Assent is defined as the affirmative agreement by a child or an adult who lacks full decision-making capacity to participate in a research or clinical investigation. Mere failure to object may not, absent affirmative agreement, be construed as assent [45 CFR §46.402(b) [21 CFR §50.3(n)]. Investigators are responsible for preparing assent forms that fit children's/adults' ages and research circumstances and for explaining the rationale for desired procedures to the IRB. IRBs are charged with considering the nature of the proposed research, the ages, maturity, and psychological state of the prospective participants, whether obtaining assent is appropriate, whether the person's assent should be documented, and the form and content of the information to be conveyed to the prospective participants. Decisions about appropriate assent requirements require considerable judgment and tolerance for variations from any arbitrary norm.

Resources: See GUIDANCE: Pediatric Research “Assent” Decision Matrix” for full details. The UA IRB uses this guide for assent by adults as well as by children. IRB members and investigators are also referred to http://www.hhs.gov/ohrp/researchfaq.html for other information on assent.

The purpose of this document is to provide general guidelines for assent and two examples. These are only guides, as assent is highly situation-specific.

1. Assent documents should be shorter and simpler than a consent form. Unless the children are nearly of legal age, do not follow the template for informed consent. Reading level is especially important in these documents.

2. The key elements to appear in an assent form are:
   a. I/We are doing a study . . .
   b. We want to learn more about/how—how first graders learn to read/ how kids with diabetes do or do not take care of themselves when out with their friends/how adults with Down Syndrome like their jobs and try to do well.
   c. We are asking children/adults to—play some computer games with pictures, numbers, and letters/watch some videos about kids doing right
things and wrong things and tell what you would have done/tell us what you do about eating and testing your sugar when you’re hanging out with friends/tell us what you like and don’t like about your job and how you try to be a good worker on your job.

d. These games.this talk/this meeting will take about X minutes/hours

e. Your mother/father/family/name of LAR knows we are asking you to do this and it is OK with them.

f. No one will be able to tell what you said or did during this study. We will only talk about all the kids/people together so no one knows who you are. (Or, we will not tell your parents/your teachers (specific category of person) what you said.

g. If something makes you feel bad while you are in the study, please tell (name). You do not have to finish the study. You can stop whenever you want—just tell us.

h. You can ask me/other person or your parent(s)/LAR questions about this study right now or at any time.

i. If child cannot read or write) Do you think you would like to be in this study? Record YES or NO on assent sheet.

j. (If child/adult can write and written documentation is required) If you want to be in this study, please write your name/make an X on this line.

k. Risks and benefits—Varies with age or capacity of child or adult. For very young children, saying “most kids think this is fun” or “this will not hurt” or “you may get bored/tired” will probably do. Older children and adults need an age/capacity and protocol-specific explanation.

Example 1

First graders, one research encounter. No direct benefit to child. To be read to children. Reading level is 2.1; first graders can understand this when read to them.

Hi, (Child’s name). My name is _______. I go to school at the University of Alabama. I am doing a study of how kids in first grade learn new words. You are in first grade so I am asking you if you would like to be in my study.

Here’s what will happen. You and I will go into a small room with a computer. You will play some computer games where first you match sounds and letters and then you
match words and pictures. It will take about 30 minutes. Most kids think the games are fun.

Your parents know I am asking you to do this and it is OK with them.

Nobody but me will know what you did on the computer games. I will not tell your parents or teachers.

If something makes you feel bad while you are playing the games, please tell me. If you decide you do not like the games, you can stop playing anytime.

Do you have any questions about this? You can ask me right now.

Do you think you would like to play my computer games? YES NO

______________________________________________ DATE________
Signature of Person Obtaining Assent

Example 2

*Middle school children with diabetes (ages 11-15), multi-session study. Possible benefit to child. To be read by children and discussed with them. Reading level is 6.2.*

Dear Student:

I am from the University of Alabama. I am doing a study of how kids with diabetes in middle school decide how to take care of themselves when they are out with their friends. I would also like to know how much their ideas change over time and whether kids think it helps to discuss their problems with diabetes with other kids. This study will help nurses and doctors understand what life is like for kids your age with diabetes. Maybe we can learn some new ways to help kids make good choices about taking care of themselves.

Your parents gave me your name in response to a newspaper ad about the study. They know we are asking you to be in this study. It is OK with them. I am asking about 60 other middle school kids with diabetes from 3 Alabama counties to be in this study.
If you decide to be in the study, you will first fill out a questionnaire about your diabetes. It asks what you know about diabetes, what you do to take care of yourself, your usual blood sugar readings, your medicines, and how confident you feel about taking care of yourself. Then you will be in a discussion group at school (before or after classes) with about 4-6 other kids your age. You will be asked to talk about common situations you have to deal with, like whether and how to tell friends you have diabetes, going out to eat with friends, going on dates with a new person, and playing sports. We would like to know how you handle these things, whether the choice worked out well, and how hard the choice was. After each meeting you will be asked to rate how helpful the discussion was to you. These discussion groups will take place every six months for two years—four times in all. We will call you to remind you of each meeting. There will be two meetings at each school in hopes that you can get to one of them. Each one will last about an hour. At each meeting there will be healthy snacks and drinks, and you will receive $10 as a thank you for your time. If you do all four meetings, you will earn $40.

We will tape-record the meetings so that we have an accurate record of the discussion. These tapes will be typed up after the meeting but no names will be used. The tapes will be destroyed as soon as the typed record is made. If you do not want to be in a tape-recorded discussion, you should not be in this study.

We will not tell anyone outside the study what you or any other particular person said. We will write a report on the study that just talks about what the group said or didn’t say, but no one will be able to recognize you. We will ask kids in the groups not to talk about what was said outside of the meetings (to keep the discussion confidential) but we cannot promise this. You can control this by not saying something you would not want to have repeated. We will not tell your parents or teachers what you said.

You are a volunteer. You are helping us but you do not have to unless you want to. This is your free choice. If you start the study and decide you don’t want to continue, just let me know. No one will be mad at you. If you do not want to talk about a certain topic in the discussions or answer a certain question, you do not have to.

We do not think there are any risks or harm to you in this study. You may find the discussions helpful to you or it may make you feel good to know you are helping us to help kids with diabetes in the future.

If you have any questions about this study, please ask me now. If you have questions later, you can call (name) at the University of Alabama at (phone). You can also ask your parents questions if you wish. If you have questions or concerns about your rights in a research study, please contact Ms. Tanta Myles, the University of Alabama Research Compliance Officer, at (205) 348-8461.
If you agree to be in this study, please sign your name on this letter below. You can have a copy of the letter to keep.

Thank you very much for your interest.

Sincerely,

Investigator

_________________________________________________________________________  __________
Name of Participant              Date

_________________________________________________________________________  __________
Person Obtaining Consent         Date