Clinical research is scientific research that includes people. Scientists do it to learn more about diseases and treatments.

The rules of scientific research tell scientists to do clinical research studies in a certain order. This keeps you and other people who take part in clinical research studies safe. It also helps the studies give more accurate results.

Most clinical research studies have 4 phases. Some studies are a combination of 2 phases, such as phase 2 and phase 3. This page tells you about the different phases.

**Phase I clinical research**

Phase I studies are for first-time experimental treatments. They can include healthy volunteers or people with a certain disease or condition.

Most Phase I clinical research studies give the experimental treatment to just one (1) group of people. There is only one (1) group in the study, and everyone gets the same treatment. A fairly small number of people take part in Phase I studies. Most Phase I studies have between 10 and 80 people.

Scientists want to answer the following questions in a Phase I study.

- Is the treatment safe?
- What dose, or amount, of the treatment is safe?
- What are the side effects?

**Phase II clinical research**

Phase II studies are for treatments that have already been tested in Phase I. Scientists want to learn how well the new treatment works for you and others with a certain disease. They might test the new treatment against the regular treatment to see which works better. They might also test different doses (amounts) of the new treatment.

A Phase II study can include several different groups of people. To make sure the research is fair, scientists use a computer program to put people in different groups.

Phase II studies have more people in them than Phase I studies. For example, most Phase II studies include 100 to 200 people. Scientists study the treatment for a longer time than in Phase I. They want to learn which patients the treatment helps most and if they should do more studies.
Phase III clinical research

Phase III clinical research studies compare the new treatment with the regular treatment in large numbers of people. They also look for side effects of the new drug or treatment. They might compare these to the side effects of the regular drug or treatment.

A Phase III study usually has more than 300 people in several different groups. Scientists use a computer to assign people to different groups, to make sure the research is fair.

Phase IV clinical research

Scientists do Phase IV clinical research studies after the US Food and Drug Administration has approved a drug, treatment, or piece of medical equipment for use. Scientists doing Phase IV trials want to learn:

- More about the side effects and safety of the new treatment,
- What the long-term risks and benefits are, and
- How well the treatment works for a very large number of people.

Questions?

Ask your child’s doctor or nurse if you have questions about 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).