

<u>Sample Child/Minor Assent—Written and Signed Assent</u> A letter to the participant may be substituted for this form

The IRB suggests that investigators utilize a written and signed child assent form for older children/minors (in addition to obtaining parental consent). When drafting a written assent form, investigators may find it helpful to create a simplified version of an adult informed consent document, appropriate for the reading level of the subjects. Using simple language, short sentences, and bulleted points is also helpful; however, investigators should be aware that using language that is too simple or using the terms "children" or "child" (i.e. child assent form) may offend teenagers. The sample assent form below should be tailored appropriately.

NOTE: Remove instructions (in Italics) in the final copy. Copy submitted to IRB should appear as it

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ASSENT FORM

[Insert Study Title]

You are being asked to be part of a project. You are being asked to take part in this study because [insert reason for inclusion.] The project is about [insert general statement about study]. Your parents have already been told about this project. Please read this form and ask the researcher [or teacher, if appropriate] any questions you have. It is your choice to be part of the project or not. About [insert number of participants] will take part in this study.

[Insert "this study is being done as part of the requirements for my _____degree at Lourdes University in Sylvania, Ohio." or "this study is being done by researchers at Lourdes University in Sylvania, Ohio.]

PROJECT INFORMATION

- The purpose of this study is to [insert the research question and purpose in simple terms]
- If you agree to be in the project you will be asked to do the following things. [In simple terms, describe what participants will do (participate in an interview(s), answer questions on a survey, special tests, etc. List EVERYTHING the subject will be asked to do.
- This will take approximately [indicate duration of time involved.. (Indicate amount of time at each contact and total length of time for all contacts; e.g., "for each interview for a total of_____."]
- [For randomized studies, list the study groups and under each describe categories of procedures.]
- <u>If applicable</u>, explain any expected risks or discomforts a subject may experience. Risks may be physical, emotional, risk of embarrassment, an uneasy feeling, etc.
- <u>If applicable</u>, explain benefits of participation that will be gained by the participants or others (Note: compensation is not a benefit).
- <u>If applicable</u>, explain the compensation which is reasonably expected such as extra credit, food, gift certificate.

- <u>If applicable</u>, list any alternatives to the study (i.e. subject may choose to do an alternative class assignment for extra credit instead of participating in the project.)
- <u>If applicable</u>, explain any special situation under which you would stop the subject's participation.

PRIVACY

- <u>If applicable</u>, state that while participating in this study has very little risk; there is always a slight risk of loss of confidentiality.
- The researcher will [explain what specifically will be done to maintain confidentiality, for example it will be viewed only by the researcher and will be kept in a locked file.]
- After the study is completed, any information will be destroyed. [Explain how and when]
- No names will be included in any reports written about the project.
- *If applicable*, state that teachers and classmates will not see the information you give.
- <u>If applicable</u> (for class instructors), state that assent forms will be kept in a sealed envelope and not viewed until grades are posted to address potential coercion.
- <u>If applicable</u>, explain how data and/or assent forms will be distributed, collected, returned, and handled to ensure privacy (i.e. will assent forms or surveys be sealed by subjects in separate envelopes before they are returned, etc.)
- <u>If applicable</u>, state how tape or video recordings will be made and used, who will have access to them, and when they will be erased or destroyed.
- If applicable (for focus groups) state that while participating in this study has little risk, there is always a risk of loss of confidentiality. Other participants in the focus group will be aware of your comments. The researcher will keep notes of the discussion and will take precautions to maintain the confidentiality of your information in his/her possession. It will be viewed only by the researcher and will be kept in a locked file. After the study is completed, any identifying information will be destroyed.

THIS PROJECT IS VOLUNTARY

- This project is voluntary.
- There is no penalty or any bad feelings about you if you choose not to be in the project.
- Once you start the project you are always free to stop at any time.
- Even if your parents gave their permission, you can still decide not to be in the project or to stop at any time. The researchers will respect your decision.
- <u>If applicable</u>, add a statement about loss of benefits such as "You will not lose your extra credit if you choose to stop" or "If you decide to stop it will not affect your grades."
- <u>If applicable</u>, state that a subject may skip any questions they do not feel comfortable answering.
- <u>If applicable</u>, state that the subject may request the audio or video tape to be turned off at any time.

QUESTIONS?

- The researchers conducting this project is/are [Responsible Investigator, co-investigator, faculty advisor as applicable] from Lourdes University, Sylvania, Ohio.
- You may ask questions before you take part in the project. [State who will be available to answer questions, when this person will be available, or if appropriate, how to contact the person]

Institutional Review Board Administrator
Lourdes University
6832 Convent Boulevard
Sylvania, Ohio 43560
irb@lourdes.edu

OR
Barb Tassell DNP, RN, EBP-BC, NPD-BC
Chairperson, Institutional Review Board
btassell@lourdes.edu

You or your parents may also contact the Lourdes University Institutional Review Board:

RETURN INSTRUCTIONS

• Add any other instructions such as how to return the survey or consent forms (i.e. seal the consent form in the self-addressed envelope provided, return the survey to the instructor, etc.)

A COPY OF THIS ASSENT IS BEING GIVEN TO YOU

Please complete the form below if you want to be part of the project.

I want to be part of this project:		
Name (Please Print):		
Signature:		
Date:		
INVESTIGATOR ASSURANCE I have given the participant an opportunit	ry to ask questions about the research.	
Investigator	Date	
Investigator Name Contact Information	Faculty Supervisor Contact Information	

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