St. Jude Children's Research Hospital
ALSAC • Danny Thomas, Founder
Finding cures. Saving children.

Taking part in clinical research

What is clinical research?

Clinical research is scientific research that includes people. Scientists do it to learn more about diseases. They also test new medical treatments or combinations of treatments that doctors already use. The goal is to find new and better treatments that help patients. You might also hear clinical research called a "clinical trial," a "research study," or just a study.

All the people taking part in clinical research are volunteers. Children are in clinical research studies if their parents or legal guardians agree.

Why do people take part in clinical research?

Some reasons for taking part in clinical research include:

- Helping learn about disease,
- Helping find new treatments,
- Getting a treatment that is not available to the public yet, or
- Getting a new treatment because the usual treatment does not work well.

Clinical research is different from regular medical treatment

Clinical research often includes medical treatment. But it is not the same as regular medical treatment for a disease or condition. Scientists do research to learn and possibly improve treatment for all children in the future. Every clinical research study has a plan that scientists must follow closely. The plan is sometimes called a protocol. They cannot change the treatment for each volunteer, like a doctor can for regular patients.

Medical treatment is the specific treatment a doctor recommends for your child. Doctors know the benefits of this treatment, and they can change the treatment plan just for your child.

Your child might have both medical treatment and clinical research treatment. The medical treatment is known, but the clinical research treatment is new. It is not fully tested or approved yet. You can also choose for your child to have just medical treatment or just clinical research treatment.

Who is in charge of clinical research?

Many people work together to make sure scientists do clinical research safely and correctly. A group called an Institutional Review Board reviews every new clinical research study at a hospital or medical school before the study starts.

Revised 02/18

...*continued from page 1*

Taking part in clinical research

The Institutional Review Board, or IRB, is a group of scientists, doctors, other health care professionals, and people from the community. They consider the benefits and risks of the research study. They can approve the study or ask scientists to make changes. The IRB helps make sure the patients who volunteer to be in a clinical research study are protected.

If you are interested in clinical research

If you are interested in taking part in clinical research, or having your child take part, you meet with someone from the clinical research team. They spend time telling you about the study before you decide. They will use words you and your child can understand. The research team member will also encourage you to ask questions so you and your child know exactly what to expect.

Here are the main things the research team will explain:

- Why scientists are doing the study, and what will happen in it – including any new tests, treatments, and procedures.
- How long the study will last.
- The possible benefits of taking part in the study.
- Possible risks, side effects, or expected discomforts.
- Your child's other treatment options, including the usual medical treatments for your child's illness.
- How the study will protect your privacy.
- Who to contact with questions.

The research team member will also explain that taking part in the study is your choice. You do not lose any rights to treatment if your child does not take part. You may also take your child out of the study at any time. If you do, you can ask for regular medical treatment.

Signing the informed consent form

For your child to take part in a clinical study, St. Jude doctors will ask one (1) or both parents or legal guardians to give written permission. You do this by signing a form that explains the study. It is called an "informed consent form," or sometimes just "informed consent." If your child is 18 or older, they may sign their own consent form.

What is assent and how is it different from consent?

Assent is a way of agreeing to be in a clinical research study for children who are too young to give consent. The law says that only someone older than 18 can give legal consent. But we can ask younger children if they agree to take part in a research study. So we might ask your child between 7 and 17 years old for their "assent" (agreement) to take part.

Revised 02/18

...continued from page 2

Taking part in clinical research

Research team members do not usually ask children under age 7 for their assent. This is because they are usually too young to understand the study completely. But you must still sign a consent form for your child to take part in the study.

What if I decide not to take part in clinical research?

You might learn about a clinical research study, but decide not to have your child take part. If so, your child might still be able to get treatment at St. Jude. Or we can refer you to a different hospital for treatment. In either case, the St. Jude staff will help you.

If you want to stop taking part in clinical research

If you want to stop taking part in clinical research, you can do so. You can take your child out of a research study at any time, for any reason. If your child is older than 18, they can stop taking part on their own.

If you do stop taking part in clinical research, talk to your child's doctor first about other options or treatments.

Questions?

Ask your child's doctor or nurse if you have questions about your child taking part in clinical research. You may also ask a St. Jude social worker or the research participant advocate. The research participant advocate can help answer questions about your rights if you or your child is in a research study. To reach the research participant advocate, call 901-595-4644. If you are outside the Memphis area, dial 1-866-JUDE IRB (1-866-583-3472).

St. Jude complies with health care-related federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.

ATTENTION: If you speak another language, assistance services, free of charge, are available to you. Call 1-866-278-5833 (TTY: 1-901-595-1040).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-866-278-5833 (TTY: 1-901-595-1040).

تنبيه: إذا كنت تتحدث باللغة العربية فيمكنك الاستعانة بخدمات المساعدة اللغوية المتوفرة لك مجانا. يرجى الاتصال بالرقم 1-866-278-5833 (الهاتف النصي: 1-901-595-1040).

Revised 02/18