ASSENT

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

Is a separate assent form needed?
- Minor subjects who are able to read and understand the informed consent document (parent's permission form) may provide assent on that form with a separate signature line.
- Minor subjects (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 assent on a simplified assent form.
- Adult subjects (18 or older) who are not legally competent to give their informed consent should be given the opportunity to provide written assent on a simplified assent form.

What should be included in the assent form?
- Study Title
- Study Purpose-Provide a brief explanation of the purpose of the study.
- Procedures-Describe what the subject is being asked to do.
- Withdrawal privilege- Describe how a subject can stop participation later even if he/she agrees to start.
- Voluntary participation- Include a statement that the subject does not have to participate.
- Confidentiality-Indicate that the experimenter will not tell anyone (parents, teachers) what the subject says or does in the study.
- Signature lines-Include a signature line for the subject and for the investigator. Be sure to include a date line as well.

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

ASSENT FORM

Title of Project:
Researcher:
Contact Information
Faculty Advisor:
Department:
Contact Information:

Invitation to Participate: (State that the respondent is being invited to participate in a research study. State what you hope to learn)
Purpose of Study and Procedures: (Describe in detail the purpose and potential goals of the study in a language that your audience can understand. Avoid using technical language that might confuse your audience. Describe in detail the procedures to be followed, including their purposes, how long they take and their frequency. Describe the discomforts and inconveniences reasonably to be expected and estimate the total time required)

Potential Risks/Benefits: (Describe the risks and benefits reasonably to be expected. Do so in a manner that is easy for your participants to understand)

Participation/Withdrawal Statement: (State that participation in this research study is completely voluntary. If they do not want to participate they don't have to. If at any time they decide that they do not want to participate in this study, their participation will be withdrawn without penalty.)

Confidentiality: (Describe how participation and records will be kept confidential (i.e. lock and key for 5 years with faculty advisor). Might want to consider including a sentence defining what is meant by confidential. Indicate that the experimenter will not tell anyone (teachers, parents) what the participant does or says in the study.)

Agreement to Participate: (Include statement asking respondents to please sign and print your name where designated below if they agree to take part in the study. Remind them that their signature indicates that they have read the information in this document or had it read to them, and that they are willing to take part in this study.)

_____ _____

Signature of Respondent Date Signature of Primary Investigator Date

_____ _____

Printed Name of Respondent Date Printed Name of Primary Investigator Date