**Assent for Research Participation (ages 12 to 17)**

**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 scientific way for people to 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 you want to be in this study, you will be asked to do these things:

* Answer questions about [insert type of questions]
* Play some computer games
* Do some activities about words and sounds, kind of like what you do in school
* Have a small amount of blood taken from your [insert location of blood draw like arm or finger].

The study activities will be done [describe the location]

* If using an LCNI MRI, include this text (otherwise remove): This study will be done at the Lewis Center for Neuroimaging on the UO campus. A machine, called an MRI machine, allows us to look inside your body and brain using magnets to create computer pictures. The pictures can show us a lot of detail about different parts of your body and brain, and how they work when you are doing different tasks. No x-rays or material will be shot into your body of any kind in this MRI.

**How long will it take?**

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

**Are there any risks?**

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 caregivers if they are sick or in pain as a result of being in the study.

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.

Sometimes people do not feel good while being in this study. You might feel these things:

[List possible risks using language and length appropriate for this age group such as get embarrassed, get a headache, get a rash on your skin, get an upset stomach,” etc.]. If you feel any of these things, or other things, be sure to tell your parent or caregiver and us.

Include if using the LCNI MRI (otherwise remove):

There are safety rules to protect you from being hurt while in the MRI machine. We will ask you questions about any metal you may have on you or in you. This is to make sure you are not hurt. Depending on what you are wearing (like a shirt with metal buttons or pants with metal zipper), you may be asked to go into the bathroom and change some clothing and put on 'scrubs'. 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.

The strong magnet in the scanner is more risky if some metal objects (like pens or paper clips or scissors) are brought into the room. There is a risk these objects may be pulled to the MRI or they may cause heating or burns to you. This can also occur if your body or our equipment are not positioned properly inside the MRI. We will carefully place you in the MRI with special pads.

The MRI scanner makes loud thumping, pounding and whining sounds during scans. These sounds may be annoying. You will wear headphones and/ or earplugs during the scan to protect your ears. You can bring your own earplugs from home or we will give you a set at the lab.

You may be nervous and/or tired by lying in the MRI machine. Some people are scared of small or enclosed places and may not like the scanner. If you want to get out you can tell us.

We [choose one: may/will] ask you to do a ‘practice’ session in our ‘mock’ scanner (which looks and sounds just like the ‘real’ scanner) before your session to see how you feel. You can also ask us if you want to do a practice session in our ‘mock scanner’.

Before the scan starts we will give you a squeeze ball and show you on how to use it to stop the scan. If you want to stop while the machine is going, just squeeze the ball at any time to stop the scan. We will take you out of the machine.

Since you are under 18, your parents or caregiver have given permission for you to participate in the study. However, participating in the study is still your choice. You can refuse to be in the study even if you parent or caregiver said yes.

If you think you may be pregnant, you should not participate in this study. Although there are no known risks to having an MRI when pregnant, it is a time when the heart and brain are growing and we want to be extra safe. It’s your choice. You can choose not to participate at any time and we will not ask for a reason why. We also won’t tell your parent or caregiver why you didn’t want to participate.

It is ok to stop participating in the study at any time. If you decided to stop, no one will be upset with you.

Include if there are physical risks to participation (otherwise remove):

Although we do not expect you to get hurt from being in the study it is possible that [describe what could hurt them]. Your parent(s) or caregiver(s) have been given information on what to do if you are hurt at any time during this study. If you are hurt, please tell your parent(s) or caregivers.

**Are my answers private?**

Describe how their information will be kept confidential. Explain situations where their private information may need to be shared with others. Include information about whether their information and/or samples may be shared with other researchers.

If you are in the study, we will keep your answers private. There are certain times when we have to tell someone what you said. The times we would have to tell someone else your answers are explained below.

* If we learn that someone has been hurting you or if we think you will hurt yourself or someone else, we may have to tell your parents or other adults because we want people to be safe.
* People who are paying for the study can ask to see your information and so can the people who review the study to make sure it’s safe.

