***Page 15 of 20 SOP 1201: Vulnerable Subjects in Research*2.6.2.2 Assent from Children**

The IRB is responsible for determining that adequate provisions are made for soliciting the
assent of the children, when in the judgment of the IRB the children are capable of providing
assent. This judgment may be made for all children to be involved in the study, or for each
child, as the IRB deems appropriate.

When the IRB determines that assent is not a requirement of some children, the IRB determines and documents which children are not required to assent. When the IRB determines that assent is not a requirement for some or all children, the IRB determines and documents one or more of the following:

• The children are not capable of providing assent based on the age, maturity, or
psychological state. UNC does not require written assent from children six years of age or younger.
• The capability of the children is so limited that they cannot reasonably be consulted.
• The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.
• Assent can be waived using the criteria for waiver of the consent process.

 It is important to note that the FDA regulations do permit the IRB to waive the assent
requirement if it finds and documents that:

 1. The clinical investigation involves no more than minimal risk to the subjects;

 2. The waiver will not adversely affect the rights and welfare of the subjects;

 3. The clinical investigation could not practicably be carried out without the waiver; and 4. Whenever appropriate, the subjects will be provided with additional pertinent
information after participation.

 Because “assent” means a child’s affirmative agreement to participate in research, the child
must actively show his or her willingness to participate in the research, rather than just
complying with directions to participate and not resisting in any way.

 The IRB should take into account the nature of the proposed research activity and the ages, maturity, and psychological state of the children involved when reviewing the proposed assent procedure and the form and content of the information conveyed to the prospective subjects.
For research activities involving adolescents whose capacity to understand resembles that of adults, the assent procedure should likewise include information similar to what would be
provided for informed consent by adults or for parental permission. For children whose age and
maturity level limits their ability to fully comprehend the nature of the research activity, but
who are still capable of being consulted about participation in research, it may be appropriate
to focus on conveying an accurate picture of what the actual experience of participation in
research is likely to be (for example, what the experience will be, how long it will take, whether
it might involve any pain or discomfort). The assent procedure should reflect a reasonable
effort to enable the child to understand, to the degree they are capable, what their
participation in research would involve.

Parents and children will not always agree on whether the child should participate in research.

Where the IRB has indicated that the assent of the child is required in order for him or her to be
enrolled in the study, dissent from the child overrides permission from a parent. Similarly, a
child typically cannot decide to be in research over the objections of a parent. There are
individual exceptions to these guidelines but in general, children should not be forced to be
research subjects, even when permission has been given by their parents.

**2.6.2.2.1 Documentation of Assent**
When the IRB determines that assent is required, it also is also responsible for determining
whether and how assent must be documented. When the research targets the very young
child or children unable or with limited capacity to read or write, an oral presentation
accompanied perhaps by some pictures with documentation of assent by the person obtaining
assent in a research note is likely more appropriate than providing the child a form to sign. In
this case, the investigator should provide the IRB with a proposed script and any materials that
they intend to use in explaining the research.

When the research targets children who are likely able to read and write, investigators should propose a process and form that is age appropriate and study specific, taking into account the typical child's experience and level of understanding, and composing a document that treats the child respectfully and conveys the essential information about the study. The assent form should:

1. Tell why the research is being conducted;

2. Describe what will happen and for how long or how often;

3. Say it's up to the child to participate and that it's okay to say no;

4. Explain if it will hurt and if so for how long and how often;

5. Say what the child's other choices are;

6. Describe any good things that might happen;

7. Say whether there is any compensation for participating; and 8. Ask for questions.

Whenever possible, the document should be limited to one page. Illustrations might be helpful,
and larger type and other age appropriate improvements are encouraged when they have the
potential to enhance comprehension. Studies involving older children or adolescents should
include more information and may use more complex language.