

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO (UCSF)**ASSENT TO BE IN A RESEARCH STUDY
ABOUT ASTHMA****For children 7-11 years old****Why are we meeting with you?**

We want to tell you about something we are doing called a research study. A research study is when doctors collect a lot of information to learn more about something. Dr. Michael Cabana and some other doctors are doing a study to learn more about children with asthma. We are asking you to be in this research study because you had at least 1 bad asthma attack in the past year.

After we tell you about it, we will ask if you'd like to be in this study or not.

Why are we doing this study?

Most people with asthma use an action plan to guide their asthma treatment. Written asthma action plans are usually color-coded. "Green" means that asthma symptoms are well controlled. "Yellow" means that asthma symptoms are not well controlled and asthma treatment may need to change. "Red" means a severe worsening of symptoms. Red zone treatment is usually an oral corticosteroid like prednisone.

The study will compare the good and bad effects of two treatments which would either increase asthma medication or keep the medication the same when you are having asthma symptoms (in the yellow zone).

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

If you want to be in the study, this is what will happen:

You will be asked to come to 8 visits at UCSF and participant in 6 telephone calls. The study will last for a year.

The visits can take 30 minutes to 2.5 hours depending on what needs to be completed at the visit.

During the visits the following things may happen:

- Read and sign this form
- Answer questions about your asthma and your health
- Have a check-up by a study doctor who will prescribe medicines for you to take.
- Be checked to see how tall you are.
- Do the breathing test called spirometry. To do this test, you will wear a nose clip and blow hard into machine.
- Do a different breathing test called a methacholine test. The methacholine test will find out if you have asthma and how 'twitchy' your airways are. During a methacholine test, you inhale a mist. If you have asthma, the mist will cause your lungs to squeeze down

and it might feel like you are having asthma symptoms. If you have asthma symptoms, the study staff will give you medicine called albuterol (like the medicine you use from your 'rescue' inhaler) to make the symptoms go away quickly. A study doctor will be in the clinic in case you have any problems.

- Be shown how to use an electronic diary (e-diary) to record how you are feeling
- Be shown how to use an electronic peak flow meter to measure how well your lungs are working when at home
- Give a urine sample to see if you are pregnant (only for girls who have started having periods). You cannot participate if you are pregnant. The study doctor will inform you, depending on your age, or your caretaker of any positive pregnancy test results.
- We will also give you albuterol and wait 15 minutes and do spirometry again.
- Give a blood sample. Blood will be taken from a vein in your arm. All of the blood can usually be collected with one poke.
- Learn how to take study medications.

There are also things you will need to do at home.

If you qualify, you will start doing tasks at home every morning and evening. These include:

- Answering questions in your electronic diary
- Measuring your lung function using your peak flow meter

Will this study hurt?

You might have some side effects and discomfort while in the study. Your study doctor will check on you and try to help you feel better if you feel pain.

- When we take blood from your arm, the needle might hurt and you might get a bruise. This pain will go away quickly.
- The questions we ask you as part of the study might seem strange and might make you feel sad or embarrassed. If you don't want to, you don't have to answer these questions.
- The breathing tests might cause coughing, wheezing, trouble breathing, or might make you feel dizzy. If you have these problems, the study doctor will be there to help.
- The medicines might cause problems like losing your voice, an infection in the mouth or your growth to slow down. They could also make your heart beat fast or you might feel shaky, cause you to feel sick to your stomach, or even have trouble sleeping.

Will you get better if you are in this study?

We do not know if being in this study will help you to feel better. We hope to learn something that could help other people in the future who have asthma.

Do you have any questions?

You can ask questions any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else.

Do you have to be in this study?

You do not have to be in this study if you don't want to. Your doctor may be able to give you other treatments to help your asthma outside of the study.

If you join the study and then change your mind, it is okay for you to leave the study. If you want to be in this study, just tell us.

The doctor will give you a copy of this form to keep.

What about my privacy?

We will do everything possible to make sure that your medical records are kept private. Some or all of the research results may be included in your medical records.

Unless required by law, only people from certain groups or organizations can review your study records. The people that see this information are all required to keep your personal information private.

We will not give your answers to specific questions to anyone outside the study unless we are worried about your safety or the safety of someone else. If we learn something important about your health, we will tell your parent or legal guardian about that.

Also, if your parent or legal guardian has given permission, information about your asthma and treatment will be sent to the doctor who was treating your asthma before the study. This will happen after each study visit and when the study is complete.

Will you receive any payment or gifts if you are in the study?

Yes. For each visit you finish your parents will get paid a certain amount based on your time and effort. This includes attending the visit, as well as doing your home procedures every morning and evening, and remembering to bring your study medications and e-diary to the visit.

SIGNATURE OF PERSON CONDUCTING ASSENT DISCUSSION

I have explained the study to _____ (*print name of child here*) in language he/she can understand, and the child has agreed to be in the study.

Signature of Person Conducting Assent Discussion

Date

Name of Person Conducting Assent Discussion (*print*)