

This is intended as general educational information. Talk to your doctor about your own care.

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For More Information

National Institutes of Health, DHHS:

- Finding up-to-date information on clinical trials:
<http://www.clinicaltrials.gov>
- Educational information on participating in research:
<http://www.nlm.nih.gov/medlineplus/clinicaltrials.html>
- The Privacy Rule and Research:
<http://privacyruleandresearch.nih.gov/patients.asp>

National Cancer Institute

- Finding information on research studies on cancer:
<http://cancertrials.nci.nih.gov/>
- Clinical Trials: Questions and Answers
<http://www.cancer.gov/cancertopics/factsheet/Information/clinical-trials>

Other Sources

- Centers for Disease Control & Prevention, DHHS:
<http://www.cdc.gov/hiv/pubs/brochure/unc3bro.htm>
- Food and Drug Administration, DHHS:
<http://www.fda.gov/oashi/clinicaltrials/default.htm>

- Office for Human Research Protections, DHHS:
www.hhs.gov/ohrp
- US Department of Veterans Affairs
<http://www1.va.gov/resdev/programs/PRIDE/veterans/default.cfm>
- GetResearchSmart LLC:
<http://www.getresearchsmart.org>
- Should I Enter a Clinical Trial? A Patient Reference Guide for Adults with a Serious or Life-Threatening Illness. A Report by ECRI Commissioned by the American Association of Health Plans:
www.ecri.org/Patient_Information/Patient_Reference_Guide/prg.pdf



Place your office contact information here.



VOLUNTEERING

for a
RESEARCH
Study

Talk with Your
Doctor About
What You
Should Know



What You Should Know About Research

Patients have many reasons for volunteering for research studies. Some hope to improve care for future patients with health problems like theirs. Others hope to receive the newest treatments. Some want more careful monitoring of their conditions and treatments. Still others hope for free care they need, but can't afford.

Choosing to be a research volunteer, also called a research or human subject, is a complicated decision. Your doctor can help you make an informed decision.

Research is different from regular medical treatment because the goals are different.

The goal of regular treatment is always the well-being of the individual patient. A doctor recommends the tests and care that are best for a specific patient by balancing the risks against the likely benefits for that patient.

In contrast, the goal of research is to increase knowledge of human health and to better understand medical problems and diseases to improve future patient care. You can consider this worthy goal when deciding whether to participate in research.

A researcher asks you to participate in a study because you meet the specific requirements of that study, not necessarily because he or she knows the study will benefit you personally.

Participating in a research study may or may not help you personally. Each study is based on an action plan called a protocol, not on the specific needs of the individual study volunteers.



Some elements of the research study may be part of your usual care and others may not. The study may require that you have tests or procedures done just for research purposes.

You may or may not receive the new product or intervention being studied. Some studies compare a new product, such as a drug, against a drug already prescribed by doctors and/or against no treatment at all.

Study volunteers may receive the new product, the established product, or an inactive "sugar pill" called a placebo. Usually, neither the volunteers nor the researchers know who is receiving what.

Your decision to volunteer as a research subject should be based on your needs and values, not on a desire to please your doctor.

Your decision shouldn't change your relationship with your doctor or your access to regular care.

You have the right to ask questions about a study and to quit a study at any time.

Before you agree (consent) to participate in a study, you must understand the purpose of the study, what will be involved, the potential risks and benefits, and the alternative options for treatment.

Making an Informed Decision

Questions You Should Ask About the Research Study

- What is the study about?
- Why should I be in the study?
- What exactly will happen to me in this study and what will I have to do?
- What are the potential benefits and risks to me of participating in the study?
- Are there established treatment options that I should consider instead of participating in the study?
- Could my participation in the study affect or limit my treatment options in the future?
- Who is paying for this study? Who will make money from the results?
- If I participate, will I receive free health care? Will I be paid for participating? Will there be costs to me or my insurance company for my participation?
- Who do I talk to if I have questions or concerns about the study? What if I decide to quit the study? Will I be penalized in any way?
- What will be done with the study results? Will I be informed?

Questions You Should Also Ask When Your Doctor is Doing the Research

- Why are you doing the research? Do you benefit if I participate? How?
- As both a researcher and my doctor, how will your research goals affect your decisions about my regular care?
- How will I know the difference between when you are working as a research scientist on the study and when you are working as my doctor providing regular care?
- How will this study affect my regular ongoing care?
- What if I quit the study? Will it affect our regular doctor-patient relationship? What about future treatment for the condition being studied?
- How will my privacy be protected? Who will have access to my study record? Will my regular medical record be separate from the study records?
- Will you keep me informed of developments in the study that might be important to me?

