University of Michigan

 Assent To Be Part Of A Research Study

For Children ages ~10 to 14

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.

* The name of this study is:
* The researchers are:

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:

* 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)
* 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\_\_\_\_

Some of the ways you could be helped are:

* You could \_\_\_\_\_\_[get better]
* 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 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:

* 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]

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.

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| --- |
| 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):* |  |
|  |

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:* |  |
|  |  |