Commonly asked questions regarding assent

1. Does CGIRB have a template assent form?
In September 2011, CGIRB released a new template assent form. Click here to view.

2. What is the age for written assent?
The regulations do not require the documentation of assent (i.e. a signed assent form), however the IRB has the discretion to determine when written assent is required. These decisions are based on the age, maturity, and degree of literacy of the subject.

In general, CGIRB does not require a signed assent form for children under the age of 10. CGIRB will determine what type of assent process is appropriate depending on the subject population, and this information is communicated to the sponsor as part of the initial review.

3. Do parents need to sign the assent form in addition to children?
Parents are not required to sign the assent form that is signed by the child.

The regulations require a signed permission form from the parents of pediatric subjects when the research involves more than minimal risk. CGIRB generally reviews a separate Parental Permission form for nearly all research studies involving children, regardless of the risk determination.

As part of the initial review process, CGIRB determines whether the permission of one parent or both parents is appropriate for a study, and this is also communicated to the sponsor as part of the initial review.

4. Should older children read and sign the Parental Permission form?
In the FDA Information Sheets, the FDA acknowledges that older children may be well acquainted with signing documents through prior experience. Therefore, signing a form to give assent may be appropriate for an older child.

In some cases, the IRB may determine that older children can sign a separate assent section at the end of the Parental Permission Form, or the IRB may request that older children be offered a copy of the Parental Permission form to read in addition to the assent form. The IRB will make this determination at the time of the initial review.

5. What assent process should be used when the study population cannot provide written assent (i.e. children with severe disability or disease).
If the pediatric subject population is generally not able to read and sign an assent form, there should be a process for documenting that assent took place. One method that is used is to have an independent third party verify, by signature, that the assent of a child was obtained.

The IRB may also decide in some cases that documentation of assent is not warranted, for instance, if the capability of some or all of the children is so limited (infants or toddlers) that it prohibits obtaining assent.

*******Remember, obtaining assent is a process. Researchers should consider issues of privacy, such as allowing the opportunity for older children to converse with the person obtaining assent one-on-one.***