

Department of Veterans Affairs New York Harbor Healthcare System Participant Outreach Corner

1. WELCOME to the Participant Outreach Corner. VA New York Harbor Healthcare System is committed to assuring that all of its research activities involving human subjects are conducted in a way that promotes the rights and welfare of subjects. Your comments and suggestions are welcomed; please contact us for questions, concerns, or complaints about research, research related injury, and questions about the rights of research participants. Any member of the research community, investigators, research co-coordinators or anyone involved in research that may have questions, concerns and/or suggestions are welcome to directly contact the following individuals who are available to respond to your research questions, concerns and suggestions:

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2. Frequently Asked Questions

a) What is a Clinical Trial?

"Clinical trial" is the scientific term for a test or study of a drug or medical device in people. These tests are done to see if the drug or device is safe and effective for people to use. Doctors, health professionals, and other researchers run the tests according to strict rules set by the Office for Human Research Protections ([OHRP](http://www.hhs.gov/ohrp/)) and the Food and Drug Administration ([FDA](http://www.fda.gov/)). For more information see: <http://www.fda.gov/oashi/clinicaltrials/default.htm>.

b) What are the Phases of a Clinical Trial?

Clinical trials are conducted in a series of steps, called phases - each phase is designed to answer a separate research question.

* **Phase I:** Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

* **Phase II:** The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.

* **Phase III:** The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

* **Phase IV:** Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

Additional information on clinical trials can be found at <http://clinicaltrials.gov/info/resources>.

c) Why Should Minorities and Women Participate In Clinical Trials?

In the past, most drug testing has been done on white men. This means that some groups, such as African Americans, Hispanic Americans, American Indians, Asian Americans, and women, have not always been included in the tests done on drugs. But sometimes drugs work differently on people in these groups than on white men. So the FDA encourages people from many different groups to participate in these studies.

d) Points to Remember

- * Clinical trials are tests of medical treatments to see if they are safe and if they work.
- * Before you agree to take part in a study, you must be given complete information about the study, including possible side effects and benefits.
- * You must sign a special agreement called "Informed Consent" before taking part in the study.
- * You can leave the study at any time.

e) Informed Consent Protects Research Participants

To help you decide if you want to be a research participant in a study, the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) require that you be given information about the study before you agree to take part. This is known as informed consent. FDA requires that research participants be told:

- * that the study involves research of an unproven drug or device
- * the purpose of the research
- * how long the study is expected to take
- * what will go on in the study and which parts of the study are experimental
- * possible risks or discomforts
- * possible benefits
- * other procedures or treatments that you might want to consider instead of the treatment being studied
- * that FDA may inspect study records, but the records will be kept confidential
- * whether any medical treatments are available if you are hurt, what those treatments are, where they can be found, and who will pay for the treatment
- * the person to contact with questions about the study, your rights, and injuries related to research
- * being in the study is voluntary and you can quit at any time.

Informed consent information should be written so you can understand it. If you don't, be sure to ask the doctor, researcher, or other medical person to explain it. Make sure you understand all of it before you agree to be in the study.

The informed consent form should state you can leave the study at any time for any reason.

f) Other Ways Research Participants Are Protected

* Institutional Review Board (IRB) -- Scientists, doctors and other people from the local community serve on Stanford's IRB to review and monitor their hospital's or research institution's medical research involving people. They monitor studies to help make sure that there is the least possible risk to research

participants and that the risks are reasonable in relation to the expected benefits. IRBs make sure research participant's selection is fair and that informed consent is done correctly.

[Click here to view our current IRB member roster for more information.](#)

* Data Monitoring Committees -- These committees are used mainly when one treatment is being compared with another and in studies where treatments are selected for patients at random. These committees are particularly important in tests of treatments for serious or life-threatening disease. These experts review information from studies to make sure they are being done in a way that is safest for the research participants. During a study, if the committee finds that the treatment is harmful or of no benefit, it will stop the study. If there is evidence that one treatment gives a greater benefit than another, the committee stops the study and all research participants are offered the better treatment.

* FDA Inspections -- FDA inspects records, clinics, and other research sites involved in a study to make sure research participants are being protected and studies are being done correctly. From time to time such inspections are done in response to complaints.

g) Why do people participate in research studies?

By taking part in a clinical trial, you can try a new treatment that may or may not be better than those already available. You can also contribute to better understanding of how the treatment works in people of different ethnic backgrounds and genders.

h) What are the risks?

Many studies require that neither the patient nor the doctor know whether the patient is receiving the experimental treatment, the standard treatment or a placebo (an inactive substance that looks like the drug being tested). In other words, some research participants may be getting no treatment at all.

Some treatments that are being tested have side effects that can be unpleasant, serious or even life-threatening. Because the treatments being studied are new, doctors don't always know what the side effects will be. Many side effects are temporary and go away when the treatment is stopped. But others can be permanent. Some side effects appear during treatment, while others may not show up until after the treatment is over. The risks depend on the treatment being studied and should be fully explained to you in the informed consent material.

3. Questions to Ask

Here are some questions to ask your doctor to help you decide if you want to take part in a clinical trial:

- * What is the study trying to find out?
- * What kinds of test and exams will I have to take while I'm in the study?
- * How much time do these take? What is involved in each test?
- * How often does the study require me to go to the doctor or clinic?
- * Will I be hospitalized? If so, how often and for how long?
- * What are the costs to me? Will my health insurance pay for it?
- * What follow-up will there be?
- * What will happen at the end of the study?
- * What are my other treatment choices? How do they compare with the treatment being studied?
- * What side effects can I expect from the treatment being tested? How do they compare with side effects of standard treatment? How long will the study last?

a) How Can I Find Out About Clinical Trials?

One good way to find out if there are any treatments in clinical trials that might help you is to ask your doctor. Other sources of information include:

* For cancer, please contact Stanford's Cancer Clinical Trials Office at 650-498-7061 or visit their [Patient Information Web site](#). Also, call the National Cancer Institute at 1-800-4-CANCER (1-800-422-6237) or visit their Website: <http://www.cancer.gov/clinicaltrials>.

* For AIDS and HIV, please visit Stanford's AIDS Clinical Trial Unit at <http://www.stanford.edu/group/aids/>. Also, call the National Institute of Health at 1-800-448-0440 or visit their Website: <http://aidsinfo.nih.gov>

* For general information about clinical trials, call FDA's Office of Special Health Issues at 301-827-4460 or visit this World Wide Website: <http://www.fda.gov/oashi/home.html>

* For other clinical trials, visit this World Wide Website: <http://www.nih.gov/health/trials/index.htm>

4. Brochures and Patient Complaint Policy

- [Volunteering in Research 1](#)
- [Volunteering in Research 2](#)
- [Volunteering in Research \(Spanish\)](#)
- [Research Patient Complaint Policy](#)