

Key Questions to Ask Before Your Child Participates in a Clinical Study

1. What is the purpose of this study?
2. What has been learned about the study treatment and are any study results published?
3. Will I have to pay for any part of my child's study? Will our insurance cover these costs?
4. Will we be able to see my child's doctor?
5. If the study treatment works for my child, can my child keep using it after the study?
6. Will my child receive any follow-up care after the study has ended?
7. Does the physician/investigator have any financial or special interest in the clinical study?
8. Does the study need to be done? Can the same information be found using adult volunteers?
9. What are the obligations and expectations of my child as a volunteer?
10. How many visits to the study center are required? How often are the visits? Are overnight stays in a hospital required?
11. What undesirable event or other type of discomfort has to happen for my child to be removed from the study? If that happens, will some alternative therapy be offered?
12. Are there any rules regarding what might end the entire study early?
13. Will my child's study results be reviewed throughout the study by an independent third party?
14. What are my other options if I choose not to have my child participate in this study?



Resources

General

Search Clinical Trials- A public service, which conducts a search for clinical trials on someone's behalf, checking multiple websites and clinical trial registries. The results are then printed out, the important information is highlighted and the customized packet of information is mailed to the individual.
www.SearchClinicalTrials.org • 1-877- MED HERO

CISCRP- Resources to help you make an informed decision about your child's participation www.CISCRP.org • 1-877-MED HERO

ClinicalTrials.gov- a registry of federally and privately supported clinical trials conducted in the United States and around the world.
www.ClinicalTrials.gov

CenterWatch- Clinical study information and listing service. Includes pediatric and neonatal studies.
www.CenterWatch.com • 1-866-219-3440

Government

Children and Clinical Studies
<http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php>

Children's Assent to Clinical Trial Participation
<http://www.cancer.gov/clinicaltrials/understanding/childrensas-sent0101>

Should Your Child Be in a Clinical Trial?
<http://www.fda.gov/consumer/updates/pediatrictrial101507.html>

National Cancer Institute- Search NCI's list of 6,000+ clinical studies now accepting participants
<http://www.cancer.gov/clinicaltrials/search> • 1-800-4-CANCER

National Institute of Allergy & Infectious Diseases- conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases.
<http://www3.niaid.nih.gov/Volunteer/> • 1-866-284-4107

Disease specific

Juvenile Diabetes Research Foundation (JDRF)

www.jdrf.org • (800) 533-CURE

Cystic Fibrosis Foundation

www.cff.org • (800) FIGHT-CF

American Cancer Society

www.cancer.org • 1-800-ACS-2345 (English & Spanish)

Arthritis Foundation

www.arthritis.org • 800-283-7800 (English & Spanish)



Helping you make an informed decision about your child's participation in a clinical study.



CISCRP is an independent non-profit organization founded for the purpose of educating the public, patients, media, and policy makers in order to promote greater understanding and awareness of clinical research participation and the role it plays in public health.



1-877-MED HERO • www.MedHero.org



How Pediatric Volunteers are Protected

- To protect the rights and welfare of clinical research participants, U.S. Federal Agencies, including the Food & Drug Administration (FDA) and the National Institutes of Health (NIH), oversee much of the medical research in the U.S.
- Institutional Review Boards (IRBs) oversee the centers where clinical research studies are conducted. IRBs review and approve study protocols to ensure that a clinical study is ethical and that volunteers' rights are protected.
- The written permission of a pediatric volunteer's parents or legal guardians is required before a child enrolls in any study.
- The FDA Office of Pediatric Therapeutics monitors and oversees the growing number of pediatric studies in the United States.
- You and your child will have access to the IRB that reviews the research, as well as the study physician and study staff conducting the research.

CISCRP is not involved in recruiting patients for clinical studies nor is it involved in conducting clinical studies.

About Clinical Studies

What are pediatric clinical studies?

- A research study, which aims to answer specific questions about children's health.
- Clinical research studies are performed according to a plan called a 'protocol'
- A 'protocol' describes what types of volunteers may enter the study; contains the schedules of study-related tests and procedures; study medications and dosages; length of study as well as the outcomes that will be measured.
- The parents or guardians of each child volunteer participating in the study must agree to follow the protocol

Why are pediatric clinical studies conducted?

- To see if a study medication, therapy or device is safe and effective for children to use
- To find new treatments and improve upon existing treatments for children
- To compare existing treatments
- To determine the appropriate dosages for children

What are some of the possible benefits of my child's participation?

- Your child will have access to potentially new study medications, therapies or devices that are not otherwise available
- Your child will receive study-related medical care for the condition being studied
- You and your child will be helping other children by contributing to medical research and treatment advances

What are some of the possible risks of my child's participation?

- There may be unpleasant, serious, or even life-threatening side effects as a result of the study medication, therapy or device
- Your child's study medication, therapy or device may not be effective
- Your participation in the research study may be demanding and time consuming.

For answers to additional questions, please visit our website www.MedHero.org or call 1-877-MED-HERO



CISCRP – helping you to make an informed choice.