

Children's Hospital Institutional Review Board

Information Sheet

Consent Form Preparation

The consent form is a written summary of the communication taking place between the researcher and the research participant. It does not take the place of personal interaction between the participant and the researcher, but it may serve as a catalyst for discussion about the research and participating in it. Consent can be an ongoing process. When study participation spans several months or years, researchers need to take steps to review with the participants the elements of consent described at the time of signed consent.

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

The consent 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 Consent Form and Assent Form Checklist under Forms, Consent and Assent Forms, lists the federal and institutional requirements for consent forms.

The language and syntax of the consent 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 [sample consent form](#). The sample consent form contains all the required elements of consent and is written at a 6-8th grade reading level. Use this form as a template, adding the information specific to your research study. When preparing and reviewing the consent form for your research project, consider the following tips:

- Use lay language.
- Use short sentences.
- Use the active voice.
- Use 12-point font for readability. Fonts with serifs are considered easier to read.
- Provide sufficient space in the margins and between paragraphs.
- Use simple visual aids, e.g., tables, diagrams, pictures, flow charts, if appropriate.
- Provide the IRB with the readability score* of your consent form.

* 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.