Assent is “a child’s affirmative agreement to participate in research.” 1 {sec. 402 (b), 2{sec. 50.3(n)}. A researcher should provide opportunities to children to express and discuss their willingness or unwillingness to participate.

Things to remember:

1. A child’s passive resignation to submit to an intervention or procedure must not be considered assent.
2. The assent process should be developmentally appropriate.
3. Assent should be obtained from children 7 years and above
ASSENT FORM

TITLE OF RESEARCH: ................................................................................................................

INVESTIGATOR(S): .................................................................................................................

The investigators named above are doing a research study.

These are some things we want you to know about research studies:
We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things.

Whether or not to be in this research is your choice. You can say Yes or No. Whatever you decide is OK. We will still take good care of you.

Why am I being asked to be in this research study?
You are being asked to be in the study because .................................................................

What is the study about?
The ..........................................................................................................................................

What will happen during this study?
If you agree to be in this study, you will
• Have ...
• Take ...
• Get ...

Will the study hurt?
Some of the tests might hurt. ..........................................................

What else should I know about the study?
................................................................................................................................................

What are the good things that might happen?
People may have good things happen to them because they are in a research study. These are called “benefits.” ..........................................................

What if I don’t want to be in this study?
You do not have to be in the study if you do not want to. ....................................................

Who should I ask if I have any questions?
If you have any questions about this study, you or your parents can call ..........................

Do I have to be in the study?
No, you do not have to be in the study. Even if you say yes now, you can change your mind later. It is up to you. No one will be mad at you if you don’t want to do this.