



FRANCISCAN MISSIONARIES OF OUR LADY UNIVERSITY

Guidelines for Parental Consent and Assent for Minors

Children are considered a vulnerable population. Researchers must take particular care to ensure their rights as research participants are protected.

Unless otherwise specified, the child's parent (one or both) or legal guardian must give consent before a child is permitted to participate in a research study. Furthermore, even if the parent consents on behalf of the child, the research cannot take place unless the child gives *assent* to participate.

What is Assent?

- Assent refers to a child's agreement to participate in a research study.
- Children must be old enough to understand what will happen and what they will be expected to do.
- Encourages the child to ask questions.

The language used in the assent process must be age appropriate. For example, an assent form written for a seven-year-old child would not be detailed enough to explain a research study's potential risks and the participant's rights fully and clearly. Thus, it would not be adequate to serve as a means of obtaining informed consent. Furthermore, a seven-year-old child would not necessarily have the cognitive ability to fully understand the concept of informed consent. Therefore, assent, plus parental informed consent, would have to be sufficient.

Age of Minor Participant	Assent Form Recommended?	Separate Parental Permission Form Recommended?
Infant-6 years old	No	Yes
7-12 years old	Yes	Yes
13-17 years old (Option A)	Yes	No. Create a single document addressed to the adolescent with signature lines for assent and parental permission
13-17 years old (Option B)	Yes	Yes

An effective informed consent process involves, at a minimum, the following elements:

- Conducting the process in a private location
- Providing adequate information
- Answering participants' questions

- Ensuring participants understand the information provided
- Obtaining voluntary agreement to participate (i.e., assent)
- Continuing to provide information as required

One or Both Parents?

- Some projects would require both parents' consent, while others would only require consent from one parent.
- If both parents are available to provide consent, researchers should seek consent from both parents
- One-Parent Consent
 - Minimal risk protocols
 - Greater than minimal risk, but provides a direct benefit to the child
- Two-Parent Consent
 - Greater than minimal risk
 - Research not otherwise approvable, but could significantly address a serious problem threatening the health and welfare of children
- What if Parents Disagree?
 - The child cannot participate in the research study unless disagreement can be resolved.
 - Applies to all permissible categories, even if only one parent's signature is required.
 - If a parent was not involved or was unavailable for the original consent later becomes involved or available, the two parents must agree.
 - In the state of Louisiana, when parents disagree, the father's choice prevails.