

## **ASSENT STATEMENT FOR CHILDREN AND ADOLESCENTS**

If you want to talk to the study doctor by yourself please ask. This form may contain words you do not understand. Please ask the study doctor or staff to explain anything you do not understand.

### **What is this research study about?**

You are being asked to be in a research study. This research study will test a medicine that may help your breathing called XXXXXXXX using the XXXXX. Inside the device is XXXXXXXX.

### **What will happen during the study?**

If you want to be in this study, you will come to the study doctor's office a total of 6 times. The study doctor will check on how you are doing at each visit. Also during the visit, vital signs (blood pressure, pulse, and respirations) will be taken. There will be some blood drawn and the study doctor will arrange for you to have an electrocardiogram (ECG-tracing of electrical activity of the heart). You will also do a number of breathing tests into a machine called a spirometer.

Between visits, you and your parent(s)/guardian will be asked to keep track of your medications including asthma medicine.

Starting at Visit 2, all of the patients will XXXXXXXXXXXX. Some XXXXXXXX will contain medicine and some will not. You and your doctor may not know which ones contain medicine and which ones do not, but your doctor can find out if he needs to.

### **For girls in the study**

If the study medicine is taken by a girl who is pregnant (having a baby), it may harm the baby. If you have had your first menstrual period and have started sexual activity, it is possible for you to become pregnant. If you have had your first menstrual period, a blood pregnancy test will be done at your first visit to make sure you are not pregnant.

If you have had your first menstrual period, regardless of whether or not you are sexually active, you must use a reliable method of preventing pregnancy. If you are having sex, but are not sure if the type of sex you are having can cause you to have a baby, please ask the study doctor to explain.

If you think you might be pregnant, you must stop using the study medicine and you must notify the study doctor or the study staff to let them know immediately.

### **Will you feel uncomfortable during this study?**

Sometimes medicines make people feel uncomfortable. Be sure to tell your parent(s) or guardian right away if you feel anything bad or unusual while you are in the study.

Your asthma may get a lot worse while you are in this study. You must tell your parent(s)/guardian, or teacher, or doctor right away, if your asthma is getting worse. This new medicine may make you feel sick. You must let your parents and your doctor know if this happens. Your doctor may have to do more tests on you if you get sick.

**Do you have to be in this study?**

No. Being in this study is your choice and the choice of your parent(s) or guardian. You do not have to be in this study to be treated. There are other ways to treat your condition that your study doctor can tell you about. If you do not want to be in this study it is okay and no one will be angry at you because of that.

**ASSENT STATEMENT**

You will not be in this study unless you want to be.

If you agree to be in this study, you are saying these things:

- You have read this form, or it has been explained to you
- You have asked all the questions you want to ask. You can ask more questions any time
- You have talked with your parent(s)/guardian about this study, and you want to be in it
- You know that you can quit the study at any time and you won't get in trouble

If you want to be in the research study, tell the study doctor. If you don't want to do this, it's okay to say no. If you say no, you will continue with your usual care.

I agree to be in the study and I know that I can stop being in the study if I want to.

I have read this paper or have had it read to me. I understand what I have to do in this study, and I agree to take part in it.

\_\_\_\_\_  
Printed Name of Child

\_\_\_\_\_  
Signature of Child (if capable of signing)

\_\_\_\_/\_\_\_\_/\_\_\_\_  
\_\_\_\_:\_\_\_\_AM/PM  
Date

Time

\_\_\_\_\_  
Printed Name of Parent/Legally Authorized Representative

\_\_\_\_\_  
Signature of Parent/Legally Authorized Representative

\_\_\_\_/\_\_\_\_/\_\_\_\_  
Date

\_\_\_\_:\_\_\_\_AM/PM  
Time

Check which applies (to be completed by the person explaining assent):

- The child is capable of reading and understanding the assent form and has signed above as documentation of assent to participate in this study.**
- The child is not capable of reading the assent form, however the information was read and explained verbally to the child who has verbally given assent to take part in this study.**

\_\_\_\_\_  
Printed Name of Person Administering Assent

\_\_\_\_\_  
Signature of Person Administering Assent

\_\_\_\_/\_\_\_\_/\_\_\_\_  
Date

\_\_\_\_:\_\_\_\_AM/PM  
Time

## INVESTIGATOR'S STATEMENT

The subject and the appropriate representative signing the consent and assent forms have had the study fully and carefully explained and the subject and appropriate representative have been given an opportunity to ask any questions regarding participation in this research study.

\_\_\_\_\_  
Printed Name of Investigator

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_/\_\_\_\_/\_\_\_\_  
\_\_\_\_:\_\_\_\_AM/PM  
Date

Time