# Empathetic Communication

## How Clinical Research Teams Interact with Children and

ENROLLING CHILDREN IN CLINICAL TRIALS ENGAGES MULTIPLE STAKEHOLDERS beyond just the primary participant- this includes clinical staff, the child's physician, and the child's family.

By definition, a child is too developmentally immature and without the legal agency to independently decide to enroll in a clinical trial. Her parents or guardians must provide informed consent. The child's parents should be comfortable with the research team and feel empowered to ask any and all questions about the trial and their child's participation in it. In fact, parents have the legal right and responsibility to speak up.

Older, more mature children can sometimes make the decision to participate in a trial and provide informed assent. However, for younger subjects, parents may need to decide on their behalf. Ideally, the decision to enroll should be made jointly between parent and child. In each case, an empathic and experienced research team member must listen, provide information, and above all, encourage the family to ask questions.

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The research nurse is often the first and primary resource for these questions as families consider enrollment. Questions in this phase of study participation typically revolve around whether the study is appropriate for a child, even though he may not directly benefit from participation (as in the case of a placebo-controlled randomized clinical trial). Parents need to understand the fundamental objectives of the clinical trial – to generate knowledge about the safety and efficacy of the investigational treatment on their child's condition – and that there may or may not be a direct or immediate benefit to their child from participating. Ensuring the child and his parents understand this information is critical to the integrity of informed consent.

Once the decision to participate is made, the family may have questions that are tactical in nature, such as: what should I do if my child spits out the study drug, or, should I still administer the dose if my child seems sick? Other questions may have to do with the logistics of the trial protocol – the number of tests, particularly blood draws, the frequency of site visits, and the degree of risk represented by the investigational therapeutic intervention. Parents want to know how long the study will last, how long the treatment has been studied in other children, and the credentials of the principal investigator.

The research team should continually remind and encourage parents and children to keep asking questions- if they don't understand, they should ask again. It should be stressed that no question is insignificant, and families should feel comfortable asking simple things such as where to park, if childcare is available, and if meals are provided. While seemingly mundane, these issues significantly impact the child's and family's participation experience. Ensuring realistic and accurate expectations for the child and family is key to retaining patient participants.

Having a child in a pediatric trial can become a family activity. Parents often are tasked with keeping medication diaries or records of side effects. This can be a challenge when the parents are dealing with their own anxiety and uncertainty about their child's diagnosis and prognosis. Additionally, parents of an in-study child frequently have to miss work or arrange for childcare for their other children, adding to their baseline stress level and increasing the obstacles to clinical trial participation.

A child's participation in a clinical trial not only affects the child's parents but also impacts their siblings. This can be a particular concern when the child has a chronic condition and requires considerably more attention over a long period of time. Other siblings may feel neglected, which can introduce tension and complicate family dynamics in an already stressful and difficult situation.

While some pediatric studies can be very short and place few demands on the child and her family, other studies can go on for years and require monthly or weekly site visits or even extended inpatient stays for various assessments. These longer studies can put quite a burden on the parents and family.

Awareness of these "meta-study" issues and close communication between research teams and families are critical elements for the successful participation of children in clinical research. This communication works best when built on a foundation of understanding, empathy, comfort, and trust.

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# Their Families

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