

***Institutional Review Board***

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**APPROVED**

**This Form May Not Be Used After**

Assent Form – Minors Participating in a Research Study

*(This is just an example of the types of information that should be provided in an Assent form.*

*You are free to create your own form for the IRB to evaluate)*

**Project Title and Protocol number:** *Provide*

**Principal Investigator:** *Name, and Phone/email*

**What is a research study?**

* Research studies help us learn new things and test out new ideas. First, we ask a question. Then we try to find the answer.
* We need help from people like you to do our research study.
* This paper talks about our study and the choice you have to be a part of the study or not.
* We want you to ask us any questions that you have - at any time.

**First: The** **Important things to know…**

* You get to decide if you want to take part in the research study.
* You can say ‘No’ or you can say ‘Yes’.
* No one will be mad or upset if you say ‘No’.
* If you say ‘Yes’, you can always change your mind 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…... *(keep this very brief and simple)*

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

*(Include only the appropriate items from list below. If necessary, create new list of items in age appropriate terms and list only procedures/items for which assent is required.)*

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

* + Talking: A person on the research team would ask you questions. Then you would say your answers out loud.
  + Questions: We would ask you to read questions on a piece of paper. Then you would mark your answers on the paper.
  + 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.

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

* We will try to make sure that no bad things happen.
* Some of the questions might be hard to answer (or some of the tests might make you uncomfortable).
* You can say ‘no’ to what we ask you to do for the research at any time and we will stop.

*(If blood draw/finger prick will occur, consider including 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).*

**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. But, we do hope to learn something from this research. And someday we hope what we learn will help other kids (or……)

**What else should you 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 the most appropriate statement for your study:*

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.

OR

You would not be paid (or receive any gift) to be in the study.

**Questions and Signing**

* You can ask us any questions you have. If you think of a question later, you can ask us next time
* Now we need you to decide if you want to be part of our research. Please take the time you need to make your choice.
* Signing here means that you have read this paper (or had it read to you) and that you are willing to be in this research study. If you don’t want to be in this study, don’t sign.
* Remember, being in this study is up to you, and no one will be mad at you if you don’t sign this or even if you change your mind later.

Your Signature Date

Your Name (printed)

Signature of person obtaining consent Date

Printed name of person obtaining consent

***This assent form will be kept by the researcher for five years beyond the end of the study.***