Sometimes people see or hear the answers that they shouldn’t, but we will try very hard to not let that happen. We will take your name off of your answers whenever possible so only those who are supposed to have your information can see it. If the research involves the collection of identifiable private information and/or identifiable biospecimens, one of the following statements must be included:

When we take your name off of your answers, we might share that information with other researchers. -OR-

Your information will only be used for this research and will not be shared with other researchers even if your name and other identifiable information is removed.

Include if using LCNI MRI (otherwise remove):

We store all of the pictures securely. Only people who are supposed to have access to your identifiable information will be able to know which pictures are of you.

If the minor will be receiving a pregnancy test because of the research, also include this language as applicable:

After you are enrolled in this study and during the research, pregnancy testing will be performed. The result of the pregnancy test is confidential. We will tell you the result of the pregnancy test in private. Every effort will be made to maintain confidentiality regarding positive pregnancy test results. Whenever possible, we will not tell your parent(s) or caregivers(s) without your permission. However, under certain circumstances, we might be forced to reveal this information. For example, if your life or someone else's life was at risk or if abuse was suspected, it may be necessary to inform your parent(s) or caregiver(s) of a positive pregnancy test. If we believe it is necessary to tell your parent or caregiver of a positive pregnancy test without your permission, we will meet with you first in private to discuss our concerns before telling anyone any information about the pregnancy.

During the research, if you do have a positive pregnancy test, we may withdraw you from the study. This means that even if we do not reveal the results, your parent(s) or caregiver(s), may suspect that you are pregnant despite our best efforts to maintain confidentiality. If you become pregnant or if there is any chance that you might be pregnant (late menstrual period, broken condom, missed birth control pills, etc.) please contact the study personnel immediately.

If this study is NIH funded or otherwise has a certificate of confidentiality, include this language (otherwise, remove):

This study has an additional protection in place called a certificate of confidentiality. This protection limits the information that researchers can share with others who request personal information about you that includes your name or other identifiers for lawsuits or other court filings. Only researchers in this study will have information from this research study, unless there is a law that requires us to share the information (such as to report child abuse, communicable diseases, or harm to yourself or others). If you and your parents or caregivers give us permission, we could share this information for lawsuits or other court filings.

Additionally include the following language if has a certificate of confidentiality *and* is FDA regulated or if otherwise applicable (otherwise remove):

People who are in charge of the study and people who work to protect people like you who participate in research can still see your research information even with the certificate of confidentiality. This includes [THE AGENCY] which is funding this project [and/or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA)]. The certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to someone outside of the study like your doctor, or any other person not connected with the research, you and your parents or caregivers must give us permission to share that information.

Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the assent of research participants:

If you and your parents or caregivers give us permission to share information from this research with other people, like your doctor, the certificate of confidentiality won’t stop us from doing that.

**Are there any benefits?**

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.

We do not think you will benefit directly from being in our study, but you will help us learn more about [reiterate purpose].

We do not know if you will be helped by being in this study. 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.

**Will I get anything?**

Explain any payments or incentives they will receive. If there are none, remove this section.

If you decide to be in the study, you will receive [insert compensation information].

**Do I have other choices?**

Describe any alternative procedures that might be available to the child other than this study. For example, for educational research, maybe the alternative is to do some other type of classwork; or for clinical research, maybe the child can still see their clinician, but their information won’t be used for research. If none, this section can be removed.

If you do not want to be in this study, you can say no. If you say no to being in this study, you will [insert alternatives if any to participation].

**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 you do not want to be in the study, no one will be upset with you. You won’t be punished for saying no and you won’t lose any benefits you already get. If you say yes and start the study, you can always change your mind later and stop being in the study. You can say no even if your parent or caregiver said you can be in the study.

**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 agree to participate.

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Researcher Name Researcher Signature Date