**Instructions:**

* **Use this assent form for children ages 11-14.**
* **Update the version date in the header each time you make a change.**
* **Blue highlighting: This is for your reference only. Delete before submitting to the IRB.**
* **Yellow highlighting: Insert the requested information, or choose the appropriate response and delete the other options.**
* **Delete all << >> marks in the document as you go.**

Subject name: Subject date of birth:

# Aurora Health Care, Inc.<<or other institution name>>

# Agreement to be in a Research Study

# (Assent form for children ages 11-14)

|  |  |
| --- | --- |
| **Study Title** | <<title (must match protocol)>> |
| **Study Investigator** | <<principal investigator name>><<phone number (daytime)>> <<phone number (24-hour contact number)>> |
| **Sponsor<<delete if n/a>>** | <<insert name>> |

Why is this study being done?

You are being asked to take part in a research study because we want to learn more about kids with <<disease or condition>>. This study will <<describe study aims in simple language, such as. “see if a new medicine called \_\_\_ will help your asthma.”>>. You are being asked to be part of this study because you <<insert reason for child’s inclusion in the study, such as “have asthma.”>>.

Your doctor has already talked to your parent(s)/guardian(s) about this study, and they said it’s OK for you to be in it.

What will happen during the study?

If you decide to be part of this study, you will <<include a simple, but complete discussion of diagnostic tests, blood draws, or other study activities that are required for study participation. Use simple, short sentences and make sure the language can be easily understood by a child of this age group.>>

<<Use the following language if a pregnancy test is required for the research and the test results will be entered into the medical record.>>If you are a girl who can have a baby, the doctor will also do a <<blood>> <<urine>> test to make sure you are not pregnant. The doctor will tell you if you are pregnant or not. You can ask the doctor not to tell your parents what the test said, but they can still find out the results if they ask to see your medical records.

<<Use the following if the child will be asked to complete questionnaires or interviews>>During the study, we will ask you to answer questions about <<insert simple, description of what will be asked and how often, e.g. “…how you feel when you are taking the study medicine. We will do this three times while you are in this study.”>>. There are no right or wrong answers. It is not a test, and you don’t get a grade or score. You don’t have to answer all of the questions if you don’t want to. If you start to feel tired, it’s OK to stop.

How long will I be in the study?

You will be part of this study for <<length of study participation>>.

Could anything good happen if I am in this study?

<<Describe any benefits the child may experience from participating in this study, both personally and from information generated from the study, e.g. “Being in this study might help your asthma, but it might not. We hope that this study will help doctors treat other children with asthma in the future.” As in all consent forms, it should be clear that benefits of study participation cannot be guaranteed.>>

Could anything bad happen if I am in this study?

<<Describe any risks that might be part of the study, including physical and emotional risks. The language should be easy for a child of this age group to understand.

Examples:

* “The study medicine could make your throat hurt, give you a stuffy nose, make you cough, or give you a headache.”
* “A needle will be put in your arm to get blood samples for this study. This will hurt some, but only for a short time.” [include if EMLA will be used prior to blood drawing.]
* “Talking about your cancer may make you feel sad or upset you.”>>

<<Use the following when pregnancy tests are required and the test results will be entered into the medical record>> We think the drugs used in this study might hurt an unborn baby. If you are a girl and have started having your period, your doctor will talk to you about things you should do to make sure you don’t have a baby. Your parent(s) can be there to help explain things to you and to answer any questions you have, if you choose. If you don’t want them to be there, you should know that they can still find out the information if they ask to see your medical records.

Do I have to be in this research study?

No, you don’t have to be in this research study if you don’t want to. If you choose not to be in it, your doctor will still take care of you. Nobody will get mad at you or feel bad if you say no.

Will other people know I was in this research study?

For this study, the doctor will use a special code number instead of your name. Only your doctor will have the list that matches your name with the special code number. This way, other people won’t know you were in this study.

Your doctor will tell your parent(s)/guardian(s) about anything that happens to you while you are in this study.

Sometimes your doctor might have to tell other people about your being in this study because they need the information to do their jobs. When your doctor has to do this, it will be for a good reason. Be sure to ask if you have any questions about it.

What if I have questions?

You can ask your doctor questions about this research study any time you want. You can also ask your parent(s)/guardian(s) questions about being in this study. You can ask questions now or you can ask them later.

What do I do now?

You have to decide if you want to be part of this research study or not. You do not have to be in it if you don’t want to. If you don’t want to, just tell your doctor. Nobody will get mad at you or feel bad if you say no. You can say yes now and change your mind later. Nobody will get mad at you or feel bad if you change your mind. It’s up to you.

Mark an X by your choice:

 YES, I want to be in this study.

 NO, I do not want to be in this study.

Print your name:

Sign your name:

How old are you? years old

Write today’s date:

*To be completed by the person obtaining assent:*

This is the name of the person who explained this study to me

Name of person obtaining assent (print) Title Phone number

Signature of person obtaining informed consent Date

**FILE A SIGNED COPY OF THIS FORM IN THE PATIENT’S MEDICAL RECORD (if applicable).**

**Keep the original in the investigator’s research records.**

***Form IC 701E v. 5-2-13***