

A Goodness-of-Fit Ethic for Child Assent to Nonbeneficial Research

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How can scientists balance the obligation to respect the right of children to be treated as members of the moral community with the need to protect them from the consequences of immature decisions? David Wendler and Seema Shah (2003) rightly point out that U.S. federal regulations offer little guidance on the “age, maturity, and psychological state” determining children’s assent capacity. As a remedy they propose eliminating the assent requirement for children younger than 14 years. I shall draw upon empirical data to argue that this solution is neither respectful nor beneficent, fails to fulfill the intent of federal regulations, and that respectful assent procedures require scientists to strive for goodness-of-fit between children’s developing decisional capacities and the assent context.

Although children’s assent-relevant cognitive maturity and experiences are not at adult levels, Wendler and Shah’s claim that autonomous research choice is lacking prior to age 14 is unsupported. Nine-year-olds can express participation preferences based upon their understanding of research goals, procedures, risks, and confidentiality, as well as the ideas that research produces information and that their participation can help others. Even younger children understand that participation can be enjoyable, boring, stressful, hurtful, or take them away from something they like to do (Ruck, Abramovitch, and Keating 1998; Broome 1999; Bruzese and Fisher 2003). Preadolescents might not understand that experimentation is *solely* designed to produce knowledge, but many adults find this concept difficult as well (Appelbaum et al. 1987; Horing and Grady 2003).

Young children might not reason about altruism abstractly, but they do know what it means to “help” someone. They also show empathy, sympathy, and prosocial behaviors, traits that might provide the moral motives for adult altruism (Hoffman 1990; Eisenberg et al. 2002; Bernhardt et al. 2003). Nonetheless, Wendler and Shah contend that children lack altruism by assuming that adult self-reports about altruistic motivations are more reliable than empirical observations of child empathy and helping behaviors. Not only are adult self-reports known to be fraught with biases toward presenting socially desirable images, but research also demonstrates only modest relationships between measures of adult moral reasoning and moral behaviors. Thus, the ability to reason about altruism does not mean adult consent or dissent decisions are based on such reasoning. Since we rarely challenge

adults to defend their participation choices in non-beneficial research, basing the right to assent on age-predicated reasoning skills can deny children freedom of choice grounded in more concrete or emotional factors that are equally legitimate expressions of the rights of personhood (Fisher 1999).

Based on their limited literature review, Wendler and Shah contend that it is beneficent and respectful to substitute child assent with the right to dissent once participation begins. The moral basis for this alternative rests on the presumption that after an adult stranger has given them no choice about initiating research participation, children will nevertheless feel free to exercise their right to dissent once the study is underway. This assumption is both counterintuitive and inconsistent with research demonstrating the greatest risk to autonomous decision making is children’s submissiveness to adult authority (Broome 1999; Bruzese and Fisher 2003).

I do not agree with Wendler and Shah’s implication that scientists’ responsibility to generate data creates a corollary obligation on children to be altruistic, which in turn holds privileged status over their self-determination rights. The moral claims of children on nonbeneficial research are no different from those of adults. They have the right to assume scientists will communicate with them honestly, do them no harm, treat them fairly, and protect their autonomy and privacy. Federal assent guidelines for nonbeneficial research recognize this claim by requiring an increasingly personalized progression of child protections acknowledging assent vulnerabilities while maintaining respect for children as developing persons. First, institutional review boards (IRBs) decide whether risks and prospective benefits are ethically justified for the general child population to be recruited. Second, parents decide whether the risk-benefit balance is appropriate for their children’s unique characteristics and experiences. Lastly, children decide whether the research procedures and purposes, *as they understand them*, represent an activity they want to participate in at a given time and place.

Children’s assent vulnerabilities require developmentally fitted efforts to ensure these claims are met. Wendler and Shah’s solution is to eliminate the assent requirement, and substitute a dissent doctrine reliant on scientists’ ability and willingness to detect and alleviate experimentally induced distress. I argue instead that assent vulnerability creates a morally-binding obligation on the investigator to

strive for goodness-of-fit between children's maturing skills and the assent context that optimizes decision making (Goodin 1985; Fisher 2002; 2003). Such efforts can include age-appropriate assent language and presentation modalities (e.g., pictorial illustrations) and pre-assent tutorials on research procedures and human-subjects protections (Bruzzeze and Fisher 2003). Children have limited experience exercising their rights in response to requests from adult authority figures, especially within school, healthcare, or unfamiliar settings. Constructing procedures that concretely demonstrate that dissent will not be penalized and providing opportunities to practice decision making can optimize voluntary participation choices. Within a goodness-of-fit ethic, autonomy need not be conceptualized as isolated or isolating (Walker 2002). Like all persons, children are connected to others in relationships of dependency and trust. Creating opportunities for supported decision making involving parent-child discussion about research is another mechanism for creating assent contexts that minimize stress, optimize children's input into the participation decision, and ensure that their wishes and concerns are adequately communicated.

Respectful and compassionate assent contexts require understanding of children's ways of thinking, their assent strengths and weaknesses, life experiences, and practical concerns. Using data on children's and young adolescents' assent vulnerabilities as a rationale for rejecting their autonomy rights in nonbeneficial research is to reject scientists' responsibility to create assent procedures that reduce or eliminate these vulnerabilities. Federal guidelines requiring IRB approval and guardian permission provide adequate safeguards against harms that might arise if children's assent was the only factor determining their participation (Kodish 2003). Developmentally-fitted assent procedures that promote children's maturing autonomy are essential to a scientific ethic of respect and care. ■

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