STUDY PARTICIPANT NUMBER:

* The investigator or designate will identify prospective participants, and invite the participant and obtain Consent/Assent.
* The participant and parent will be told that they are free to ask any questions at any time throughout the discussion.
* The investigator or designate will guide the participant and the parent/guardian through the information presented in the Consent/Assent Form, stopping to ensure each point is understood and asking whether there are any questions or concerns.
* The participant may be asked to explain the study back to the investigator at his/her own level of understanding to ensure the investigator he/she has the ability to understand the research and the consequences of participating.
* The capacity of a minor child to provide assent will be determined by the investigator or designate. The investigator will ascertain if the child is capable of providing assent or consent based on the nature of the study and the level of maturity and cognitive capacity of the minor child.
* If, in the opinion of the investigator, the minor child has the capacity to consent, the minor will be the one to give consent.  If, in the opinion of the investigator, the minor is not mature enough, then the parent/guardian will consent with the minor giving verbal assent. The verbal assent will be documented by use of a checkbox on the signature page.
* If a minor child is deemed to be sufficiently mature to consent on her/his own behalf, an optional signature of the parent/guardian or a box for the researcher to check, indicating that the parent/guardian is aware of the participation of the minor child in the study (making it clear that the participant is still the one giving consent) will be utilized.
* If a situation arises in which a parent and the assenting minor child disagree, the child will not be enrolled in the study.
* If a minor child dissents, he/she will not be enrolled in the study.

The space below will be used to note if there were any deviations to this SOP in individual cases (e.g., one or both parent present or missing, presence of extended family members, child not feeling well that day, etc) or anything that may have influenced (or not) the decision of the child to participate. If there is uncertainty whether assent was obtained freely, the consent will be considered invalid.