

Consent and Assent in Pediatric Research: Whose Right Is It Anyway?

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Although the right to health care is not written into the U.S. Constitution, moral and ethical tenets govern the delivery of optimal medical care universally and across the life continuum (De Lourdes Levy, Larcher, & Kurz, 2003). Pertaining to children, in accordance with the Geneva Declaration of the Rights of the Child of 1924 and the United Nations Human Rights General Assembly adoption of the Rights of the Child in 1959 (United Nations Human Rights Office of the High Commissioner, 1990), parents or guardians are responsible for the health and well-being of a child until age 18 years. Much consideration is needed regarding the anatomic, physiologic, emotional, and cognitive development of children when making decisions regarding their health care and, particularly, when enrolling them into research studies.

Guidelines encourage alternatives to conducting research on participants younger than age 18 years, when possible (Gill et al., 2003). In recognition of how children differ from adults with their varying stages of development, it is not always possible to simply apply results from adult studies to children. Regulations are in place, however, to not only minimize risks to pediatric research participants, but also ensure that such risks are less than those taken by adult research participants (Diekema, 2006). When it is necessary to conduct research on children, the usual

protocol is for parents or guardians to consent as proxies (Leibson & Koren, 2015) and for children to give assent starting as young as age 7 years (National Cancer Institute, 2014). Assent is the child's agreement to participate in the study. Ideally, the discussion with the child is conducted during several sessions before the research team feels confident that the child understands what study participation will entail and agrees to participate (National Cancer Institute, 2014). However, challenges arise when the parent or guardian and child have differing wishes. In addition, considerations are needed in situations where children may be more educated than adults, which is sometimes the case in disparate communities. Assent issues are compounded when the study involves genetic and genomic investigations. Anyone conducting research in individuals younger than age 18 years should consider these factors.

Evaluating Children's Rights and Capacity

Researchers generally assume that adults are informed and have the capacity to make decisions for and in the best interest of children. Researchers also think that children are not cognitively mature enough to have autonomous authority (De Lourdes Levy et al., 2003). In fact, the impetus for the adult consenting process for children is under the premise that