Children participate in health care research within two broad categories. These include involvement in medical research and as participants in social science research. Medical research generally involves participation in clinical trials, which evaluate treatment or drugs in different combinations. Social science research obtains data from an individual and tends to focus on perceptions, assess a specific concept, or evaluate the effect of an intervention. Since the aim and data collection methodologies are different, there are varying issues when children are included in either type of research.

Children are defined by the National Commission for the Protection of Human Subjects (1978) as “persons who have not yet attained the legal age of consent under the applicable law in the jurisdiction in which the research will be conducted” (p. 1). For most of the U.S., the legal age is 18 years, with few exceptions. The basic model recommends that parents (legal guardians) provide permission for the child to participate in the study or for the researcher to contact the child. The child then provides assent for study participation. According to these regulations, parental permission can only override a child’s dissent when the research provides direct benefit to the health or well being of the child, which is only available in the research context. These regulations do not stipulate an age at which the child is capable of assent. This determination is left up to the local Institutional Review Board (IRB), although it is recommended that the child’s age, maturity, and psychological status be taken into account when making this determination. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research recommends that assent be obtained from all children under seven years of age.

Medical Research

In 1998, the National Institutes of Health (NIH) published guidelines that include children as participants in research supported by the NIH. This policy mandated that when and where appropriate, children should be included in clinical trial research. This policy change was designed to cease the application of medical treatment testing results performed on adults to the pediatric population. As a result of this guidelines change, the testing of prescription drugs when labeled for use in pediatric patients must undergo testing with children as participants.

There are several government policies that outline and dictate standards when children are involved as study participants. Since the implementation of the NIH guidelines, research funded by the NIH must address children as participants within the research plan. If children are excluded, a rationale must be provided. If children are included, the research plan must address the developmental and facility needs of this population. The NIH guidelines outline seven justifications for excluding children in research. In addition, the NIH Office of Extramural Research (1999) provides a policy related to the inclusion of children as study participants.

Children and adolescents who participate in research studies are known to be more vulnerable than adults. Within the federal regulations of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978), four classifications of approval research involving children are provided. These are located within Subpart D of Title 45, Part 46. In 2004, an Institute of Medicine (IOM) committee concluded with these recommendations (Goodman & Fisher, 2005).

The issue of consent is one specific legal concern when children are used as study participants in medical research. The Gillick competency test has been used to determine participation in medical and health care research (Shaw, 2001). Legally, the Gillick test defines competency as the ability to understand the health care information. This must include the purpose, nature, likely effects and risks, chances of success, and other alternatives available. If competent, the individual may make the choice; unwise choices are permitted, and choices may not be rationale. The Gillick test has been applied in many health care legal situations and appears to provide legal guidance in these situations. In general, experts agree that when a treatment is simple, effective, and carries little adverse effects, the patient who refuses is more likely to be deemed incompetent (Shaw, 2001).

Legal and medical personnel agree that it is inappropriate to give any consenting responsibility to children below the age of eight years because they lack

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developed and emotional maturity. While the legal system defines maturity at 18 years of age, health care professionals have placed the maturity threshold as low as 10.3 years (Devereux, Jones, & Dickinson, 1993).

Opinions regarding the capability or ability of children to participate in research vary. Wendler (2006) postulated that it is important to allow children to participate in research, and that they are capable of providing assent when they understand the research question, which Wendler believes is at approximately age 14. He further stated that until instruments are developed that can assess this ability, this age should be used as the threshold for assent.

Pearce (1994) stated that when young people refuse treatment, they need to demonstrate a greater degree of understanding than those who consent. The use of a consent checklist provides a mechanism for assessing the child’s cognitive and emotional states, their relationships, the nature of the illness, and its treatments. This checklist has been helpful in determining if children have sufficient understanding of their condition and are capable of consenting. Pearce recommends that when refusal of treatment is involved, the most stringent guidelines be used.

