

## ADOLESCENT ASSENT FORM FOR YOUTH AGES 12-17

Version November 2014

Your parent has given permission for you to be in a project called a research study. But first, we want to tell you all about it so you can decide if you want to be in it. If you don't understand, please ask questions. You can choose to be in the study, not be in the study or take more time to decide.

### What is the name of the study?

Long-Acting Beta Agonist Step Down Study (LASST)

### Who is in charge of the study?

The doctor in charge of the study is Dr. Kathryn Blake.

### What is the study about?

We would like to find out what is the best way to decrease the amount of asthma medicine that people with asthma take and still be well controlled.

### Why are you asking me to be in this study?

You are being asked to be in the study because you are between the ages of 12 and 17, have asthma that is well controlled and you are on a combination of medications called inhaled corticosteroids (ICS) and long-acting beta agonists (LABA).

### What will happen to me in the study?

If you decide to be in the study, here is what will happen:

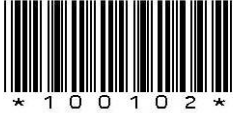
- You will be in the study for up to 56 weeks (13 months) and come to the clinic for 11 scheduled visits.
- You will take study medication two times each day and write down that you took it. The study medication will either be Advair or Flovent. Neither you, your parents, the nurses, nor the study doctors will know which medication you are taking.
- You will blow in to a tube called a Peak Flow Meter every morning and write down the number.
- You will write down some additional information about how you are feeling and any other medicines you are taking for asthma each day.
- You will come in for visits about once every 4 to 6 weeks. The nurse will ask you lots of questions about your health and asthma. You will be asked if you smoke, about your menstrual periods (girls only), and if you are on birth control (girls only), but you will be asked this privately.
- You will have some tests done to check how you breathe. You will take deep breaths in and blow out hard and fast through a tube. You will be given albuterol.
- A doctor will listen to your heart, your lungs, and check your stomach, eyes, and throat. This will be done at the start and end of the study and at 2 follow up visits.
- You will complete forms that ask you lots of questions about your asthma and how you feel.
- You will pee in a cup two times (for girls only).
- You will also have some blood taken for tests using a needle one time. If requested, a numbing cream can be used to help ease the pain associated with the blood draw.
- You have to come see the study doctor when told to. You need to tell the study doctor or nurse if you do not feel well or if anything is wrong. You also need to tell them about any other medicines you are taking.
- Your information and leftover samples of blood will be saved and might be used in future research about other diseases related to asthma and allergy.



Approved by the Nemours IRB:

Valid from: 09/04/2015 through 09/03/2016

IRB# JAX: 288148



Abbreviated Study Title: LASST

There are often some risks to people who take part in research studies. The main risks that you would face by taking part in this study are:

- There might be side effects of the study medication that we don't know yet. If you feel different during the study please let your parent and the study staff know. You could have a rare allergic reaction.
- Drawing blood may hurt when the needle is first put in your skin. Sometimes you may feel dizzy or you may get a bruise.
- Some of the breathing tests may leave you light-headed or tired. Albuterol could also make you feel shaky.
- You might feel embarrassed and bored by some of the questions and procedures.

Taking part in this research may also cause some good things to happen to you. The medicine may help you have less asthma symptoms and you may feel better knowing that this study may help others. You will also get a peak flow meter to use during the study. This device will help you keep closer track of your asthma. You can keep it after the study is over.

**Information for girls who have started having periods or might begin having periods during the study.**

We do not know if the research procedures (such as drugs or tests) could hurt an unborn baby. For this reason, you should not become pregnant while you are in this study. If you are having sex, you should use effective birth control to prevent pregnancy. The study doctor may talk to you about effective methods of birth control.

Girls can sometimes become pregnant even when using birth control. For this reason, we will be doing pregnancy tests. We will tell you the results of any pregnancy test that is done during the study. By law, you have a right to confidentiality when talking about pregnancy and birth control with a doctor. This information will be shared with your parents only if you agree.

You should tell the study doctors immediately if you think that you might be pregnant during the study. Anyone who is pregnant may be taken out of the study. If this happens, other people may realize that you are pregnant. We encourage open honest communication between children and their parents about sexual activity and possible pregnancy.

**Will I be paid to be in this study?**

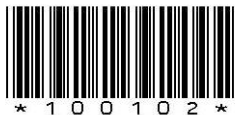
You will be paid for being in this study. You will be paid up to \$825 for completing all the study visits. You will receive payments for each visit except for the phone visit. If you decide that you should leave the study before finishing all visits, you will be paid for the parts you have completed. We also offer the opportunity for students to earn community service hours for participating in this study; our staff will be pleased to complete the required paperwork.



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**Do I have to be in the study?**

You don't have to do the study if you don't want to. If you are in the study, you can stop being in it at any time. Nobody will be upset with you if you don't want to be in the study or if you want to stop being in the study. The doctors and nurses will take care of you as they have in the past. If you have any questions or don't like what is happening, please tell the doctor or nurse.

You have had the study explained to you. You have been given a chance to ask questions. By writing your name below, you are saying that you want to be in the study.

\_\_\_\_\_  
Name of Adolescent (**Print**)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Adolescent

\_\_\_\_\_  
Name of Person Obtaining Assent (**Print**)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Person Obtaining Assent