

## What Parents Should Consider When Enrolling Children in Research

Medical breakthroughs for children begin with carefully planned research studies; parents should seek these options, understanding that each has different requirements.

### How Parents Find Out About Different Types of Studies

Parents might hear about a study for their child in many ways. Their physician might tell them directly about a study; a researcher could contact them by telephone, email, or text message; or parents might see a poster or online post. However, it can be hard to tell what the study is about, what it entails, or how safe it is.

There are many different kinds of research studies for children and all should have had an institutional review board approving the study, marked somewhere on the information parents see. The best research comes with explanations that are easily understood with clearly documented risks and benefits. There are 2 official categories: minimal risk and greater than minimal risk. Examples of minimal-risk studies include patient registries, parent or child interviews, focus groups or surveys, or use of technology like a mobile app for medication reminders. Studies that have greater than minimal risk include clinical trials for new medications or devices, a new vaccine, or a behavior study that includes asking sensitive questions. Parents may feel differently about risks if their child is healthy or if their child has a health concern. Some studies may pay for your time or travel, while others may not. Finally, studies may be a 1-time event or require multiple visits over a year or longer. These are all important factors to consider when asked if your child can participate in a study.

### What Is Informed Parental Consent? What Is Assent?

Only a parent or guardian, with full legal custody, can decide whether their child can enroll in a study (unless the child is 18 years or older). This is called parental consent and includes a document that should contain all the study details, what to expect, the length of participation, how many visits, any costs or compensation, and its possible risks and benefits. The study team must review the informed parental consent document with the parent, answering questions and ensuring understanding of the study. There may be some rare situations where a decision must be made quickly, but usually parents should be given plenty of time to decide. When a parent gives consent, their child will be asked to give assent. The assent process is similar to parent consent, depending on the child's age, and should allow the child to ask questions, ensure understanding, and provide their permission to be part of the study.

Deciding to join a study or a clinical trial should be seen as a partnership. It is through these experiences that we can best understand children's health, if a new technique or medication works in children, and if there are ways to improve the care we are giving chil-

### Enrolling children in research studies: what to consider

Medical breakthroughs for children require carefully planned research studies and close partnership between parents or guardians, children, and researchers.

#### Assessing potential health risks

##### Minimal-risk studies

- Patient registry
- Parent or child interview
- Focus group or survey
- Use of technology such as a mobile app

##### Greater than minimal-risk studies

- Clinical trial for a new medication, device, or vaccine
- A behavioral study that may ask some sensitive questions

#### Agreeing to participate

##### Informed consent of parent/guardian

Health risks and possible benefits, study location, duration, and number of visits have been clearly explained and understood.

##### Assent of the child

The study has been explained in an age-appropriate way for the child. They have had time to ask questions before giving their permission to participate.

#### Additional considerations

- That the study has had institutional review
- Current health of the child
- Possible benefits the study may provide
- Location, duration, and number of visits required
- Reimbursement for time and travel costs



#### For More Information

US Department of Health & Human Services:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html>

American Academy of Pediatrics:

<https://publications.aap.org/pediatrics/article/139/5/e20163648/38730/Ethical-Conduct-of-Research-in-Children>

dren. Parents should seek out excellent research opportunities and must be comfortable choosing or not choosing to participate based on their understanding of the study procedures and any potential risks and benefits.

**Authors:** Lindsay A. Thompson, MD, MS; Rebecca Mercado, MS

**Published Online:** January 31, 2022. doi:10.1001/jamapediatrics.2021.6025

**Author Affiliations:** Department of Pediatrics, University of Florida College of Medicine, Gainesville (Thompson, Mercado); Department of Health Outcomes and Biomedical Informatics, University of Florida College of Medicine, Gainesville (Thompson).

**Conflict of Interest Disclosures:** None reported.

The JAMA Pediatrics Patient Page is a public service of *JAMA Pediatrics*. The information and recommendations appearing on this page are appropriate in most instances, but they are not a substitute for medical diagnosis. For specific information concerning your child's medical condition, *JAMA Pediatrics* suggests that you consult your child's physician. This page may be downloaded or photocopied noncommercially by physicians and other health care professionals to share with patients. To purchase bulk reprints, email [reprints@jamanetwork.com](mailto:reprints@jamanetwork.com).