**Project Title:**

**Sponsor:**

**Principal Investigator:**

**What is a research study?**

Research studies help us learn new things. We can test new ideas. First, we ask a question. Then we try to find the answer.

This paper talks about our research and the choice that you have to take part in it. We want you to ask us any questions that you have. You can ask questions any time.

**Important things to know…**

* You get to decide if you want to take part.
* You can say “No” or you can say “Yes:
* No one will be upset if you say “No”.
* If you say “Yes”, you can always say “No” later.
* You can say “No” at anytime.
* We would still take good care of you no matter what you decide.

**Why are we doing this research?**

We are doing this research to find out more about…

**What would happen if I join this research?**

***Include only the appropriate list items from below. If necessary, create new list items in age appropriate terms. Only list procedure/items for which assent is required.***

If you decided to be in the research, we would ask you to do the following:

* Blood draws: You may need a needle poke so we could test some of your blood. If possible, we will try to get blood without a new poke.
* Questions: We would ask you to read questions on a piece of paper. Then you would mark your answer on the paper.
* Talking: A person on the research team would ask you questions. Then you would say your answers our loud.
* Medical records: We will look at your past doctor visits and use information about your care.

**Could bad things happen if I join this research?**

Some of the tests might make you uncomfortable or the questions might be hard to answer. We will try to make sure that no bad things happen.

**If research poke will or may occur, include the following:**

This poke to test your blood can hurt. Sometimes the needle can leave a bruise on the skin. We can put a cream on your skin before we take blood. This cream would help so it won’t hurt as much.

You can say “no” to what we ask you to do for the research at any time and we will stop.

**Could the research help me?**

**Include most appropriate statement for your study:**

We think being in this research may help you because \_\_\_\_\_\_.

**OR**

This research will not help you. We do hope to learn something from this research though. And someday we hope it will help other kids who have \_\_\_\_\_\_\_ like you do.

**What else should I know about this research?**

If you don’t want to be in the study, you don’t have to be.

It is also OK to say yes and change your mind later. You can stop being in the research at any time. If you want to stop, please tell the research doctors.

**Include most appropriate statement for your study:**

You would not be paid to be in the study.

**OR**

To thank you for being in the study, we would give you \_\_\_\_\_. You should talk with your patents about how you would like to use this.

You can ask questions any time. You can talk to List research team member name \_\_\_\_\_\_. Ask us any questions you have. Take the time you need to make your choice.

**Is there anything else?**

If you want to be in the research after we talk, please write your name below. We will write our name too. This shows we talked about the research and that you want to take part.

***Name of Participant*** ­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(To be written by child/adolescent)

***Printed Name of Researcher*** ­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature of Researcher*** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

­­­­­­­­­­­­­­­­­**Date** **Time**

***Interpreter Information (applicable if LEP participant)***

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*Printed Name of Interpreter during initial presentation of study Date*

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*Printed Name of Interpreter when translated form is presented Date*

**Original form to:**

Research Team File

**Copies to:**

Parents/Guardians

**Medical Records (if applicable)**