

EXAMPLE

**Genesys Regional Medical Center
Office of Research
Child's Assent Form**

TITLE: _____
(Title of study)

PROTOCOL No.: _____
(Entire name of study protocol)

I, _____, have been asked to be in this research study.
(Child's name)
Dr. _____ or staff has explained it to me.

Why is the study being done?

This study is being done to learn more about _____.

What will I be asked to do? What are my requirements?

Here are some things the study doctor or nurse will do:

(Indicate what will be happening in a child's level language)

Examples:

- *The study doctor or staff will examine you. (Take temperature, weight, or blood pressure) explain and show each.*
- *You will have a tube placed in your arm to give you the study medication. (Show tube)*
- *You will be asked to blow into a machine so the doctor can take some breathing tests.*

You will be in the study for at least _____ (time: hours, days, or weeks) or until you are discharged from the study site. The study doctor or staff will call you approximately 14 days following your discharge to find out how you are feeling.

What bad effects can happen to me by being in the study?

When you take study medicine you might feel sick.

You may have one or more of the following:

- Tiredness, stomachache, upset stomach, fever, headache, dizziness, rash, cough, stuffy nose, you may feel like you have the flu. You may have an allergic reaction that will cause you to have hives and make you feel itchy.

The breathing test may make you short of breath and dizzy.

If you feel sick or other effects not mentioned here, tell your parents and the study doctor.

What benefit (good) can I expect?

This study may not help me. If it works, it may make me feel better.

No one will know your answers or results, except the _____.

Can I refuse (say no) to be in the study?

I don't have to be in this study if I don't want to. I can stop at any time and no one will be mad at me. My doctor will still take care of me. I can ask any questions about this study at any time. This research is funded (paid for) by a grant from Merck & Co., Inc. to the Hospital to do this study.

Yes, I would like to be in this study.

Printed name of Child

Signature of Child *Date/Time*

Signature of Person Conducting Assent Form Review *Date/Time*

**NOTE: This is an example form – delete any portions that do not apply to the study.
(Delete this statement)**