Participating in Research

Know Your Rights and Protections

What is a research study?

Research studies are done to discover new information or to answer a question. Some studies might involve simple tasks like completing a survey, being observed among a group of people, or participating in a group discussion. Other studies, called clinical trials, involve procedures like testing a new drug or medical device.

Who can participate?

Each research study has its own set of criteria to determine who can participate. This depends on the research question being asked and may include restrictions based on age, behaviors, health status, or other traits.

Why should I participate?

Research is designed to benefit society. While there are several reasons why people choose to participate in research, most people participate based on the possibility of helping themselves or others.

How am I protected?

Research studies involving humans must be approved and monitored by an Institutional Review Board (IRB). An IRB is a committee of individuals responsible for reviewing research to ensure protections are in place for the people who participate. For each study reviewed, the IRB checks to see that:

- Risks to subjects are minimized
- The risks related to participating are reasonable in relation to the anticipated benefit
- The selection of subjects is equitable
- Subjects will be provided enough information about the study, in an understandable manner, to make an informed decision about participation
- Adequate protection is in place to protect subjects' privacy and maintain confidentiality
- Additional safeguards are included for vulnerable subjects (children, pregnant women, prisoners)
- If you are a parent or guardian, and your child/adolescent is the research subject, the consent process is also referred to as parental permission. Additionally, we like to know that your child understands what they're participating in. If your child is 7 to 17 and is capable of understanding, we also will ask them if they are willing to participate.

How will my information be protected?

Protecting the information you provide to researchers is a high priority, particularly if you provide health-related or sensitive information. As part of the IRB approval process, all researchers must provide a plan to protect the information they plan to collect in order for the study to be approved.

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What are the risks of being in a study?

Most studies involve some risk, though the risks can range from very small to very serious. Some examples of risks include

- Side effects or reactions to experimental drugs, treatments, or procedures
- Feeling anxious or uncomfortable
- Breach in confidentiality

Side effects or other risks you might experience may be temporary or go away with treatment. There may also be risks in participating that we don't yet know about.

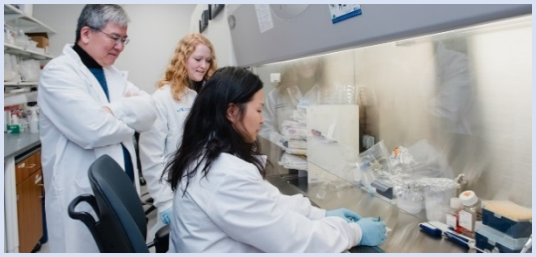
Can I change my mind about being in a study once I start?

Your participation in research is voluntary. You are free to withdraw from a study at any time, for any reason. Your relationship with the hospital, clinic, academic institution, or employer will not be affected and you will not lose any benefits to which you are entitled.

What do I need to know before I agree to participate?

Before you agree to be in the study, make sure you understand the following:

- the voluntary nature of the study
- why the study is being done
- who is doing the study
- the procedures, activities, tests, or treatments involved (including how long they will take, how often, and if there are any other treatment options available rather than being in the study)
- potential risks, discomforts, or side effects
- potential benefits to participating, if any
- how your privacy will be protected
- how long your participation will last
- what will happen if you are injured while participating
- the costs to you, if any
- what to do if you change your mind about participating



Who can I contact at Connecticut Children's if I have any questions or concerns?

If you have any questions or concerns about your role and rights as a research participant at Connecticut Children's, please contact the IRB via email at irbstaff@connecticutchildrens.org or 860.837.5515

Where can I find more information and resources?

Visit the U.S. Department of Health and Human Services Office for Human Research Protection

https://www.hhs.gov/ohrp/education-and-outreach/about-research-participation/index.html

https://www.childrenshospital.org/research/irb/information-families