

St. Luke's Health System  
Institutional Review Board Review (IRB)

Considerations and directions for obtaining assent.

**Assent is required for all children from the age of 10 up to 18.**

- A. Obtaining assent is an interactive, instructional process involving the investigator, child, and parent(s)/guardian(s). The goal is to assure that the child's participation is voluntary and is based on at least a simple understanding of the study purpose, procedures, and possible harms and benefits, of participating in this study.
- B. Investigators should use a question and answer format when obtaining assent, e.g., "These are some questions you may have about this study. If you do not understand the questions or answers, or have other questions, please ask me or your parents."
- C. To assure understanding, investigators and parents are encouraged to ask the child to answer each of the six questions to clarify or correct any misunderstanding *before* asking for the child's signature.

- 1. Why are we doing this study?**
- 2. What will happen to you if you are in the study?**
- 3. What things are going to happen that you might not like?**
- 4. What are the good things that might happen?**
- 5. Is it OK to say No to your parents or your doctor about being in the study?**
- 6. If you are in the study is it OK to say you want to stop?**