Assent Overview

Ascertaining how to best include children in research decisions is one of the most challenging aspects of research ethics and one that generate significant discussion at REB meetings. Two of the cornerstone ethical principles are respect for the person (and that include children) and the expressed consent. One of the best guidelines in that regard are those of the assent task force of the Children's Oncology Group (COG) (attached).

This is what the guidelines are saying about documentation of assent:

Documentation of assent: Investigators should describe the child's role in the decision-making process in a note documenting the consent discussion. This description should include whether assent was sought, and if so whether it was granted. If the investigator did not seek assent, the note should justify this decision. Such documentation is preferable to a requirement for signed assent, because it allows the necessary flexibility and adaptation to circumstance while permitting IRBs and others to hold investigators accountable for the appropriate inclusion of children in research decisions

The role of older adolescents in decisions about research: Though the data are imperfect, it appears that under optimal circumstances older adolescents can make decisions about research participation based on a level of comprehension approaching that expected of adults. When adolescents are able to participate in the decision-making process in a mature fashion, their agreement (or refusal) to participate in research is ethically analogous to the decision of an adult subject. To signify the weight given to the adolescent's agreement in such circumstances, he or she should be offered the opportunity to cosign the consent form along with his or her parents.

Although still subject of debate within the REO and the REB, this is by-and-large the approach we are currently following. Assent is required and must be documented in the research file. We have moved away from assent forms as in almost all the ones we have seen, they are extremely difficult to tailor to a particular age group or varying degrees of maturity within an age group. The research site should have a SOP on assent when conducting research with children. The REB has on occasion inquired how this is done at particular sites. It is something we will require of all studies in the revised application form.

As for older children, we agree with the view expressed in the COG guidelines above.

So, the standard practice is to leave a line for the signature of the participant if in the judgment of the investigator, the adolescent has the capacity to understand what is required in the context of a research study. This is what is happening on all children oncology studies. With appropriate documentation in the research file that assent has been done according to a standard procedure at the site and the rationale why a signature of the participant is (or is not) required should satisfy any audit requirement. In actual fact, simply checking a box that assent was done without further documentation of how it was done and of the outcome is insufficient.

A signature line for older participants should remain on the consent form for those individuals able to agree to participate in the study on their own behalf along with the mandatory signature line for the parent/legal guardian.