Chaperones

The Rockefeller University Hospital has developed a chaperone policy for the comfort of you and your child during physical exams.

A chaperone is a neutral observer present during the exam.

An investigator (research doctor) will explain the purpose and scope of all exams to you. If your child is at least 7 years old, the investigator will also describe the exam to your child in language that your child can understand.

You are free to observe your child's physical exam, unless you or your child choose otherwise.

The investigator may decide to provide a chaperone for your child, even when no request is made, unless you or your child object. In some cases having a chaperone present may be a requirement for participating in the study.

Investigators recognize that there may be situations when it is in the best interest of the child volunteer to meet with the investigator without the presence of a parent or accompanying adult. Whenever a decision to offer a chaperone is made, the investigator takes into account the requests of the child and the parent.

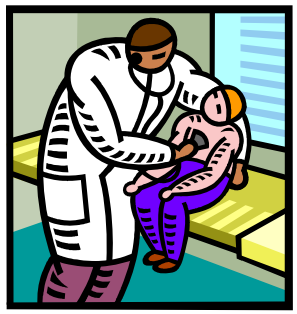
Who can I talk to about my rights and my child's rights?...

- The Clinical Research Officer is available to meet with you in a confidential setting to discuss any concerns about research participation.
- The Clinical Research Support Office advocates for you and your child in the areas of
    - the safety of research studies
    - the integrity of the informed consent process,
    - the research environment for volunteers
    - Education of research staff.

When issues arise about study conduct or a volunteer's rights, often the Clinical Research Support Office can help sort things out.

The Clinical Research Support Office is located in Room 107, on the first floor of The Rockefeller University Hospital. Staff are available Monday through Friday, from 9am-5pm. For urgent issues outside of regular hours, the head nurse can contact the Clinical Research Officer for you.

What is Pediatric Clinical Research?



The Clinical Research Support Office

The Rockefeller University Hospital

The Rockefeller University Hospital has been recognized for excellence in biomedical research since its founding in 1910. Many important discoveries have been made here including many that have led to the awarding of a Nobel Prize.

All studies conducted at The Rockefeller University Hospital have been carefully examined by two committees. A Scientific Committee reviews each study to ensure that it meets high standards for scientific merit. The Institutional Review Board (IRB), which includes individuals who are not affiliated with The Rockefeller University, makes sure that the known risks and benefits of participating in the study are appropriate for children and disclosed. To determine appropriateness, the IRB draws on strict federal guidelines designed to protect the safety and rights of research volunteers.

What is Clinical Research?

"Clinical research" is an "experiment" or a "research study" involving human volunteers. Clinical research may involve filling out a survey, giving a blood sample, or receiving experimental treatments or drugs. Knowledge gained from clinical research improves our understanding of health and disease and may help scientists develop better ways to prevent, diagnose, and treat

Are there Risks Involved in Participating in Research?

Yes. There are risks involved in participating in clinical research, just as there are risks involved in standard (non-experimental) treatment and the activities of daily living.

Known risks to participation in a research study are described in detail in the informed consent form. You are asked to sign the consent form before your child takes part in research.

Informed Consent

Your child's participation in any research study is voluntary. For every study your child wishes to participate in, you will receive a document called the "Clinical Investigation Consent Form." Children 7 years old or older, must understand the study procedures and express agreement to participate before the study begins. Your child will not be required to undergo any procedure against his or her will.

The Consent Form explains the study in language that is easy to understand. A member of the research team will discuss the study with you and your child, explain its details, and answer you and your child's questions. In most cases, both parents are asked to give their permission for the child to participate in the study. However, here is a process in place for obtaining permission from one parent when the other parent is unavailable. ***Any time after signing the informed consent form, you and your child are free to change your mind and drop out of the study.***

What You Should Know About Your Child's Participation in Research

As a research volunteer, you and your child's rights are protected by the New York State Patients' Bill of Rights. As a research volunteer, you and your child have additional rights.

You and your child are entitled to:

1. Learn the nature and purpose of the research study.
2. Receive an explanation of the procedures and any drug or device to be used.
3. Receive a description of any discomforts and risks that you could experience from the study.
4. Learn about any benefits you might expect from the study.
5. Learn about the risks and benefits of any other available procedures, drugs or devices that might be helpful to you.
6. Learn what medical treatment will be made available to you if you are injured because of the study.
7. Ask questions about the study or the procedures involved.
8. Quit the study at any time. Your decision will not be used as an excuse to hold back necessary medical treatment.
9. Receive a copy of the signed and dated consent form.
10. Decide to consent or not to consent to a study without feeling forced or obligated.