University of Michigan

Assent To Be Part Of A Research Study

For Children ages ~10 to 14

Do not alter the header at the top of the page. The information will be completed when the IRBMED approves the document in eResearch.

Instructions

1. Researchers should be familiar with the [guidance for assent](https://az.research.umich.edu/medschool/guidance/assent-children-research). 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.
1. Depending upon the nature of the research it may be appropriate to have one assent form for 9 to 11 year olds and another for 12 to 14 year olds. The 10/12- to 14-year-old form could also be used for 15-17-year-olds or you can use the parental permission form for older children. The suggested age range in the title of this document should not be read as a ‘directive.’

In some cases an addition of an ‘assent section’ to the parents’ permission document (the ‘informed consent document’) may adequately serve for assent but is not recommended when a study raises privacy issues important to the child subjects (e.g. studies that require birth control).

1. For Instructions on how to complete this form, view the Assent Template – Instructions document. To complete the form for IRBMED approval, use the Assent Template document which is a ‘clean’ copy of the form.
2. You should complete the text below, choosing or inserting appropriate information wherever brackets [like this] and blank lines \_\_\_\_\_\_ appear. Brackets and blank lines must be deleted before submitting the form to the IRB for review.
3. 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 permission form to meet the regulatory requirements. For example, it would be inappropriate to list long-term medical side-effects that the parent is better suited to judge. Focus on what a child will experience or could upset the child, e.g., pain or visits to the hospital. If the study involves testing for drugs, pregnancy, or birth control take appropriate steps to *warn adolescents and protect their privacy.* Depending on the study you may need to tell children something about privacy and confidentiality but you do not have to include the level of detail required for HIPAA (the parents retain the responsibility of providing HIPAA authorization).
4. Maintain font sizes and white space for better readability.
5. Researchers may find it useful, for some types of studies, to share with parents and children the NIH’s website for "Children in Clinical Studies" which includes videos and information helpful in deciding whether or not to participate in research: <http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php>.

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. This is the way we find out if drugs or other treatments are safe and if they work.

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 investigators 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 simple/layperson name of medical condition or other 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 the benefits and risks of this study are 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. It could be the risks seem too great or that the benefits seem too low. 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’ permission form. Focus on procedures that are important to the child, from a child's view point.

* We will have you
* We will ask you to.
* We will ask girls to take a pregnancy test (this is a urine test, not a pelvic exam)

Delete this bullet if the study does not involve pregnancy testing or girls of child-bearing potential. Edit to indicate if the test is a blood test or a urine test. If the study does involve pregnancy testing, include the additional paragraphs from the IRB [Pregnancy Assent Modules page](http://www.med.umich.edu/irbmed/ict/modules/modules.htm#assent) as appropriate.

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

Explain in simplified terms, in a bulleted list, what will be done, including an explanation of the randomization if appropriate to the study, the different treatments, etc. Complicated, long-term studies may also want to have a separate study calendar that is referred to here. The bulleted list in the template is to give you an idea of how to simplify procedures. See the [example templates](http://www.med.umich.edu/irbmed/ict/modules/modules.htm#assent) for further illustrations of language.

Some of the ways you could be helped are:

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

Benefit Section: Delete this if the study does not offer potential of direct benefit for the subjects.

Describe expected benefits in a bulleted list. Remember to focus on what matters to children. See the [example templates](http://www.med.umich.edu/irbmed/ict/modules/modules.htm#assent) for further illustrations of language.

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 name of medical condition or subject matter of study]someday.

There is a chance that during the research you could feel uncomfortable, afraid, lonely, or hurt. 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:

Risk Section: If the study does not involve any discomfort, pain, etc. modify or delete this sentence as appropriate to the study.

If appropriate to the study elaborate on what will be done in the bulleted list. For example, if the study will cause pain tell the subject if you will provide pain medicine.

* You could \_\_\_\_\_\_\_[e.g. get a bruise]\_
* Some kids feel\_\_\_\_\_\_
* Sometimes the questions we ask can make you feel [embarrassed/sad/uncomfortable]
* The \_\_\_\_\_ may hurt
* The research\_\_\_\_[drug/device/treatment] could make you feel \_\_\_\_\_[dizzy, have an upset stomach]

Describe possible risks, e.g., discomforts and/or side effects in simple language, in a bulleted list. The bulleted list in the template is to give you an idea of how to simplify risks. Remember to focus on what matters to children. See the [example templates](http://www.med.umich.edu/irbmed/ict/modules/modules.htm#assent) for further illustrations of language.

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 doctor or your parent or guardian if you want to stop at any time. [insert the next sentence if the researcher also provides the child’s clinical care] Your doctor will still take care of you if you don’t want to be in the study.

Delete if this is not an interventional type of study or otherwise a study where children might be concerned about this.

|  |
| --- |
| **Signature:** |
| I have read this form or someone has read it to me. If I did not understand something, I asked the doctor or the assistant to explain it to me. I can always ask the doctor or the assistant 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:* |  | Age # |  |
|  |
| *Patient ID:* |  |  | *Date of Birth (mm/dd/yyyy):* |  |
|  |

Delete ‘Patient ID’ as appropriate to the study at hand.

This section can be deleted if and only if the protocol and/or the IRB application articulate that this information will be recorded elsewhere. You must explain where the information will be recorded (e.g., "in the subject's research file" or "in the medical record"). Documentation of these considerations must be provided upon request of the IRB or other appropriate oversight entity.

The following should be completed by the study member 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.

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| *Printed name of person obtaining agreement:* |  |
|  |
| *Signature of person obtaining agreement:* |  |
|  |
| *Date of signature:* |  |
|  |  |