Parental Permission and Authorization Document

for Minimal Risk Research

BACKGROUND

Your child is being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you will allow your child to take part in this research study.

This study is called ED-Initiated School-based Asthma Medication Supervision (ED-SAMS). Children with asthma are often prescribed daily inhaled corticosteroids (ICS) for their asthma. Sometimes it is hard for families to get ICS and to supervise the child who is taking the medication. The purpose of this study is to see if children who are prescribed daily ICS for their asthma will have fewer asthma symptoms and increased ability to take ICS daily if the ICS is provided to the child's school and if daily ICS use is supervised by the school. We will enroll about 90 children with asthma who are 6-12 years of age at three centers in the United States. About 30 children will be enrolled locally.

The study is being paid for by the National Heart, Lung, and Blood Institute.

STUDY PROCEDURES

You and your child are being asked to participate in ED-SAMS because your child is currently being treated in the emergency department (ED) for symptoms of an asthma attack. You are being asked to read this consent form and ask any questions you have about the study. If you agree for your child to participate in the study you will be asked to sign this consent form. We will also explain the study to your child and ask your child if they want to be in the study, if your child is the age of assent If you both agree, the following will take place.

All of your child's usual emergency room care, including all tests, procedures, and treatments needed to make your child's breathing better before sending your child home will be completed before you begin the study.

There are two groups in this study: the ED-dispensing with home supervision group and the ED-dispensing and school supervision group. Before your child is discharged home, he or she will be randomized (like flipping a coin) into one of the two groups. Your child has an equal chance of being in either group. Your child's emergency room doctor or research study staff will not know ahead of time into which group your child will be enrolled.

If your child is in the ED-dispensing group (visit will take about 1 hour):

1) Your child will be given:

a. Oral prednisolone based on body weight to achieve a daily dose of 2mg/kg/day not to exceed 40 mg per day for 5 days or its equivalent (provided in the emergency department).

b. 360 µg of budesonide inhalation powder once-daily for at home use (ICS), and

c. albuterol sulfate inhaler as needed for relief of acute respiratory symptoms for at home use.

d. Parents will be instructed to supervise their child's ICS at-home.

2) You and your child will receive general asthma education including specific training on how to use the inhalers.

3) You will be advised and/or scheduled to complete a follow-up visit with your child's healthcare provider within 7 days of ED discharge.

4) Your child's healthcare provider will be notified of your child's participation in the study and your child's assigned medications. You will receive a letter to take to your child's follow-up visit.

5) As the parent/guardian, you will be asked to complete 4phone interviews (about 20 minutes each) over the next four months (at 30, 60, 90 and 120 days after your child's randomization). We will ask you about your child's asthma symptoms, health care utilization, medication use, and satisfaction with the program during the past four weeks. We will also send a text message survey once daily for 7 days, after each of the first three phone interviews. The text message survey will consist of one multiple-choice question and require about 2-3 minutes of your time.

If your child is in the ED-dispensing with home and school supervision group (visit will take about 1 hour)**:**

1. Your child will be given:

   a. Oral prednisolone based on body weight to achieve a daily dose of 2mg/kg/day not to exceed 40 mg per day for 5 days or its equivalent (provided in the emergency department),

   b. 360 µg of budesonide inhalation powder once-daily for at home use (ICS), and

   c. albuterol sulfate inhaler as needed for relief of acute respiratory symptoms for at home use.

   d. Parents will be instructed to supervise their child'sICS at-home use only on weekends, holidays, and school absences.

2. We will send a budesonide inhaler and an albuterol sulfate inhaler to your child's school health office within 5 business days after ED discharge. School health staff will supervise your child's use of once-daily ICS each school day. You will still need to make sure your child takes the ICS on non-school days.

3. You will be advised and/or scheduled to complete a follow-up visit with your child's healthcare provider within 7 days of ED discharge.
4. Your child's healthcare provider will be notified of your child's participation in the study and your child's assigned medications. You will receive a letter to take to your child's follow-up visit.
5. You and your child will receive general asthma education including specific training on how to use the inhalers.
6. As the parent/guardian, you will be asked to complete 4 phone interview (about 20 minutes each) over the next four months (at 30, 60, 90 and 120 days after your child's randomization). We will ask you about your child's asthma symptoms, health care utilization, medication use, and satisfaction with the program during the past four weeks. We will also send a text message survey once daily for 7 days after each of the first three phone calls. The text message survey will consist of one multiple-choice question and require about 2-3 minutes of your time.

If you give permission for you and your child to take part in this research study, you and your child's total participation in the study will last for about 120 days (four months).

RISKS

The known risks to your child for participating in this study are described below. The primary risks are related to the asthma medications. These risks are a part of standard medical care for asthma. Children in this study will likely have used albuterol and ICS previously. Should your child have an adverse event, we will follow up with you until the event resolves or refer you to your primary care practitioner.

Privacy

There is a potential risk of loss of your child's confidentiality (privacy). However, we will reduce this risk to the greatest degree possible by insuring only persons working with the study see your child's information.

Questionnaires

You may feel discomfort when answering study questionnaires, completing phone calls or completing the text message surveys. You do not have to answer any question that they do not want to answer. If they feel upset by any experience, you can tell the research staff, and they will tell you about resources available to help.

