

Instructions for Informed Consent/Assent

Writing your consent forms starts with downloading the templates. You will need:

- A Parent Consent form
- A Child Assent form if you plan to enroll children ages 7–12
- Or an Adolescent Assent form for subjects ages 13–17
- Bill of Rights/Teen Bill of Rights except for the Child Assent
- See Forms

Subjects who are age 18 and older are considered adult subjects unless they are mentally disabled or incapable of giving legal consent.

Here are the basic things you need to remember when writing a consent form:

- Write to a 13 year old reading level—think high school freshman
- No technical language - say what the word means
- You can use the medical/technical work in parenthesis
- Use bulleted lists where ever possible
- Use short, direct sentences and brief paragraphs
- Use a lot of white space; it's easier to read
- Do NOT right justify; left justify only Adolescent Assent Form (See Forms)

This form is almost just like the parent form. If you've written the parent form to a 13 year old reading level you won't have to make a lot of changes. If you do find yourself making a lot of changes, your parent form is too advanced and should be simplified. For the adolescent assent you need to write in the "you" tense, speaking directly to the teenager. Do not include statements under the Injury clause about who has to pay for what costs; the teenager won't be paying for anything and this information should be excluded.

Otherwise, follow the parent consent tips and keep the language simple, direct and straight forward.

Assent Form

- Use a separate form for children ages 7–12
- Adolescent assent may be a separate form or it may be a signature line on the parent form
- Only talk about what will happen that is research related
- Use very simple words and concepts
- Always say that no one will be mad if the child says no
- If the child will be getting some type of treatment regardless of the research, you can tell them so in the assent
- Always use check off boxes for yes or no
- Children under the age of 7 do not need a form to sign, but active agreement should be sought where appropriate
- The assent form for ages 7–12 should be one page, unless you really can't fit it all on a single page.

Always Remember: Consent is not a single event that happens once at the beginning of a study. It is a process that lasts through the entire study.