

Research



As a Research subject you have a right to information about:

- Why the study is being done.
- How participating would change your medical care.
- The discomforts and risks of the things that will be done to your child in the study.
- Possible benefits of taking part in the study.
- Other treatments that are available if you choose not to be in the study.
- Medical treatment if problems occur during the study.

You also have the right to:

- Decide NOT to take part in the study
- Not be pressured to take part in the study
- Stop being in the study at any time
- Ask questions before, during, and after the study
- Ongoing information about the study

For More Information

For more information about clinical research going on at The Children's Hospital please feel free to contact any of the following:

Pediatric General Clinical Research Center
(303) 837-2957

Research Institute
(303) 861-6310

Clinical Trials Organization
(303) 764-8430

Questions

For questions regarding your rights as a clinical research study participant contact:

COMIRB
(303) 724-1055



The Children's Hospital

Denver, Colorado

www.childrenshospitalden.org

Clinical Research



What is it all about?

**Information about
what clinical research
is and how to decide
if participating is
right for you.**



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Clinical Research: *What is it all about?*



Introduction

The Children's Hospital (TCH) is considered a Teaching Hospital. This means that the hospital has medical students and various internships for other professions. It also means that TCH is involved in clinical research. Clinical research allows us to be at the cutting edge of the latest clinical treatments and practices. Sometimes being asked to participate in clinical research can be confusing. We hope this pamphlet will help you understand more about research and decide if you might want your child to be in a research study if asked to participate.

Definitions

Clinical Research: the study of health and disease treatment and practices.

COMIRB (Colorado Multiple Institutional Review Board): The committee that evaluates studies and makes sure that the rights of the participants are protected.

Informed Consent: A document that explains what happens during the study, what the possible benefits and risks are, possible side effects and other important information. You will be asked to sign an informed consent before entering the study.

Clinical Research Studies

Who takes part?

- Each study is different and needs people with certain conditions to be in the study.
- You will probably be asked a few questions to see if your child fits the guidelines to be a part of the study.
- If your child fits the guidelines, someone involved in the research study (usually your doctor, nurse or dietitian) will tell you more about the study.

How to decide whether or not your child should take part:

- The decision to take part is yours. You may want to take some time to think about it.
- Ask questions about what you and your child will have to do. For example, "Are there extra visits to the hospital?" or "Will I have to fill out paperwork for the study?"
- What are the risks? Do potential benefits outweigh the risks?

What if I don't want my child to be in the study?

- You **ALWAYS** have the right to say you do not want your child to be in a research study.
- Your medical care will not be changed because you decide not to be in a study.
- You do not give up your legal rights if you participate.

Who protects my child's rights?

The COMIRB committee reviews any research study done through The Children's Hospital to make sure the patients' rights are protected.

How long does a study take?

Every study is different. Some may take a few hours, some a few months, others may last a few years.

Will I have to pay anything?

Research studies generally do not pay for care your doctor routinely provides. Usually any added research costs are paid for by a research grant.