**Assent to Participate in a Research Study**

***Note to the Investigator:*** *Under the usual conditions of research, informed consent is obtained from the prospective participant. In the case of an adult with diminished decision-making capacity or a non-autonomous child, obtaining informed consent may not be possible and permission from a legally authorized representative must be obtained. However, individuals capable of some degree of understanding (generally, a child of seven or older or individuals with diminished decision-making capacity) should participate in research only if they assent (agree). Assent means a participant’s affirmative agreement to participate in research.*

*It is particularly important that the assent is written in language understandable to the people being asked to participate.*

***DIRECTIONS FOR USE OF THIS TEMPLATE:***

* ***Do not adjust the bottom margin or use the footer.*** *Do not delete the watermark fields in the footer.*
* *Replace bracketed items in the header, such as “[Title of Study]” with the requested information.*
* *Read guidelines for each section, complete as applicable for your project and then delete the template guidelines.*
* *Example text may be used if needed but should not be italicized.*
* *Instructions in red font should be replaced or deleted.*
* *Phrases such as “I understand…” or “You understand…” are not appropriate and should not be included in the document.*
* *The document should be written at an appropriate grade level for the group of participants. Most word processors include the ability to assess the reading level.*

**Who are we and what are we doing?**

Begin the assent document with an introduction. Who is conducting the research study? Define “research study”.

*Example: We are from the <<insert affiliation, e.g. University of Utah, Primary Children’s Hospital, Shriners Hospital>>. We would like to ask if you would be in a research study. A research study is a way to find out new information about something.*

*Example (additional text for biomedical research, if applicable): This is the way we try to find out if the <<insert “medicine” or “type of care”>> is safe and if it works.*

*Example (additional text for social-behavioral research, if applicable): This is the way we try to find out how <<insert “kids” or “people”>> feel about <<complete statement with study objective>>.*

**Why are we asking you to be in this research study?**

Explain the purpose of the research and what the researchers expect to learn.

*Example: We are asking you to be in this research study because we want to learn more about <<outline what the study is about in language that is both appropriate to the assenting individual’s maturity and age>>. We want you to be in this study because <<insert reason for inclusion or simple name of medical condition >>.*

## What happens in the research study?

Describe the procedures and the duration of participation. Describe what will take place from the assenting individual’s point of view in a language that is both appropriate to the assenting individual’s maturity and age or comprehension.

*Example: If you decide to be in this research study and your <<insert “parent or guardian” for children or “legally authorized representative” for adults with impaired decision-making capacity>> agree, this is what will happen <<insert simplified explanation of study procedures>>.*

*Example (additional text if applicable):*

* *We will <<insert procedure(s)>>.*
* *We will ask you to <<insert procedure(s)>>.*
* *We will look at <<insert “information about you” or “your answers”, etc.>>.*
* *You will be in the study for <<insert amount of time>>.*

## Will any part of the research study hurt you?

Describe any risks to the assenting individual that may result from participation in the research. Risks should be explained in a language understandable to the assenting individual. However, the investigator should not minimize the actual risk by using simple language. For example, a bone marrow aspiration should not be described as a “poke”.

*Example: There is a chance that during this research study you could feel afraid, uncomfortable, or hurt. We will try to help you feel better if this happens. You can stop at any time if you want to.*

*Example (additional text if applicable):*

* *You could <<insert risk, e.g. get a bruise, get an upset stomach, throw up, feel dizzy, etc.>>.*
* *The questions we ask might make you feel <<insert risk, e.g. embarrassed, sad, uncomfortable, etc.>>.*
* *The <<insert procedure>> may hurt.*

## Will the research study help you or anyone else?

Describe any benefits to the assenting individual from participation in the research. Describe any benefits to society from the research.

*Example: We do not know for sure if being in this research study will help you. It is possible that we could learn something to help other people with <<insert subject matter of study or medical condition>> some day.*

## Who will see the information about you?

Explain how the records will be kept confidential.

*Example: Only the researchers or others who are doing their jobs will be able to see the information about you from this research study. <<insert “We will not tell anyone else that you are in the study.”* ***OR*** *“We will talk about this information with you, your doctors, and your parents.”>>

OPTIONAL LANGUAGE:
For Pregnancy Testing: If we find out that you are pregnant, we will talk with you about this and help you tell your parents.

For instances where the child may harm him/herself: If you tell us that you want to hurt yourself, we will tell other adults about it so that we can help you feel better.*

## What if you have any questions about the research study?

Provide contact information for the study investigator or study team.

*Example: It is okay to ask questions. If you don’t understand something, you can ask us. We want you to ask questions now and anytime you think of them. If you have a question later that you didn’t think of now, you can call <<insert PI name and telephone number>> or ask us the next time we see you.*

*Example (additional text for biomedical research, if applicable): You may call at any time to ask questions about your disease or treatment.*

## Do you have to be in the research study?

Explain that the study is voluntary.

*Example: You do not have to be in this study if you don’t want to. Being in this study is up to you. No one will be upset if you don’t want to do it. Even if you say yes now, you can change your mind later and tell us you want to stop.*

*Example (additional text if applicable): You can take your time to decide. You can talk to your <<insert “parent or guardian” for children or “legally authorized representative” for adults with impaired decision-making capability>> before you decide.*

 *We will also ask your <<insert “parent or guardian” for children or “legally authorized representative” for adults with impaired decision-making capability>> to give their permission for you to be in this study. But even if your <<insert “parent or guardian” for children or “legally authorized representative” for adults with impaired decision-making capability>> say “yes” you can still decide not to be in the research study.*

*Example (if study is related to treatment): Your doctors will continue to take care of you even if you decide not to be in this research study.*

**Agreeing to be in the study**

Please include an assent statement. State that a copy of this form will be given to the individual providing assent.

*Example: I was able to ask questions about this study. Signing my name at the bottom means that I agree to be in this study. My <<insert “parent or guardian” for children or “legally authorized representative” for adults with impaired decision-making capability>> and I will be given a copy of this form after I have signed it.*

|  |  |
| --- | --- |
|  |  |
| Printed Name  |
|  |  |  |
| Sign your name on this line |  | Date |

|  |  |
| --- | --- |
|  |  |
| Printed Name of Person Obtaining Assent |
|  |  |  |
| Signature of Person Obtaining Assent |  | Date |

The following should be completed by the study member conducting the assent process if the participant agrees to be in the study. Initial the appropriate selection:

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_ | The participant is capable of reading the assent form and has signed above as documentation of assent to take part in this study. |
| \_\_\_\_\_\_\_\_\_\_ | The participant is not capable of reading the assent form, but the information was verbally explained to him/her. The participant signed above as documentation of assent to take part in this study.  |