For more information

Citizens For Responsible Care and Research
www.circare.org

United States Food and Drug Administration
www.fda.gov/oc/gcp

United States Department of Health & Human Services
Office for Human Research Protections
www.hhs.gov/ohrp

United States Department of Veterans Affairs
Research & Development
http://www.research.va.gov/default.cfm

The Center for Information & Study on Clinical Research Participation
http://ciscrp.org

The Joint Commission

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SpeakUP™

What you should know about research studies

Medical research helps improve the quality of life for people around the world. Research studies test new medicines, treatments, devices and equipment. This brochure has questions and answers about research studies.

Research studies are also called

clinical experiments	experimental trials
clinical research trials	experiments
clinical studies	research
clinical tests	research experiments
clinical trials	research tests
experimental studies	test studies
experimental tests	trials

Will your doctor be doing the research study?

The study may be done by your doctor, another doctor, or a researcher.

Will your health insurance pay for the cost of the research study?

Not always. Ask the doctor or researcher and your insurance company if you will need to pay for any of the research study costs.

What happens during research studies of new medicines?

First, a few volunteers test the safety of the medicine and how much should be taken. Then, larger groups of people test the long term safety of the medicine and how well it works. Find out which group you will be in.

Are you guaranteed to get the new medicine or treatment?

You could get a "placebo" in some studies. A placebo is a medicine or treatment that won't affect your health. Or, you could get a substitute medicine or treatment. The substitute is compared to the new medicine or treatment.

Will the study help you if you get a placebo or substitute?

Probably not, but your participation can result in information that will help others.

Can the research study make your condition worse?

Ask the doctor or researcher what could happen to you during the study. Ask for a copy of the study "protocol" or plan. Ask about side effects of the medicine, treatment, device or equipment. Look for side effects while you are in the study.

What is "informed consent?"

This means that the doctor or researcher told you about the research study and its risks. It also means that you understand what you were told. You will be asked to sign an informed consent form. Take the form home and read it with your family before you decide if you want to sign it.

What should you do if you don't understand the informed consent form or study protocol?

Ask your doctor or the researcher to explain them. You can also ask your doctor or the researcher to recommend a patient "advocate." This person helps patients understand their treatment and their choices in treatment.

Who can you call if you have concerns about the research study?

Many research studies are reviewed by an Institutional Review Board. This board makes sure that the study is safe. It can also stop a study if there is a concern about safety. If the study is paid for by the federal government it must be registered with the Office of Human Research Protections.

Questions to ask the doctor or researcher

- Why is the research study being done?
- Who is doing the study?
- How long will the study last?
- Will you be able to continue seeing your own doctor?
- Is there any cost to you? Will you be paid to participate in the study?
- Does anyone receive money for your participation in the study?
- What tests or treatments will be used in the study?
- What are your other choices if you decide not to take part in the study?
- Will the new treatment help you more than the regular treatment?
- Could you get a "placebo" or a substitute?
- What could happen to you if you take part in the study? Has anyone reported any bad effects? How serious were they?
- Could your condition get worse during the study? What happens if it does? If your condition worsens, will you be told? How?
- Who pays for your care if you're injured during the study?
- Can you stop participating in the study if you change your mind? Is there any danger to you if you stop participating?
- What will happen to you after the study?
- Will you be told the results of the study?
- Who do you contact for information about the study?
- Are there any patient advocates you can talk to? The advocate should not be employed by the clinic or laboratory that is doing the research study.
- Who could benefit financially from the results of the study?
- Does the doctor or researcher personally benefit if you participate?

The goal of the Speak Up™ program is to help patients become more informed and involved in their health care.