

APPENDIX D

ASSENT FORM

What is assent?

Assent is defined as an “agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.”

(IRB Guidebook: http://www.hhs.gov/ohrp/irb/irb_glossary.htm).

When is assent generally required?

- Participants are minors between the ages of 7 and 17. Children below the age of 7 are generally not asked to provide assent.
- Participants 18 or older who are intellectually or emotionally impaired and not legally competent to give their informed consent.

Is a separate assent form needed?

- Minor participants who are able to read and understand the Informed Consent Release (parent's permission form) may provide assent on that form with a separate signature line.
- Minor participants (aged 7 or older) who are too young or intellectually immature to read and understand the parent's permission form should be given the opportunity to provide written agreement on the Assent Form.
- Adult participants (18 or older) who are not legally competent to complete this Informed Consent Release should be given the opportunity to provide the Assent Form.

Language Level

- Write the form using language that is appropriate for the age level and mental capacity of the participant.

What should be included in the Assent Form?

1. Title of Study.
2. Purpose of Study - Provide a brief explanation, in non-technical language, of what the study is about.
3. Procedures - Describe what the participant is being asked to do.
4. Withdrawal privilege - Describe how a participant can stop participation at a later time even if s/he agrees to start presently.
5. Voluntary participation - Include a statement which indicates that the participant does not have to participate in the study.
6. Confidentiality - Indicate that the investigator will not tell anyone (e.g., parents, teachers) what the participant says or does in the study.
7. Signature lines - Include a signature line for the participant and for the investigator. Be sure to include a date line as well.

SAMPLE ASSENT FORM

Example - Exercise And Nutrition Study

“My name is *(give your name)* and I work at the University of Mary Washington.

“I am asking you to take part in this research study because I am trying to learn more about exercise and nutrition. I want to learn about the types of exercises kids your age do and what kinds of food they eat.

“If you agree, you will be asked to complete a survey. You will be asked how often you exercise and what kind of exercises you do. You will also be asked the kind of foods you eat. You will be asked to give us your height and weight. Answering these questions will take about 20 minutes. You do not have to put your name on the survey.

“You do not have to be in this study. No one will be mad at you if you decide not to do this study. Even if you start, you can stop later if you want. You may ask questions about the study.

“If you decide to be in the study I will not tell anyone else what you say or do in the study. Even if your parents or teachers ask, I will not tell them about what you say or do in the study.

“Signing here means that you have read this form, or have had it read to you, and that you are willing to be in this study.”

print participant's name _____

signature of participant _____

signature of investigator _____

date _____