# *Assent Form (Children Age 7-12)*

**Instructions (DO NOT INCLUDE THIS INFORMATION IN YOUR ASSENT):**

* **Children younger than 7 years old are not cognitively able to provide assent; documentation of assent is not required.**
* **If your study does not include all ages from 7-12 [e.g., study includes only subjects ages 9-11], please use age appropriate to the protocol.**
* **Font must be Times New Roman and at least at 12 point.**
* **Must be paginated.**
* **Bottom margin must be at least 1 inch.**
* **All footer information must be either on the left side of the page or the middle.**
* **A version number and date must be included in the footer of the document**
* **If the text below is in blue, this language must be used exactly as written.**
* **Use language that the average child is likely to understand (at the age level appropriate for the youngest participants).**
* **Write using second person (i.e., subject addressed as “you” and clinical investigators as “I/we”).**

# *Assent to Participate in a Research Study (Minor Age 7-12)*

**TITLE OF RESEARCH:**

**IRB NUMBER:**

**SPONSOR PROTOCOL NUMBER:**

**INVESTIGATOR NAME:**

**INVESTIGATOR ADDRESS:**

**INVESTIGATOR PHONE:**

**SPONSOR:**

The investigators named above are doing a research study.

**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. When we do this, we call it a study.

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 any time.

We will 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 (Insert disease or procedure).

**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 procedures/items for which assent is required. Add other procedures that may occur (IE: MRI, X-Rays, Exams, etc.)

If you decide 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. If you need help with reading, we can read the questions to you. Then you would mark your answers on the paper. You do not have to answer any question that you do not want to answer.

**Talking**: A person on the research team would ask you questions. Then you would say your answers out loud.

**Medical records**: We will look at your past doctor visits and use information about your care.

 **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.

**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:

The 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.

If you feel sick or afraid that something is wrong with you, tell an adult at once.

If research medication is to be given, include an explanation of the most common side effects.

**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 study at any time. If you want to stop, please tell your parents and the research doctors.

**Will I receive anything for being in the research?**

Include most appropriate statement for your study:

You would not get any money by being in the study.

OR

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

**What if I have questions about the research?**

Ask us any questions you have and once you sign this paper and you have new questions you can ask them. You can talk to List research team member name     . Ask us any questions you have.

**Is there anything else?**

You do not have to be in this study. You can stop being in the study at any time, and no one will be mad at you. 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. Do you want to be in the study? Take the time you need to make your choice.

[ ] *Yes, I want to be in the study* *[ ]  No, I do not want to be in the study*

Name of Child (Print) Date of Birth

Signature of Child Date

Name(s) of Parent(s)/Legal Guardian(s) (Print) Relationship to Child

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Signature of Parent Date

For the Research Investigator—I have discussed with this subject, and the parents/guardians of the subject the procedure(s) described above and the risks involved; I believe he/she understands the contents of the assent document.

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**Signature of Principal Investigator Printed Name Date**

**Or Person Obtaining Consent**

**Witness to Consent\***

I was present during the explanation of the research to be performed under Protocol **(INSERT PROTOCOL NUMBER HERE)**.

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**Witness Signature Printed Name Date**