

Perspectives on Informed Consent Practices for Minimal-Risk Research Involving Foster Youth

Mary V. Greiner, MD, MS, Sarah J. Beal, PhD, Armand H. Matheny Antommara, MD, PhD

There are >430 000 children in protective custody (ie, foster care) in the United States.¹ Despite known health disparities,²⁻⁵ there continues to be limited research to develop an evidence base for diagnosing and intervening to improve health conditions for children in foster care.⁶ One identified obstacle to recruitment is obtaining informed consent, the legal requirement for understanding and voluntary agreement to participate in research. Foster youth do not have a traditional parent or guardian and instead have many adults playing different roles in their lives, including their children's services caseworker, their foster caregiver, their biological parent, their court-appointed special advocate or guardian ad litem (GAL), and their judge or magistrate. Each plays a role in decision-making for the child and could participate in the informed consent process.

Previous work has demonstrated inconsistent approaches for obtaining informed consent for youth in foster care to participate in minimal-risk research; a review of 49 publications revealed 14 different combinations of individuals used for informed consent, ranging from judge, caseworker, and caregiver consent with youth assent to biological parent consent only.⁷ For pediatric researchers wanting to develop evidence-based health guidelines and interventions for this population, obtaining consent from a legally empowered guardian for foster youth may appear to be an insurmountable barrier. Consensus would be beneficial to promoting research and improving health outcomes of foster youth. As a first step toward developing consensus, the varying perspectives of stakeholders must be solicited.

To better understand perspectives regarding informed consent for minimal-risk research addressing foster care health, we interviewed 16 men and women, ranging in age from 18 to 69 years, who currently are or previously were involved in research or in the child welfare system. This included members of the institutional review board (IRB), a principal investigator, a caseworker, a biological parent, a foster parent, a GAL, a judicial magistrate, and foster youth. Feedback reflected 3 general themes: (1) a shared consensus that research is important to improve the health of foster youth, (2) widespread variation on who should be included in the informed consent process, (3) a shared recognition of the



University of Cincinnati and Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio

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Address correspondence to Mary V. Greiner, MD, MS, Department of Pediatrics, Cincinnati Children's Hospital Medical Center, 3333 Burnet Ave, ML 2011, Cincinnati, OH 45229. E-mail: mary.greiner@cchmc.org

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importance of youth assent. We organize our discussion below around these themes.

THE VALUE OF RESEARCH

There was recognition and appreciation that medical research has intrinsic value and is essential to improve the lives of children. Participants noted many direct benefits (eg, opportunities for medical treatment, self-expression, and giving youth a voice) and population benefits (eg, better data reflecting experiences of foster youth and opportunities to examine disparities in health outcomes) to foster youth participation. For example, one interviewee stated:

This is such a vulnerable population. They have increased health needs.... They have less support, and they have generally poor coordination of care. There [are] disparities in all aspects of care when you look at that population compared to the general pediatric population. And so, I think there's a tremendous opportunity to learn why the disparities exist, what barriers are to improving care and ultimately can better care in that population.

A second interviewee noted, "So, when you say the risk of participating, my mind, I'm sorry, jumps to the risk of not participating. You know, you got a whole section of kids that really could advance your thought process, your policies, your procedures here that you can't get the voice of."

LACK OF A CLEAR CONSENTING AUTHORITY

Many interviewees reported that decision-making for foster youth participation in research should be done cooperatively and collaboratively. An IRB member noted that it was important to "pay attention to the benefits, risks, and what's being asked of all involved." A GAL added that "communication with foster care advocates" is essential, and another IRB member proposed that there

should be a "time and a place to talk to everyone." Despite the general sentiment that collaborative decision-making would be ideal, opinions about each stakeholder and their involvement in the decision regarding foster youth's participation in minimal-risk medical research varied. One of the most discussed factors was the stakeholder's knowledge of the individual child, which is not always information available to the researcher. Many reported concerns about child welfare serving in the role of consentor, noting large caseloads and high turnover rates impacting the length of time the caseworker has known the youth. There were similar mixed opinions on the roles of biological parents, many hinging on the circumstances of removal and long-term goals for the case. Opinions on the role of foster caregivers in consenting for foster youth participation similarly varied. Those in favor of foster caregiver participation focused on the logistics of participation, including scheduling and transportation. Concerns for using the court for consent included the time required and the lack of knowledge by the court for the individual child. There was more support for involvement of the GAL or court-appointed special advocate, often contingent on their relationship with the child.

THE VALUE OF THE YOUTH'S ASSENT

Although a few stakeholders identified concerns regarding some children's cognitive abilities and mental health, all participants reported assent should be obtained from youth for minimal-risk research conducted in a health care setting. For example, one interviewee stated, "I guess the answer is sometimes if any child that is old enough to understand the risk and benefits of participating [in] that research, I think that assent process should be—should take place just like it would with any child who's not in foster care."

These interviews illustrate that although there is a strong appreciation for the value of research for youth in foster care, there remains a considerable lack of consensus on the informed consent process with this population. Stakeholders struggled with identifying the best legal representative but also recognized an ethical obligation to identify a representative who had personal knowledge of the child's interests. These regulatory challenges occur for medical researchers all over the country and result in foster youth being excluded from participation in research, including studies on the treatment of chronic diseases such as asthma and studies on foster care-specific outcomes such as placement instability. This prevents the advancement of health care for this extremely vulnerable population.

We endorse a universal waiver of parental consent by all IRBs for minimal-risk research involving youth in foster care who are old enough to assent for themselves, with a requirement that researchers inform all stakeholders of the study and give them the opportunity to provide input if desired without the burden of written informed consent. This would alleviate general concerns about consent identified by stakeholders and would simultaneously be feasible to pediatric researchers who may be naïve to which stakeholder is best positioned to provide consent. We believe that pediatricians have an obligation to advocate for foster youth participation in research, with appropriate safeguards on a local, state, and national level. Pediatricians can assist by challenging research plans that exclude foster youth to simplify recruitment and enrollment. Pediatricians can propose, lead, and collaborate on informed consent policies for foster youth by helping our colleagues to achieve the legal and best-interest standards recommended for informed consent

in minimal-risk research.⁷ We also encourage professional associations, such as the American Academy of Pediatrics, to develop a policy on this issue. Promoting participation in research is required to advance the health of children in foster care nationally.

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ABBREVIATIONS

GAL: guardian ad litem

IRB: institutional review board

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