



You and your child also have the right to:

- Decide for any reason NOT to take part in the research study.
- Not be pressured to take part in a research study.
- Ask questions before, during, and after the research study.
- Quit the study at any time. This decision will not be used as an excuse to hold back necessary medical treatment.

Chaperones

The Rockefeller University Hospital has a policy to ensure that you and your child feel comfortable during your child's physical exam.

A research doctor will explain the purpose and scope of all exams to you.

Usually, a parent or guardian will observe their young child's exam. If you prefer, you may request that a chaperone be present. A chaperone is a person not conducting the research who is present during the exam. Typically, family members are not present for adolescents' exams.

The investigator may decide to provide a chaperone for your child. In some cases having a chaperone present may be a requirement for participating in the study.

There may be situations when you, the investigator, and your child think it best for your child to meet with the research doctor alone.

Who can I talk to about my rights and my child's rights?...

- The Clinical Research Officer can meet with you to answer your questions and discuss your concerns. All conversations are kept confidential.
- The Clinical Research Officer oversees the University's
 - research study safety,
 - the informed consent process,
 - the quality of the research environment for volunteers,
 - the education of research staff,
 - the rights of research volunteers and their parents.

The Clinical Research Officer and the Clinical Research Support Office staff are available Monday-Friday, from 9am-5pm. For urgent issues outside of regular hours, call the head nurse at (212) 327-8448 who will contact the Clinical Research Officer for you.

Clinical Research Office, Rockefeller University Hospital, Rm. 123, 1230 York Avenue, NY, NY 10065, (212) 327-8408 or 327-7709.



THE ROCKEFELLER UNIVERSITY HOSPITAL

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

What is Pediatric Clinical Research?

DISCOVERIES ADVANCING MEDICINE



The Rockefeller University Hospital

The Rockefeller University Hospital, founded in 1910, has been the site of important discoveries, including many that have led to a Nobel Prize.

All studies conducted at The Rockefeller University Hospital are reviewed by:

- A *Scientific Committee* that examines each study for scientific excellence.
- An *Institutional Review Board (IRB)* that makes sure that the risks and benefits of taking part in the study are appropriate for children and that the risks and benefits are shared with you and your child. The IRB adheres to strict federal guidelines protecting the safety and rights of research volunteers.

What is Clinical Research?

“Clinical research” is an “experiment” or a “research study” involving human volunteers. For example, participating in research could include filling out a survey, giving a blood sample, or receiving experimental treatments or drugs.

Who Takes Part?

- Each study is different and needs people with certain conditions to participate.
- You and your child will probably be asked a few questions to see if your child meets the guidelines for the study.

How To Decide Whether or Not to Enroll Your Child in the Study

- If your child meets the guidelines, a research doctor or nurse will tell you more about the study.
- You will receive a consent form that gives you and your child detailed information about the study.
- The consent form is part of the process of learning about the study and deciding if taking part is right for you and your child.
- The decision to take part is up to you and your child.
- Before you and your child make a decision, you may want to take some time to think things over.
- Answers to the questions listed below may help you and your child make a good choice.

What Should You Know About Your Child’s Participation in Research?

As a research volunteer, you and your child have a right to information about:

- Why the study is being done.
- What joining the study would involve, e.g. a physical exam, blood draw, questionnaire.
- How participating in the study might change your child’s medical care.
- The discomforts and risks of participating in the study.
- Treatments available if your child does not join the study.
- Medical treatment if problems occur during the research study.

The researcher or nurse will explain about the study and what it involves using language appropriate for your child’s age and ability to understand. If your child is 7 years or older, the researcher or nurse will ask your child if she or he agrees to participate in the research study.