poor response to communications (email, texting, phone calls), or the lack of completion of forms, or for any other reason. Also, the funding sponsor (National Institute of Health) may stop the study at any time due to discontinued funding for the project or other important reasons.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Stanley Szefler, immediately. His phone number is 720-777-0985.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?
You may contact Dr. Stanley Szefler, the contacting primary researcher running this study to answer your questions or discuss concerns. You may ask any questions you have now or questions, concerns, or complaints you have later. Dr. Szefler can be reached at 720-777-0985. You will be given a copy of this form to keep for your records.

You may have questions about your rights as someone taking part in this research study. You can call Dr. Szefler with questions. You can also call the responsible Institutional Research Review Board (COMIRB) at 303-724-1055.

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. This Web site will not include information that can identify you. The Web site will include a summary of the study design and results. No identifying information will be included. You can search this website at any time.

Being placed on a recruitment list for future studies:

We may be doing other studies in the future and would like to make a list of people who are interested in doing more studies. Please indicate below if you would or would not like to be included on a list of people interested in future asthma studies conducted through the University of Colorado | Anschutz Medical Center, Children's Hospital of Colorado or National Jewish Health. If you decide now that we can keep your name on a list, you can change your mind at any time and be removed from the list. If you change your mind, contact Dr. Stanley Szefler and he will remove your name from the list.

Initial next to your choice:

I would like to be included on a list of people who will be contacted about

future asthma studies._____Initials

I would **not** like to be included on a list of people who will be contacted about future

asthma studies._____Initials

Certificate of Confidentiality:
This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Who will see my research information?
The University of Colorado Denver (UCD) | Anschutz Medical Campus and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) and the Federal Educational Rights and Privacy Act (FERPA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- Children's Hospital Colorado (CHCO)
- National Jewish Health
- Your health care provider

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Stanley Szefler, MD Children's Hospital
Colorado 13123 E. 16th Ave. B518
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- Officers at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- The National Heart, Lung and Blood Institute, who is the agency paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private and out of the reports.

You have the right to request access to your personal information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Research/study Visits and Assessment/questionnaire records

Release of Information

To support better communication about asthma care for my child, I understand that my asthma navigator, school nurse/school health team and health care providers treating my child's asthma will share information about my child's asthma control and factors related to asthma control. For transparency, I will receive copies of all written communications shared by the navigator and school with my child's healthcare team.

What happens to Data that is collected in this study?
Researchers at the University of Colorado Denver | Anschutz Medical Campus UCD|AMC) and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study is important to this study and to future research. If you join this study:

- The data given by you to research team for this research will no longer belong to you.
- Both the researchers and any sponsor of this research may study/review/examine the data collected from you.
- If data is in a form that identifies you, UCD|AMC or the hospitals involved in this study may use them for future research only with your consent or Institutional

Review Board (IRB) approval.

- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures –
In this form, you were given the option to agree to additional, optional research procedures (such as visits and completion of assessment questions). You must also give us your permission, under HIPAA rules, to use and disclose/share the information collected from these optional procedures, as described above, to your health care providers.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. If I choose to be in this study, I will get a signed and dated copy of this consent form.

Child's Name: _____ _____

First Middle Initial Last Date of birth

Parent/Guardian Consent for Child's Participation:

I consent to allow my child to participate in this study.

_____ _____
Parent/Guardian Signature Date

Print Name: _____ _____
Relationship to Participant: ☐ **Mother** ☐**Father** ☐**Guardian** Time

Consent form explained by

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

_____ _____
Signature Date
Title: ☐ Principal Investigator ☐ Sub Investigator ☐ Research Coordinator

Print Name: _____ _____
Time