Kimberly, Hoehn, Fueldtner, Nelson, and Schreiner (2007) determined that the IRB “differed substantially in how they operationalized compensation and assent in the informed permission procedure for pediatric human subject research” (p. 1710). Kon (2006) outlined challenges associated with assent as a result of ambiguities in the language used by the federal regulatory commissions. These authors described the inconsistent manners in which IRBs apply the federal policies and how these inconsistencies ultimately impact children’s ability to participate in research.

Social Science Research
Children have no voice in health services (Fulton, 1996); however, many are major users of health care services. Mahon, Glendinning, Clarke, and Craig (1996) argued that children have a unique perspective that should be taken seriously. Yet, the perspective of children as research participants represents a gap in the literature, and therefore, a knowledge deficit among researchers.

Despite the abundance of federal recommendations, there are few guidelines that address nursing concerns when children are study participants. Knox and Burkhart (2007) reviewed the unique legal and ethical issues inherent when children are study participants. Diekema (2006) provided an excellent history of the development of pediatric regulations. Diekema stated that individuals who perform research involving children should have a strong sense of humility and be acutely aware of the balance between the social value of involving children and the protection of children from unnecessary harm.

Hunter and Piercioneck (2007) argued that the Gillick test should be extended to include participation in all research. These authors outline two situations when Gillick competency might be legally applied. These include when the participants will be exposed to relatively minor risks but generate significant advantages, and when minimal risk may be present for the participant, parental objection may also be present, and the possibility for great societal benefit exists. Incorporating the Gillick test will ensure autonomy and protect against personal interest.

In a study of school-age children with orthopedic conditions, Alderson (1993) concluded that children younger than 10 years of age understood their treatment and its consequences quite well. Results of this study described the resentfulness and anger children experience as they grow older and must cope with the consequences of decisions where they had no involvement.

Performing quantitative research with children as participants requires that all data collection forms be readable and comprehensible, and at a grade level consistent with the study participants. The use of the readability statistics is frequently used to document the level of education required for comprehension of the document. There are unique challenges when conducting research with children as participants. Campbell (2008) described difficulties encountered in obtaining ethical approval and enrolling participants for research to be performed in Australia. Beigay (2007) described IRB concerns and included recommendations for complying with regulatory requirements when including children in research. Miller (2003) described her experience when performing qualitative research with children as participants.

Personal Experience
As a researcher, I have performed several studies in which children were assenting participants after their parents provided permission. Obtaining data directly from the child provides a different, not yet heard from perspective, and it fills a gap in health care knowledge. Children have opinions about their disease, life, treatments, and health care, and these opinions deserve to be heard. Challenges to performing research with this population can be grouped into three categories – the IRB, the parents, and maintenance of study data integrity.

In general, any IRB that is charged with approving a study where children will be the participants will scrutinize the protocol and demand that confidentiality and anonymity are maintained. I have never had a study exempted or expedited when children are involved. While additional time is required for these reviews, my belief is that this provides an additional level of assurance that the study complies with the federal regulations and minimizes potential trauma to the child. Securing parental permission for study participation is not difficult, especially when children verbalize their desire to participate. However, parents often request access to data provided by their child. Research guidelines provide protection for study data, and this must be followed. Thus, it is not appropriate to allow parental access to these data. To do so would diminish the integrity of the study data and violate the principal of anonymity for the study participant. Once
the study is completed, these children deserve to receive a copy of the findings. Providing copies of the report and the manuscript, if published, validate to children the importance of their participation and the value health care professionals place on children's perspectives.

One of the highlights of my career occurred at the funeral of a child who participated in the first study I did with children as participants (Hicks, Bartholomew, Ward-Smith, & Hutto, 2003). The mother of this child had many copies of the manuscript published as a result of the study. While sharing these results, she focuses on one of the quotes. She stated, “That was my child. His life meant something.” Thus, I will always value children as participants and know the unlimited consequences of providing them the opportunity to share their lives through research.

References