Guidance for Developing and Using an Assent Form

1. What is an Assent Form?

An Assent Form is a simple document used to provide affirmation that a minor is voluntarily participating in research. Assent Forms should be used for younger children as per the discretion of the Researcher. Some minors (e.g. 7 and younger) may not be able to read, understand, and evaluate an Assent Form, whereas an older minor (e.g. 15 or older) may be able to read, understand, and evaluate an adult Consent Form. The IRB application should clearly indicate which forms minor participants will be using throughout the study.

2. What are key requirements for developing an Assent process?

- All Assent Forms must be approved by the IRB prior to use. Any revision to an approved Assent Form must be approved by the IRB prior to use.
- All Lindenwood University researchers must use an assent form with the "Lindenwood" header unless negotiated prior to submission with the LU IRB.
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- Please refer to LU Health and Research Literacy Resources on the LU IRB website for additional resources for developing materials for your participant population.

3. How do I use an Assent Form during the recruitment process?

- Overall, an Assent Form provides information a minor participant would want to know as they are considering participation in a research study. An assent form is not a contract, it is the record of an ongoing conversation about assent between a researcher and a minor participant.
- Research teams should secure a private location to conduct the assent process, create time for potential participants to consider the study, and provide space to ask questions.
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- When describing risks:
    - All risks listed must match risks described in the IRB application.
    - Use bullet points to categorize risks by type and severity (e.g. "Confidentiality, Psychological Harm, Radiation Exposure").