*This assent template is for minor subjects generally ages 7-13 enrolled in a project where the MCW IRB will be serving as the IRB of record for one or more sites engaged in research. Typically, for ages 14 and up, the consent form should be used. The language used should be at a 2nd-3rd grade reading level.*

**Instructions**

To stand out both on your computer screen and in black/white copies, instructions are in bold, italic, and blue type. Instructions are in gray boxes and should be deleted in final consent.

MCW IRB-required template language is in black type and cannot be changed. No additional sections may be added to the MCW template.

Institution-specific language from the site relying on MCW IRB can replace language in green.

Rarely, changes to the required language may be necessary. To petition for a change in required language, submit proposed changes with justification on the “ICF Template Change Form” to the IRB office.

Sample language, which can be used, modified, or deleted as appropriate for your project, is in blue type. Please maintain the blue color to distinguish your project-specific information from the required template language.

* Arrows are used to show alternative choices. In the final consent, arrows can be deleted and the usual margin maintained.

**<Medical College of Wisconsin> <Children’s Wisconsin>**

**ASSENT TO PARTICIPATE IN RESEARCH**

Name of Subject: ­­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

<Title>

**LOCAL SITE NAME**

<Site Principal Investigator>

<Department>

<Telephone Number>

<Local Site Name>

<Local Site Address>

A1. WHAT IS A RESEARCH PROJECT?

Research projects help us learn new things. We can test new ideas. First, we ask a question. Then we try to find the answer. [This can help us learn about how medicines work. We can also learn why people do things a certain way or feel a certain way.]

This paper talks about our research project. We want you to ask us any questions that you have. You can ask questions any time.

There are a few things you should know about the project:

* You get to decide if you want to be in the project.
* You can say “No” or you can say “Yes”.
* Whatever you decide is OK.
* If you say “Yes”, you can always say “No” later.
* No one will be upset if you say “No”.
* We will still take good care of you no matter what you decide. [Delete this statement if the child is not also a patient or receiving care. If applicable you may want to say, “If you say no, you can still get the medicines.”]

A2. WHY ARE WE DOING THIS RESEARCH PROJECT?

***Describe why the subject is being asked to be in the project.***

***Describe the purpose including what the experimental aspect of the research is.***

You are being asked to take part in this research project because [child’s diagnosis or reason for selection into this protocol]

In this project we want to find out [more about x disease or how the medicines work in your body.]

B1. WHAT WOULD HAPPEN IF I JOIN THE PROJECT?

***Describe the project procedures clearly and simply.***

***Describe in appropriate detail the things to be done because of the protocol (what’s research vs what’s routine care).***

***Clearly identify the research component.***

***Commonly used terms such as “blinded, randomization, placebo” should be explained.***

***The amount of blood drawn should be quantified in teaspoons, tablespoons or ounces. Indicate who will be doing the blood draws. Indicate whether the amount of blood drawn is safe for the subject.***

***Whether clinically relevant test results will be disclosed and under what circumstances.***

***Give some indication about the duration of the subject’s participation. Where appropriate, state that the project will involve long-term follow-up.***

***Add that medication should not be shared with others – family or friends.***

***This section should state that subject’s will need to re-consent once they reach the age of 18 (if appropriate to the project).***

If you are going to be in the project you will [add applicable procedures].

*For randomized projects add*:

You will be “randomized” into one of the project groups described below. Randomized means that you are put into a group by chance. It is like flipping a coin. Which group you are put into is decided by a computer. Neither you nor the researcher will choose what group you will be in. You will have an [equal / one in three / etc.] chance of being placed in either group. Using randomization helps to improve the chance of determining which (if either) treatment is better.

***Include any state-specific or institution-specific laws or rules that may apply to this project (i.e. infectious disease reporting, etc.)***

*[Insert local context applicable to this project.*

*Please note – any local context information for which equivalent language is present in MCW’s template language in other areas of the consent form should not be inserted here.]*

**If pregnancy tests will be administered as part of the project, explain the procedure and the reason for needing a pregnancy test.**

[*Explanation of procedure and reason for the test…*]

The results of any test will not be shared with anyone unless you agree for this to happen.

C1. COULD BAD THINGS HAPPEN IF I JOIN THE PROJECT?

***Clearly describe the risks of procedures and tests to be done during the project solely for the purposes of the project. You do not need to describe the risks of procedures that would be done as part of routine care.***

*Examples:*

Some of the tests might hurt.

The researcher would need to test some of your blood. These pokes 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.

The <researchers/ research doctors> would need to ask you some questions. They might be hard to answer. Like, “Have you ever thought about hurting yourself?”

The researcher will ask you questions and look at or collect information about you from you or your doctors for the project. The researcher plans to keep information about you private, so no one else except the researcher and people who work with the researcher for this project will see it, but there is still a chance others may see it.

C2. IF I JOIN THE PROJECT WILL IT HELP ME?

**Clearly describe the benefits. Choose the appropriate response.**

We do not think being in this project would help you.

We think being in this project may help you because [explain].

We hope to learn something from this project. And someday we hope it will help other kids who have [xxx] like you do.

D1. WILL I BE PAID FOR TAKING PART IN THE PROJECT?

**Modify as needed for the project.**

You will be paid a total of [$xx] for being in this project.

No, you will not be paid.

D2. DO I HAVE TO JOIN THIS PROJECT?

You do not have to join this project, and if you are in it, you can stop at any time.

*If there are alternatives besides not taking part include:*

If you don’t want to be in this project, you could:

[list other alternatives]

E1. WILL INFORMATION BE CONFIDENTIAL?

We do need to share your information with people working with us on this research project. Also, we may need to share your information with the people who are paying for the research project.

We will do our best to keep your information confidential; however, it is possible that someone who shouldn’t see your information might accidentally see it.

We don’t plan to share your information or tell anyone if you join this project. But, there are a few reasons we would tell someone:

* If we found out you were in serious danger.
* If we found out someone else was in serious danger.

Here are some examples of when we would tell someone:

* If you told us you were being abused.
* If you told us you were going to hurt yourself or someone else.

We would tell to protect you or someone else from being hurt.

E2. IF I HAVE QUESTIONS, WHO DO I ASK?

You can talk to [research team member’s name]. Ask us any questions you have. You can ask questions any time. Take the time you need to make your choice.

**PERMISSION TO PROCEED**

**Writing my name on this page means:**

* That this document was read (by me/to me) and that I agree to be in this project.
* I know what will happen to me.
* If I decide to quit the project, all I have to do is tell the person in charge.

**IMPORTANT:** Your parents/guardian will receive a copy of this form. A copy of the signed consent/HIPAA authorization and assent will be kept in your medical record. Please keep this form where you can find it easily. It will help you remember what we discussed today.

***Date or Date & Time: Time on subject’s line is optional to include; if included in template, it must be completed by each subject.***

|  |  |
| --- | --- |
|  |  |
| **Documentation of Assent**  *Documentation is not specific to a cursive signature and may include whatever the child’s mark is* | **Date or Date/Time** |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **\* Name of person discussing/ obtaining consent** *please print* | **Signature of person discussing/obtaining consent** | **Date** |

*\* A member of the research team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. The Principal Investigator is responsible and accountable for the research project.*