

Seattle 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 her. *Assent* is defined as affirmative agreement by persons who do not have legal responsibility for their own activities, e.g., children and teens. In the research arena this means that the young person must verbally agree to take part in the study procedure and that failure to object alone does not constitute assent. *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 must seek assent only from all participants as required by the IRB. The team may not 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.

Dissent means to protest or disagree verbally or physically. When assent is required dissent is always respected. For example if a child agrees to be poked to gain blood for a research study but then pulls away when the provider approaches with the needle, the child is physically dissenting. The provider should ask the child if he or she has changed their mind, assuring them that it is okay to do so. If the child has changed their mind the sample cannot be collected. If the child decides that they do want to take part the provider can try to get the sample again explaining that if the child pulls away they are telling the provider that they do not want to have a poke at this time.

There are many times when dissent should be respected even when assent is not required, this is usually in the context of a research option where there is no prospect of benefit for the child. An example of this would be a blood draw for a research study where no potential benefit can be accrued to the child and the child is distressed with being poked.

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/parental permission form and can indicate written assent by signing the form as the research participant. The parent cosigns 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 (14-17years) refer to the information sheet Consent/Parental Permission 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.

Practical Pointers when presenting the option of research:

- Ensure parent/legal guardian has at least verbally agreed to the study before asking for assent
- Explain what research is—

e.g.) Research is a way to learn new things. In this research study we are learning about X. **We want you to ask us any questions that you have. You can ask us questions anytime you want to.**

There are a few things you should know about research studies:

- You get to decide if you want to be in a research study.
 - You can say 'No' or you can say 'Yes'.
 - Whatever you decide is OK.
 - If you decide say 'Yes', you can always say 'No' later.
 - No one will be upset if you say 'No'.
 - We will still take good care of you no matter what.
- Use age appropriate language to let them know what taking part in the study would mean for them. e.g.) If you say yes you want to be in the study we would take a little bit of your blood. This means we would poke you with a small needle. It will hurt a little bit but we can use a special crème that will help it not hurt as much.
 - Assess your explanation by talking with the young person
 - Ask them if they would like to be in the study
 - Respect their decision