**Instructions:**

* **Use this assent form for children ages 15-17. Attach it as an appendix to the parental permission.**
* **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 addendum for adolescents ages 15-17 – attach to parental permission form)

|  |  |
| --- | --- |
| **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>> |

You have been asked to participate in a research study about <<insert the purpose of the research study>>. Although you are not old enough to legally “consent” to be in this study, your wishes are important. If you decide you want to take part in this study, and your parent/guardian gives permission, you will both be asked to sign this informed consent document.

Before you decide whether to be part of this study, you should understand enough about its risks (bad things), benefits (good things), and alternatives (other things you can do to get medical care for <<disease or condition>>). The attached parental permission form describes the purpose, procedures, possible benefits, risks, and alternatives of this study. Before you agree to be in the study, please read these pages. Ask questions so you know what you will be asked to do. Please take your time to decide, and talk about this study with your parent/guardian, personal doctors, family members, and friends if you like.

What are your rights if you take part in this study?

You do not have to take part in this study to be treated for <<disease or condition>>. If you choose not to take part, it will not change the way anyone thinks about you. You can still get medical care from your doctor. You can change your mind about participating at any time, but make sure you talk with your doctor before you stop doing the things required for this study.

<<Include any of the following statements, as appropriate>>

You must not drink any alcohol, including beer and wine, while in this study. Drinking alcohol could make you sicker and cause serious side effects.

The <<drug>> <<procedure(s)>> for this study could hurt an unborn baby. To make sure this doesn’t happen, you will need to use birth control while part of this study if you are sexually active. We will tell you what kinds of birth control are ok to use.

You will be asked to discuss sexual activity and birth control in private. Your parents will only be included in the discussion if you want them to be there. However, your parents can find out the information from this discussion if they ask to see your medical records.

If you are female, you will have a <<blood>> <<urine>> pregnancy test. 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.

**Signature section:**

Dr. has explained to me

* what I will have to do while I am part of this research study
* any discomforts, risks, and inconveniences I may experience while I am in the study.

I have asked any questions I have, and all my questions have been answered. I know that I can ask more questions any time that I want.

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:

Your age: years old

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 701F v. 5-2-13***