

**Seattle Children's Hospital Institutional Review Board  
Information Sheet  
Consent, Assent (generally 14 and above) and Parental Permission Form Preparation**

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The consent, assent and parental permission form is a written summary of the communication taking place between the researcher, the research participant and often the parent or guardian. It does not take the place of personal interaction between the participant, the family and the researcher, but it may serve as a catalyst for discussion about the research and the option of taking part in it.

Informed consent, assent and parental permission is much more than a signature on a form. It is a continuing discussion and should be an ongoing process. This is especially true when study participation spans several months or years. Researchers need to take steps to review with the participant and the family the elements of informed consent described at the time when the parent and/or participant signs the form.

**BEFORE** any research procedures are done, signed and dated consent/assent must be obtained from a) participants and b) if participant is a minor (under 18 years), their parents/guardians. The member of the research team obtaining consent, assent, and/or parental permission must also sign and date the form.

[Note: As the researcher is required to provide the information the participant or parent needs to make an informed decision, the researcher needs to sign and date the form **prior** to the signature and date the parent and/or participant signs.]

The form must contain the information necessary for the research participants (or their representative, e.g., parent) to make an informed decision about taking part in the research. It must also contain the information required by the federal regulations and institutional policy. The template contains these sections.

The language and syntax of the form should be directed to the reader at the eighth grade or lower reading level. Scientific or medical terminology should be defined, if used, and avoided when possible. It is important to remember that people who use medical terms in conversation may not really understand their meaning. It is best to use lay language whenever possible.

The Children's IRB requests that consent forms adhere to a standard format, as shown in the template consent, assent and parental permission form. The template contains all the required elements and is written at a 6-8th grade reading level. Use this template, adding information specific to your research study. When preparing and reviewing the form for your research project, consider the following tips from PRISM Readability Tool Kit Quick Reference Guide for Improving Readability ([http://www.grouphealthresearch.org/capabilities/readability/readability\\_home.html](http://www.grouphealthresearch.org/capabilities/readability/readability_home.html))

**Guiding principles of plain language include:**

- Use language your audience can easily understand. Read your document out loud to assist you in this process.
- Write in a conversational style, as if you were speaking.

- Organize and filter content with your readers' needs in mind.
- Use reader-friendly formatting so that your document *looks* easy to read.

**The following specific strategies will help you adhere to these principles:  
Check the reading level.**

- Test Readability. \* 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 paragraph, a section, or the entire document.
- Be aware that getting a "good score" is not a guarantee that your document is easy to read.

**Choose common, everyday words.**

- Replace multi-syllable (or short but complex) words with simpler vocabulary. Avoid research and medical jargon whenever possible. If you must use a complicated term, define it in plain language and provide an example, an analogy, or a visual aid.
- Refer to the [Glossary](#) and [Language Resource Text](#) for assistance.

**Write in the first-person.**

- Use pronouns, such as "I," "we," and "you."

**Keep sentences short and to the point.**

- Break up sentences joined with conjunctions or semicolons. Its okay to begin a complete sentence with "And" or "But."
- Try to vary sentence length. Sentences should average 15 words or less.

**Limit paragraphs to one main idea.**

- Start with a clear and concise topic sentence. Remove or relocate details that do not relate to the central topic. A paragraph of 1 or 2 sentences is okay.

**Use clear and descriptive headings.**

- Meaningful headings that describe the content of different sections will give your readers "road signs" and help them navigate your document more easily.
- Use large font, bold, or other emphasis to ensure the headings stand out.