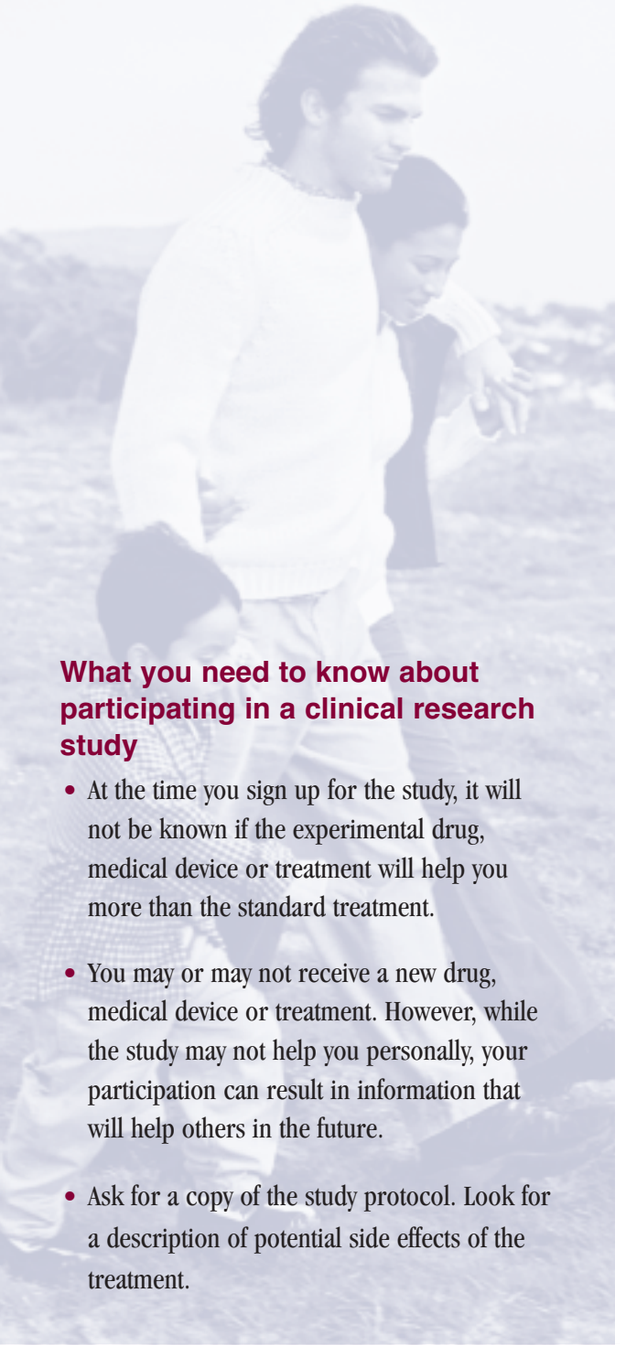
What you should know about research studies

A Speak Up™ safety initiative

Joint Commission
on Accreditation of Healthcare Organizations
Setting the Standard for Quality in Health Care

Your safety in a research study

Research involving human subjects significantly contributes to the quality of life for millions of people worldwide. Most of the advanced medical technologies available today — pacemakers, artificial limbs, drug therapies and CT scans — would not have been possible without research involving human subjects. This brochure, which is part of the Joint Commission's Speak Up™ patient safety initiative, provides guidance and a list of questions to ask if you're thinking about participating in a clinical research study. You can play a vital role in making the research process as safe as possible by becoming active, involved and informed.



What you need to know about participating in a clinical research study

- At the time you sign up for the study, it will not be known if the experimental drug, medical device or treatment will help you more than the standard treatment.
- You may or may not receive a new drug, medical device or treatment. However, while the study may not help you personally, your participation can result in information that will help others in the future.
- Ask for a copy of the study protocol. Look for a description of potential side effects of the treatment.
- Some drugs, medical devices or treatments can have side effects that may be mild, severe or even life threatening.
- The costs of participating in a research study are not always covered or paid for by health insurance. Talk to the doctor conducting the research and your insurance provider to determine if there will be any extra expense to you.
- Clinical research studies involving drugs are usually conducted in several phases, beginning with a few volunteers to evaluate initial safety and dosage, and then progressing to larger groups that evaluate long-term safety and effectiveness. Make sure you understand what phase is being evaluated and how it will affect the treatment you receive.
- You will be asked to sign an informed consent form which explains the nature of the study, the risks involved, and what may happen to participants. Take the informed consent document home, read it thoroughly, and review it with your family.
- For help in understanding the informed consent or study protocol, seek out expert advice from a family physician, a patient advocate, or a specialist who treats your disorder.
- Many clinical studies are reviewed by an Institutional Review Board (IRB). The IRB oversees the safety of the study and can halt a study at any time if there is a concern.

Questions to ask your doctor or the researcher conducting the research study

- Why is this experiment being conducted?
- Who is doing the study?
- Will I be able to continue to see my own doctor?
- Is there any cost to me or will I be paid to participate in this study?
- Does anyone receive money for my enrollment in the study?
- How long will this study last?
- What tests or treatments will be used in the study?
- What other options or choices do I have if I decide not to take part in this study?
- Is it possible that I will receive a placebo?
- What could happen to me, good or bad, if I take part in the study? Have there been any ill effects reported to date? How serious were they?
- Could my condition get worse during the study? What will happen if it does? If my condition worsens, will I be notified? How?
- Can I stop participating in the study if I change my mind?
- Could there be any danger to me if I stop participating?
- Who pays for my care if I'm injured during the study?
- What will happen to me at the end of the study? Will I be told the results of the study?
- Whom do I contact for answers to questions and information about the study? Do you have any patient advocates, independent of your institution, I can talk to?
- Who stands to benefit financially from the results of this study? Is there a conflict of interest with the researcher? If so, how is it being managed?
- Is the research program or reviewing IRB accredited?

For more information

- www.circare.org
- www.fda.gov/oc/gcp
- www.hhs.gov/ohrp
- www1.va.gov/resdev/programs/pride/veterans/default.cfm
- http://ciscrp.org