Guidance for Developing and Using an Assent Form

Researchers are required to obtain signed Assent from all minor participants unless determined otherwise by the IRB. This guidance provides essential tips for completing and using Lindenwood University Assent Form templates.

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.
- You may choose one of the following options for obtaining signatures from minors during the Assent process:
    - Obtaining only verbal assent, as the minor may be incapable of providing written documentation. In this case, the research record must include a note to file describing the minor's positive affirmation. This record will serve as a written documentation as to why the researcher feels assent was properly obtained.
    - Obtaining verbal assent or written assent depending on the researcher's judgment of the capacity of the minor. In this case, the Assent Form should include signature blanks for the minor participant to complete when applicable. If the researcher determines that the minor may not be able to fully complete the Assent Form, the research record must include a note to file describing the minor's positive affirmation. This record will serve as a written documentation as to why the researcher feels assent was properly obtained.
    - Obtaining only written assent. In this case, the Assent Form should include signature blanks for the minor participant to compete.

- In most cases, an adult Consent Form for Parents or Legal Guardians to provide consent on behalf of minors will also need to be used during the Assent process. There are cases in which an older minor (e.g. 15 or older) may be able to provide Assent in an Assent signature block on this same adult Consent Form.

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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.
- The researcher may not make any hand-written marks on the Assent Form except for signatures, printed names, and dates. Research teams may not highlight, underline, or make additional comments on this form.
- It is best practice for a researcher to complete a note to file to be retained with the Assent Form to record any additional information about the consent process.

4. How do I complete an Assent Form template?

- All text in [Orange] are instructions and should be deleted before submitting an Assent Form for approval.
- Include Page Numbers if using a paper consent form.
- Information in the header or footer of an approved Assent Form may not be altered in any way.
- Any template language must not be altered. All spaces in **[**Brackets**]** must be completed or revised by the Researcher. These spaces should:

    - Be written in simple language, with the target of a 3-5th grade reading level.
    - Use "you" to address the participant.
    - Define any technical words or concepts in layperson terms.
    - Do not use acronyms.
    - Use the active voice, telling participants: "*You will respond… You will watch*," rather than the passive voice: "*Answers will be given… Videos will be watched*."
    - Use short and simple sentences presenting one concept or instruction at a time.
    - Break information into small paragraphs of several sentences each.
    - Maintain the template 12 pt. Arial font.

- When describing study procedures:

    - Provide a brief narrative of participant involvement, from start to finish.
    - Describe all procedures in chronological order.
    - Use bullet points to create lists when multiple procedures will be performed during single study visits.
    - Feel free to use boxes to organize information, and images or diagrams to describe procedures.

- 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*").