**ASSENT DOCUMENT**

Title of Research

Name of Researcher/

Principal Investigator

**These are some things we want you to know about research studies:**

We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things.

Whether or not to be in this research is your choice. You can say Yes or No. Whatever you decide is OK. We will still take good care of you.

**Why am I being asked to be in this research study?**

You are being asked to be in the study because you have \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. The doctors have also found out that you have a \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ caused by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and called \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**What is the study about?**

The doctors need to learn more about the best way to fight \_\_\_\_\_\_\_\_\_\_\_ in the \_\_\_\_\_\_\_\_\_\_\_\_ of kids with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and come up with the safest and best combination of medicines to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**What will happen during this study?**

If you agree to be in this study, you will

Have …

Have …

Take …

Have …

Get …

After each visit, someone from the study will call and talk with you or your parents about how you have been doing.

**Will the study hurt?**

Some of the tests might hurt. The doctor will need some of your blood. The needle stick hurts for a little bit as the blood is taken.

When \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, you may get dizzy or feel short of breath.

Having a \_\_\_\_\_\_\_\_\_\_\_\_\_ sometimes makes people feel \_\_\_\_\_\_\_\_\_\_\_\_\_.

**What else should I know about the study?**

If you feel sick or afraid that something is wrong with you, tell an adult at once. You do not have to answer any questions that are asked of you.

**What are the good things that might happen?**

People may have good things happen to them because they are in a research study. These are called “benefits.” The medications in this study will be given to you to try to fight the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ in your \_\_\_\_\_\_\_\_\_\_\_\_\_\_. This might make you feel better or it may not make you feel better. The doctors hope to learn about the best and safest way to fight \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ in children with \_\_\_\_\_\_\_\_\_\_\_\_. The doctors might find out something that will help other children like you.

**What if I don’t want to be in this study?**

You do not have to be in the study if you do not want to. The doctors will still take care of your \_\_\_\_\_\_\_\_\_\_\_. If you don’t want to be in this study, you can continue to get your medical care at .

**Who should I ask if I have any questions?**

If you have any questions about this study, you or your parents can call \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ or Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at (205) --- - ----.

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

No, you do not have to be in the study. Even if you say yes now, you can change your mind later. It is up to you. No one will be mad at you if you don’t want to do this.

**Signatures**

Before deciding if you want to be in the study, ask any questions you have. You can also ask questions during the time you are in the study.

If you sign your name below, it means that you agree to take part in this research study.

Your Name (Printed) Age

Your Signature Date

Signature of Person Obtaining Consent Date

Signature of Witness Date