# Should My Child Participate?

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

CISCRP

Center for Information and Study on Clinical Research Participation

## 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 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.

## Things to Consider Before Volunteering

A clinical study is also known as a 'clinical research study', or a 'clinical trial', and aims to answer specific questions about your health and wellness. BEFORE TAKING PART in a clinical trial, certain information should also be considered:

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

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

- You and your child may help others by contributing to medical research and treatment advances
- Your child will receive study-related medical care for the condition being studied

## What are some 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 time consuming

To help you decide if your child should participate in a clinical trial, ask questions, search the library or Internet for information (See Learn More About Clinical Trials on back), and seek the advices of family members or a trusted doctor, clergyman or friend.

Remember, your participation in clinical trials is strictly voluntary and you can drop out at any time for any reason.

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

## Where Can I Go For Help?

### GENERAL RESOURCES

Search Clinical Trials - A public service that compiles clinical study listings | 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 studies conducted in the United States and around the world. | www.ClinicalTrials.gov

CenterWatch - Clinical study information and listing service. Includes pediatric and neonatal studies.
http://www.centerwatch.com/clinical-trials/listings/
1-866-219-3440

Should Health Children Participate?
https://www.cc.nih.gov/kidsinresearch/index.html

Visit CISCRP.org for more information, including disease and condition specific resources.

RESEARCH SERVICES | HEALTH COMMUNICATION SERVICES | INTERNATIONAL EDUCATION & AWARENESS | COMMUNITY ENGAGEMENT

**"Education Before Participation"**

"Should My Child Participate" is part of CISCRP's Education Before Participation resource series.

REVIEWED AND APPROVED BY A CISCRP Editorial Panel

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

CISCRP

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 and experiences in research to improve study volunteer participation. CISCRP is neither involved in recruiting patients for clinical trials, nor is it involved in conducting clinical trials.

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