

Children's Hospital Institutional Review Board

Information Sheet

Assent Form Preparation

Federal regulations define *consent* as the agreement to participate in a study by a person legally capable to decide for him or herself. *Assent* is defined as agreement by persons who do not have legal responsibility for their own activities, e.g., children. *Assent* by children must be accompanied by parental permission (consent).

Assent must be obtained from children who participate in research unless a waiver is granted by the IRB. A waiver of assent can be granted for two reasons. First, a waiver may be granted for children who are not capable of understanding what is being asked of them. Second, assent may be waived when an intervention holds out the prospect of direct benefit that is available only in the context of the research. When assent is required, the researcher may not seek assent only from compliant subjects, or rely solely on parental permission. If assent is required, and the child dissents, the child's refusal to participate in the research is binding. Children's IRB rarely waives assent for adolescents 14 and older.

More than one method for obtaining assent may be appropriate when participants represent a range of ages. For young children who are capable of understanding what is being asked of them but who cannot yet read, verbal assent may be appropriate. Children between 7 and 13 years of age should be asked to sign a simple form written at the second or third grade reading level. Children 14 and older may be capable of understanding the consent form and can indicate written assent by signing the form as the research participant. The parent co-signs the same form. Forms for parents and older children need to be written at the eighth grade or lower reading level.

The IRB approves the text of each assent form or statement, whether verbal or written. The language and syntax of the assent form need to be appropriate for the cognitive level of the children being asked to participate in the research study. Procedures that are not part of the child's routine care need to be described as optional. Any information that can affect a child's decision to take part should be included, e.g., asking the child's teacher to talk about how the child acts in school, or inviting playmates to take part in the study.

Use Children's Assent Form Template when preparing your assent form for younger children. This form should be written at the 2nd–3rd grade reading level*. For information on preparing an assent form for older children (14-17 years) refer to the information sheet [Consent Form Preparation](#).

* To test readability in Word, go to Tools, Options, Spelling and Grammar. Set your spelling and grammar options to Show Readability Statistics. After you run a spelling and grammar check, a readability score will be provided. Please note you can check readability at many levels by highlighting a sentence, a section, a paragraph, or the entire document.

Sample Format – Simple Written Assent Form. For children 7-13 years of age. To be written at a 2nd-3rd grade reading level.

**CHILDREN’S HOSPITAL AND REGIONAL MEDICAL CENTER
and
UNIVERSITY OF WASHINGTON (if appropriate)**

ASSENT FORM

Title of Study

Investigator’s name, position, department and telephone number.

Co-investigators’ and associates’ names, positions, departments and telephone numbers.

What is research?

We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things.

Being in research is your choice. You can say Yes or No. Whatever you decide is OK. We will still take good care of you.

Why are we doing this research?

In our research study we want to test **OR** learn **XX** .

We are asking children with XX to be in the research. **[EXPLAIN IN SIMPLE LANGUAGE WHY YOU ARE ASKING CHILD TO BE IN THE RESEARCH.]**

What will happen in the research?

DESCRIBE THE STUDY PROCEDURES IN SIMPLE LANGUAGE. AVOID MEDICAL TERMS OR TECHNICAL LANGUAGE. DESCRIBE THE TIME INVOLVED AND NUMBER OF VISITS. CONSIDER CAREFULLY WHAT INFORMATION WOULD BE IMPORTANT FOR A CHILD TO MAKE THEIR DECISION.

What are the good things that can happen from this research?

FIRST EXPLAIN IF THE CHILD WILL BENEFIT FROM TAKING PART. THEN EXPLAIN HOW THE RESEARCH MAY HELP OTHER CHILDREN IN THE FUTURE. FOR EXAMPLE,

“What we learn in this research will not help you now. When we finish the research we hope we know more about XX. This may help other children with XX later on.

OR “This research may help you if the study drug makes you better. Since we are testing this drug, we don’t know if this drug will help you. What we learn may help other children later on with XX.

What are the bad things that can happen from this research?

DESCRIBE THE POSSIBLE RISKS AND DISCOMFORT THAT MAY OCCUR. SOCIAL OR EMOTIONAL RISKS NEED TO BE DESCRIBED AS WELL AS THE PHYSICAL RISKS. THE LANGUAGE SHOULD BE TAILORED TO YOUNG CHILDREN AND PROVIDE INFORMATION IMPORTANT FOR THE CHILD.

IT IS FINE TO EXPLAIN WHAT WILL BE DONE TO REDUCE RISKS, E.G., USING NUMBING CREAM BEFORE A BLOOD DRAW.

IF YOU ARE ASKING THE CHILD TO ANSWER SURVEYS OR QUESTIONNAIRES BE SURE TO DESCRIBE ANY DISCOMFORT OR EMBARRASSMENT THAT MAY OCCUR FROM ANSWERING QUESTIONS. EXPLAIN THEY DON'T HAVE TO ANSWER ANY QUESTIONS THEY DON'T WANT TO ANSWER. EXPLAIN IF YOU WILL SHARE THEIR INFORMATION WITH ANY OTHERS, E.G., THEIR PARENTS, THEIR DOCTORS, THEIR TEACHERS.

What else should you know about the research?

Being in the research is your choice. You can say Yes or No. Either way is OK. Whatever you choose, we will still take good care of you.

If you say Yes and change your mind later that is OK. You can stop being in the research at any time. If you want to stop, please tell the research doctors or nurses.

Take the time you need to make your choice. Ask us any questions you have. You can ask questions any time.

Signature of Researcher _____ *Date* _____

Child's Statement

The researchers have told me about the research. I had a chance to ask questions. I know I can ask questions any time. I want to be in the research.

Signature of child _____ *Date* _____

Signature of parent _____ *Date* _____

*Copies to: Child and Parent
Researchers*