For children (i.e., those under age 18 years) invited to participate in research, ONLY their parent(s) or legal guardian(s) can serve as their Legally Authorized Representative and grant permission to participate in research. The IRB and Investigator ensure that adequate provisions are made for soliciting the assent of children, cognitively impaired adults, and others who lack decision-making capacity.

With regard to children and cognitively impaired adults the following conditions must be met:

- Only the child’s parent(s) or legal guardian(s) may grant permission (consent) for their child’s participation in research.
- Assent is to be sought from the child only after consent has been obtained from the parent(s) or legal guardian(s).
- No one other than the child’s parent(s) or legal guardian(s) may give informed consent for the child to participate in research. Consent may not be given by grandparents or other relatives; attendants, caregivers, nurses, or medical staff; or teachers, principals, or superintendents; or any individual other than parent(s) or legal guardian(s).