

Assent Template Instructions

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Researchers should be familiar with the guidance for assent. Most importantly, on studies where an assent process is approved by the IRB, the children must be asked if they wish to participate and if they do not want to, *they are not allowed to participate, even if the parents want them to be in the research*. Any allowed exceptions to this must be explicitly described in the approved application and/or IRB approval notice.

IMPORTANT NOTE: Researchers may sometimes encounter a child who wants to waive her right to assent. For example, a child may say, *“I don’t want to be the one to decide. I want my mom to decide for me.”* This situation raises regulatory and ethical issues. Regulators state that assent *“means the child must actively show his or her willingness to participate in the research.”* A child stating she does not want to decide is *not* ‘actively showing willingness to participate.’

However, when the researcher believes the parents have the child’s best interest as their core reason for the child’s participation and the researcher has no reason to believe parents would coerce or force a child into a research study, the following may be an ethically permissible course of action when a child initially waives the right to assent or dissent:

* Suggest to the child that she discuss the study with her parent(s) and then make her decision.
* If she then decides to actively assent and indicates this, she can be enrolled in the study.
* If she still expresses discomfort with making a decision, she should *not* be enrolled in the study.

You should complete the assent form below, choosing or inserting appropriate information wherever brackets [like this] and blank lines \_\_\_\_\_\_ appear. Additional instructions or sample text are provided in **green text**. Brackets, blank lines and **green text** must be deleted before submitting the form to the IRB for review. Remove this page from the assent when submitting to the IRB Office.

Complete each section with the aim of conveying what is important *for a child to know*. This is usually not exactly the same as what a parent must be told in order for the assent form to meet the regulatory requirements. Focus on what a child will experience or could upset the child, e.g., pain, embarrassment.

Maintain font sizes and white space for better readability.

For questions about assent forms, please contact the IRB Office at 724-738-4846 or irb@sru.edu.



Your department letterhead

VOLUNTEER ASSENT TO PARTICIPATE IN RESEARCH

**STUDY TITLE**

Researcher’s name and contact information

We want to tell you about a research study we are doing and see if you want to take part in it. Research is a way to learn more about something.

**Edit this sentence as appropriate. For example, for a survey it may be more appropriate to say, "This is the way we find out why kids do \_\_\_\_\_\_."**

The name of this study is:

**If title of study is complicated, use a simplified version of the title here. For example, if the name of the study was "Double-blind, placebo controlled study of ALO-395T compared to DGBalto in Relapsing Yucky Syndrome" use a title like, "Comparing two drugs for Yucky Syndrome" in the assent.**

The researchers are:

**If the study includes a long list of co-investigators or others, limit the list here to the principal investigator and those team members who will interact with the child subjects.**

It is okay to ask questions about what we are telling you. You can circle or highlight things on this paper you want to know more about. If you don’t understand something, just ask us. We want you to ask questions now and anytime you think of them.

We are working to [find out/learn more about—i.e. provide a simplified explanation of the how or why you are doing the research].

You are being asked to be in this research study because [insert reasons for inclusion].

For you to be in this study both you and your parent (or guardian) must agree to you being in it. It is the adult’s job to make sure being in this study is okay for you. But it is still up to you if you *want* to do it.

Parents and children say "no" for different reasons. It may be that you would miss too many activities or school. Whatever the reason, it is your decision. You will not be treated any differently if you say "no."

If you decide to be in this research and your parent or guardian says yes, this is what will happen:

**Procedures section: This does not have to include everything in the parents’ consent form. Focus on procedures that are important to the child, from a child's viewpoint.**

* We will have you do
* We will look at your \_\_\_\_\_ [e.g., school records about you]
* This research will take [insert how long total]
* This will take \_\_\_\_ visits that each last about\_\_\_\_

**Benefit Section:** **Describe expected benefits in a bulleted list. Remember to focus on what matters to children. Delete this if the study does not offer potential of direct benefit for the subjects.**

Some of the ways you could be helped are:

* You could \_\_\_\_\_\_[get better grades]
* Some kids feel \_\_\_\_\_[less pain]
* Feel good about helping other kids

We do not know for sure if you will be helped by being in this study.Also, we could learn something that will help other children with [insert subject matter of study]someday.

**Risk Section:** **If appropriate to the study, elaborate on what will be done in a bulleted list. For example, if the study will cause them to be tired, tell the subject if you will provide rest periods. If the study does not involve any discomfort, pain, etc. modify or delete this sentence as appropriate to the study.**

There is a chance that during the research you could feel uncomfortable, afraid, lonely, or sad. We will take steps to help you with these feelings or discomforts. And you can stop at any time if you want to. Some of these risks are:

* You could \_\_\_\_\_\_\_[e.g. get a bruise]\_
* Some kids feel\_\_\_\_\_\_
* Sometimes the questions we ask can make you feel [embarrassed/sad/uncomfortable]

You don’t have to be in this study if you don’t want to. Nobody will be mad at you if you don’t want to be in the research study. You can say okay now and you can change your mind later. Just tell the researcher or your parent/guardian if you want to stop at any time.

|  |
| --- |
| **Signature:** |
| I have read this form or someone has read it to me. If I did not understand something, I asked the researcher to explain it to me. I can always ask a question about the study if I don’t understand something. I will be given a copy of this form. |
| Please check one box: |
| **□** | **YES,** I want to be in this study and I know I can change my mind later. |
| **□** | **NO**, I do not want to be in this study. |
|  |
| *Child’s Name (print legal name):* |  |
|  |
| *Child’s Signature:* |  |
|  |
| *Date of signature:* |  |  |  |
|  |

The following should be completed by the Principal Investigator conducting the assent process if the child agrees to be in the study. Check all that apply.

* The child is capable of reading and understanding the assent form and has signed above as documentation of assent to take part in this study.
* The child is not capable of reading the assent form, but the information was verbally explained to him/her. The child signed above as documentation of assent to take part in this study.
* The child had ample opportunity to have his or her questions answered.

|  |  |
| --- | --- |
| *Printed name of Principal Investigator:* |  |
|  |
| *Signature of Principal Investigator:* |  |
|  |
| *Date of signature:* |  |
|  |  |

**You may also need to obtain dated consent for specific activities when those activities are optional. Whether an activity is required or optional must be clearly described in the main body of the consent above. Some common optional research activities are included below:**

**Photo/Audiotape/Videotape Assent Release Form:**

**We would like to take your picture/record your voice/video tape you (specify which is used) as part of our study. We ask for your permission to do this. We may use this for newspapers, magazines, websites and displays related to our study. For us to use your picture/record your voice/video tape you (specify which is used), please check one of the following boxes below:**

 **I do…**

 ** I do not…**

**Give permission for the researchers to use my pictures/voice recordings/videotapes (specify which is used) of me.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Print Child’s Name Child’s Signature Date**

**PLEASE NOTE: Should you choose not to allow your picture or voice to be used, you can still participate in the research.**

**Delete this section if not applicable to the study.**