**Assent for Research Participation (ages 7 – 11)**

**Title:** [Title]

**Researcher(s):** [Name], [Institution (e.g., University of Oregon)]

[Name], [Institution (e.g., University of Oregon)]

**Researcher Contact Info:** [Phone], [Email]

Today we are asking you to be in a research study. You can say yes or no. It is your choice. First, we will tell you about the study. Then we will ask if you want to be in it. You can ask any questions you want. We will also be talking to your parents or caregivers about the study. Even if your parents or caregivers say that it is okay for you to be in this study, you can still choose not to take part.

**What is a research study?**

Define research and explain the reason for the study using simple terms.

A research study is a way people can learn things. We are trying to learn about [insert study purpose in simple language].

**What will you do?**

Describe all the research procedures using simple terms. If any parts of the study are experimental, explain those parts. Explain any medical terms or complex topics.

If you say yes to being in this study, you will do a few activities. These include:

* Answering questions about [insert type of questions]
* Playing some computer games
* Doing some activities about words and sounds, kind of like what you do in school
* Having a small amount of blood will be taken from your [insert location of blood draw like arm or finger].

These activities will be done [describe where the research will take place]

* At your home
* In a park
* at school
* If using an LCNI MRI, include this text (otherwise remove):This study is being done at the Lewis Center for Neuroimaging on the UO campus. We want to take pictures of the inside of your body and brain using a big magnet. This magnet allows us to take pictures of how your brain and body work when you are doing activities. To take these pictures, you will lie down on a bed with the magnet around you. You may hear it called an MRI. You need to stay very still while we take the pictures. We will ask you lots of questions about metal to make sure you do not get hurt. If your clothes have metal on them, like a shirt with metal buttons, you will be asked to go into the bathroom and change your clothes and put on 'scrubs'.
* We will ask you to do a ‘practice’ session in our ‘pretend’ magnet that looks and sounds just like the ‘real’ magnet. We will do this before the real session to see if you want to do this study.

**How long will it take?**

We will see you [insert number of study sessions/visits]. Each time we see you, the visit will take about [insert hours or minutes]. We can take breaks if you get tired. Just ask us for a break.

**Could anything bad happen?**

Explain any possible risks or discomforts to the child, using simple terms. If something might be painful, state this in the assent. If there are physical risks, explain that the child should inform his/her parents or caregiver if they are sick or in pain as a result of being in the study. As the confidentiality risks are always a risk of participation, a brief statement about confidentiality should be included here.

Sometimes people feel tired or bored. If that happens, let us know and we will take breaks.

The stick from the needle to draw your blood may hurt a little, but the hurt will go away after awhile.

If you feel sick or are in pain when you do the activities, please tell your parent or caregiver and us.

If you are in the study, we will keep your answers private and not tell anyone. Sometimes people see or hear the answers that they should not see or hear. We will try very hard to make sure no one sees or hears your answers who should not.

Include if using the LCNI MRI (otherwise remove):

Only the researchers and others with special permission will see your pictures. The pictures will be stored so your name is not on them. If anyone else sees the pictures, they will not know the pictures are of you.

MRI:

* To make sure you are safe, no metal objects like paper clips or metal buttons can be brought into the magnet room where the pictures will be taken. Metal objects will get hot and burn you. If you have metal on your body, such as rings, earrings, or other piercing, you will be asked to remove it. If you can not remove the metal, you will not be allowed to continue in the study.
* We will help you get in the magnet and place special pads around you. The pads help to keep you safe.
* The magnet makes loud thumping, pounding, and whining sounds during scans. These sounds may be loud and annoying. You will wear headphones and/or earplugs during the scan to protect your ears.
* You may be nervous and/or tired by lying in the magnet machine. Some people are scared of small or enclosed places and may not like the magnet. If you want to get out you can tell us.

**Could being in this study help you or others?**

Explain any possible direct benefits to the child posed by the research using simple terms. If you don’t know if they will benefit or if there are no benefits to them directly, state that using simple terms.

Usually, kids have fun in our study, and being in our study will help us to learn more about [reiterate purpose].

We do not know if this study will help you. We may learn something that will help other children with [insert name of medical condition or subject matter of study]some day.

This study will not help you directly. We may learn something that will help other children with [insert name of medical condition or subject matter of study]some day.

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

You do not have to be in the study. It is your choice to say yes or no. If you say no, no one will be mad at you. If you say yes and we start the activities, you can always change your mind and say no. We will ask your parent or caregiver if you can be in the study. Even if they say yes, you can still say no.

Include if using the LCNI MRI (otherwise remove):

* Your parents/caregivers have also learned about what you will do. They have agreed to let you be in the study, if you want to do it.
* We will give you a squeeze ball when you are in the magnet. If you want to stop, you squeeze the ball and the machine will stop.

**Do you have any questions?**

If you have any questions, you can ask me now. If you think of a question later, you or your parent or caregiver can call me. My name is [insert name] and my phone number is [insert phone number]. If you want to talk to someone who is not part of the study, you can call Research Compliance Services at (541) 346-2510.

**Do you want to be in the study?**

Include instructions on how you want them to provide assent (examples below):

If you want to be in the study, please write your name on the line.

Name

Signature Date

Do you want to be in the study? Shake your head or say yes if you do.

**Researcher Signature** (to be completed at time of assent)

I have explained the research to the participant and answered all of their questions. I believe that they understand the information described in this form and freely agrees to participate.

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Researcher Name Researcher Signature Date