The asthma medications have possible side effects, which are detailed below

Medications

The primary risk from the inhaled corticosteroid is a yeast infection in the mouth, commonly known as thrush. Other adverse events with a ≥1% occurrence reported by patients include colds, sore throat, nasal congestion, sinusitis (sinus infection), headache, nausea, upset stomach, voice changes, back pain, fever, indigestion, and ear infections. Rare instances of glaucoma, increased pressure inside the eye,

and cataracts have also been reported with long-term use. Studies have also shown that inhaled corticosteroids may cause a reduction in the rate of growth in children. The potential for growth effects of prolonged treatment should be weighed against the clinical benefits obtained and the risks and benefits associated with alternative therapies. Growth should be monitored in children who receive corticosteroids.

Albuterol can cause jitteriness and dizziness after administration. It can also raise the heart rate.

Rare side effects of ICS include: immediate and delayed hypersensitivity reactions including a red, itchy rash, hives, swelling of the face and lips, and difficulty breathing, symptoms of hypocorticism (extreme fatigue, weight loss, abdominal pain), and hypercorticism (weight gain, easy bruising of the skin); psychiatrics symptoms including depression, aggressive reactions, irritability, anxiety, and psychosis.

BENEFITS

We cannot promise any benefits to your child from being in the ED-SAMS study. However, your child may benefit from education provided in the ED, increased monitoring of symptoms, and increased communication with your child's healthcare provider.

ALTERNATIVE PROCEDURES

You may choose for your child not to participate in this study. If you do not want your child to participate, there are other options that include, discharge to home as planned with regular asthma care.

PERSON TO CONTACT

If you have questions, complaints, or concerns about this study, you can contact *<<insert name>> at <<insert phone number>>.* If you think your child may have been harmed from being in this study, please call <<insert name>> at <<insert phone number>>. <<Insert name>> can be reached at this number during <<specify hours or state it is a number available 24-hours a day>>.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your child's rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION

You and your child's participation in ED-SAMS is completely voluntary. Research studies include only people who choose to take part. You can tell us that you don't want your child to be in this study. Your child can start the study and then choose to stop the study later. This will not affect your relationship with the investigator. There will not be any penalty or loss of benefits if you choose not to participate.

COSTS AND COMPENSATION TO PARTICIPANTS
There are no costs to you or your child for participating in the study, other than your time.

You will receive $40 for each parent follow-up interview (telephone call) and $1 for each text answered during the week after the first three telephone interviews. A total of $10 if all texts are answered. The parent follow-up interview will begin approximately one month after enrollment and will continue monthly for a total of 4 months. Total compensation is $190 if you complete all of the phone calls and text messages.

NEW INFORMATION
If any new information is developed during your child's participation in the study that might affect your willingness to participate, you will be informed by the study doctor.

AUTHORIZATION FOR USE OF YOUR CHILD'S PROTECTED HEALTH INFORMATION
Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your child's health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like name, address, telephone number, email address, and your child's school information.
- We may need your social security number to make payments to you for completing the parent follow-up interviews and the text message survey. You do not have to provide your SSN but then we may not be able to pay you.
- Related medical information about your child's asthma like family history of asthma, allergies, and/or current and past asthma medications or treatments.
- All tests and procedures that will be done while participating in the study.
- We will ask your child's school health office for information about their asthma medication administration.

How we will protect and share your child's information:

- We will do everything we can to keep your child's information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information *will not* be stored with other information in your child's medical record. We may also need to disclose information if required by law.

- However, if you disclose information that gives study staff a reason to believe that a child has been subjected to abuse or neglect, study staff will report that information to Child Protective Services or the nearest law enforcement agency as required by law.

- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
    - Members of the research team and their support staff at the University of Utah Data Coordinating Center;
    - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
    - Other academic research centers we are working with <<<remove your institution>>>:
        - The University of Arizona, ED-SAMS Clinical Coordinating Center
        - The University of Oklahoma and affiliated health center
        - The University of Wisconsin and affiliated health center
        - George Washington University and affiliated health center
    - The study sponsor: The National Heart, Lung, and Blood Institute;

- If we share your child's identifying information with groups outside of <<insert appropriate institution>>, they may not be required to follow the same federal privacy laws that we follow. They may also share your child's information again with others not described in this form.

- The research staff will only allow access to your child's health information to the groups listed above. By signing this document, you are authorizing the <<insert appropriate institution>> to use/release your child's health information for this research. They may be allowed to share it with others not described in this form.

- If you do not want us to use information about your child's health, your child should not be part of this research. If you choose not to participate, your child can still receive health care services at *<< insert appropriate institution>>*.

What if I decide to Not Participate after I sign the Consent and Authorization Form?
You can tell us anytime that you do not want your child to be in this study and do not want us to use your child's health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about your child, and your child will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your child's health care. However, your child's information from this study will not be available during the study; it will be available after the study is finished.

CONSENT

I confirm that I have read this parental permission document and have had the opportunity to ask questions. I will be given a signed copy of the parental permission form to keep.

I agree to allow my child to participate in this research study and authorize you to use and disclose health information about my child for this study, as you have explained in this document.

Signature of Parent/Guardian as Participant

_____ _____
Parent/Guardian's Signature Date

Parental/Guardian Permission

_____
Child's Name - printed

_____ _____ ❑ Parent ❑ Legal Guardian
Parent/Guardian's Name – printed Relationship to Child

_____ _____
Parent/Guardian's Signature Date

Person Who Obtained Consent

_____
Name of Person Obtaining Consent - printed

_____ _____
Signature of Person Obtaining Consent Date

This section to be completed by RESEARCH STAFF (Person Obtaining Consent)

Time of consent: _____ ❑ AM *or* ❑ PM