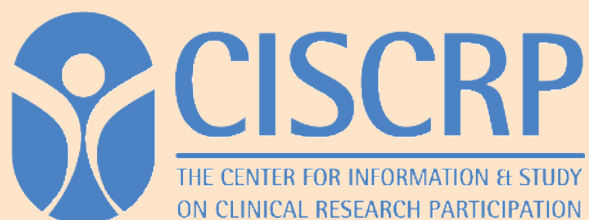


SHOULD MY CHILD PARTICIPATE?

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



HELPING YOU TO
MAKE AN INFORMED CHOICE



How My Child is Protected

To protect the rights and welfare of children participating in clinical studies, federal agencies, including the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), oversee much of the medical research in the US. The FDA also has an Office of Pediatric Therapeutics that monitors the growing number of clinical studies in the United States involving children.

Institutional Review Boards (IRBs) oversee the centers where clinical studies are conducted. IRBs review and approve study protocols to ensure that a clinical study is ethical and that your child's rights are protected.

The written permission of a parent or legal guardian is required before your child enrolls in a clinical study. And once your child is enrolled, both of you will be able to ask questions of the doctor and staff about the study.

Why are pediatric clinical studies conducted?

Many drugs and treatments prescribed to children may not have been studied in children. So, clinical studies are conducted to see if a study medication, therapy or device is safe and effective for children to use.

They are also conducted:

- To find new treatments and improve upon existing treatments for children
- To compare existing treatments and learn more about them
- To determine the appropriate dosages for children

About Clinical Studies

What is a pediatric clinical study?

A pediatric clinical study is also known as a “clinical research study”, a “research study”, or a “clinical trial”, and aims to answer specific questions about children’s health.

A pediatric clinical study is conducted according to a plan called a protocol, which describes:

- What types of volunteers may enter the study
- The schedules of tests and procedures, study medications and dosages
- Length of the study
- Number of study visits

The parent(s) or guardian of each child volunteer participating in the clinical study must agree in writing to follow the protocol. This is called giving informed consent.

Participating in a clinical study is voluntary, and your child may decide to stop participating for any reason, at any time.

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

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

- Your child may 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 may feel pride in helping other children by contributing to medical research

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

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

For answers to additional questions,
visit our web site at www.CISCRP.org
or call 1-877 MED HERO.



Key Questions to Ask



GENERAL QUESTIONS

- What is the purpose of this clinical study?
- What is my child expected to do as a volunteer?
- Will we be able to see my child's doctor?

COST

- Will I have to pay for any part of my child's clinical study? If so, will our insurance cover these costs?
- Will I be reimbursed for travel costs? for parking? for meals?

TIME

- How many visits to the study center are required and how often are the visits?
- How long will each visit take?

SAFETY

- What are the possible risks for my child in participating for this study?
- What undesirable event or other type of discomfort has to happen for my child to be removed from the clinical study? If that happens, will some alternative therapy be offered?
- Will my child receive any follow-up care after the clinical study has ended?
- Who will know that my child is participating in a clinical study?

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

CISCRP - helping you make an informed choice

GENERAL RESOURCES

Search Clinical Trials Public service that compiles clinical trial listings from multiple sources. You can also request a free search for clinical trials in your area.
www.searchclinicaltrials.org | 1-877 MED HERO

CISCRP Education Center Online portal of clinical research information and resources.
www.ciscrp.org/education-center

ClinicalTrials.gov Registry of clinical trials in both English and Spanish.
www.clinicaltrials.gov | 1-800-411-1222



Part of CISCRP's Education Before Participation resource series.



An editorial panel of patients, public and professional representatives has reviewed this educational brochure.



CISCRP is an independent non-profit organization dedicated to engaging the public and patients as partners in the clinical research process through education and outreach programs. CISCRP services also assist clinical research stakeholders in understanding public and patient attitudes & experiences in research to improve patient satisfaction.

**CISCRP is not involved in recruiting patients for clinical trials,
nor is it involved in conducting clinical trials.**

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