

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

1. WELCOME to the Participant Outreach Corner

VA NYHHS 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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VA Central Office Outreach link:

<http://www.research.va.gov/programs/pride/veterans/default.cfm>

2. Frequently Asked Questions

a) What is a Clinical Trial?

Clinical Trials are research studies that test how well new medical approaches work in people. Each study answers scientific questions and tries to find better ways to prevent, screen for, diagnose, or treat a disease. Professional trained Doctors, health professionals and other researchers must conduct the research appropriately. There are the statute and limitation in conduction Research Studies set by the Office for Human Research Protection (OHRP) and the Food and Drug Administration (FDA). For more information log onto: [http://www.fda.gov/oashi/clinical trials/default.htm](http://www.fda.gov/oashi/clinical%20trials/default.htm).

b) What are the types of Clinical Trials?

There are several types of clinical trials

- **Prevention trials** test new approaches, such as medications, vitamins, or other supplements that doctors believe may lower the risk of developing a certain type of disease. Most prevention trials are conducted with healthy people who have had a disease and want to prevent recurrence.
- **Screening trials** study ways to detect a disease earlier. They are often conducted to determine whether finding the disease before it causes symptoms decreases the chance of dying from the disease. These trials involve people who do not have any symptoms of any kind of disease.
- **Diagnostic trials** study test of procedures that could be used to identify diseases more accurately. Diagnostic trials usually include people who have signs or symptoms of a particular kind of disease.
- **Treatment trials** are conducted with people who have a pre existing disease. They are designed to answer specific questions about, and evaluate the effectiveness of, a new treatment or a new way using a standard treatment. These trials test many types of treatments, such as new drugs, and vaccines, new approaches to surgery or any other type of new treatment.
- **Quality-of-life (also called supportive care) trials** explore ways to improve the comfort quality of life patients and survivors. These trials may study ways to help people who are experiencing symptoms of their diseases. Such as; nausea, vomiting, sleep disorder, depression or other effects from its treatment.

- **Genetics studies** are sometimes part of another clinical trial. May focus on how genetic makeup can affect detection, diagnosis, or responses to treatment.

c) What are Phases of Clinical Trials?

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 in a large group 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>.

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

In the past, most drug testing has been conducted on white men. This means that some ethnic 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. Therefore, the FDA encourages people from any different groups to participate in these studies.

e) How are Participants Protected?

Research with people is conducted according to strict scientific and ethical principles. Every clinical trial has a protocol, or an action plan which acts like a “recipe” for conducting the trial. The plan describes what will be done in the study, how it will be conducted, and why each part of the study is necessary. To help you decide if you want to be a research participant in a study the Office for Human Research (OHRP) and the Food and Drug Administration (FDA) requires that you be given information about the study before you agree to take part. This

is known as the informed consent. FDA requires that research participants be told:

- What the study involves.
- Whether the drug is unapproved or approved by the FDA.
- The purpose of the research.
- How long the study is expected to take place.
- What will go on in the study and which parts of the study is experimental.
- Possible risk or discomforts.
- Possible benefits.
- Other procedures or treatments that you might want to consider instead of the treatment being studied.
- FDA may inspect study records, all records will be kept in safe, locked, and confidential place.

Please note: Information written on an informed consent should be written so that you can understand it. If you do not understand the language context please be sure to ask the doctor, research nurse, the researcher, or other medical staff to explain it. Make sure you understand all of the information provided to you, before you agree to be in the study.

The informed consent should also state that, you may leave the study at any time, for any reason. If anyone asks you to take part in a research study, you have the rights to say “no.” Your decision will not affect your VA health care or benefits. You need to weigh both the potential risk and potential benefits of the study. You can change your mind and leave a research study at any time without losing any of your VA health care benefits.

f) Points to Remember

- Clinical Trial is a Research Studies that test how well Medical approaches work in people.
- 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 may withdraw from the study at any time.

g) Other Ways Research Participants Are Protected

Institutional Review Board (IRB) --Scientists, doctors and other people from the local community serve VA NYHHS 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. The IRB make sure research participant's selection is fair and that informed consent is done correctly. View our current IRB member roster for more information.

<p><u>Voting Officials</u> Pasquariello, Christine, M.D. Bini, Edmund, MD, Co-Chairperson Norwood, Dorothy, M.D., Co-Chairperson Araten, David J., M.D. Cruz, Muriel T., RN, Ed.D. Desai, Katherine, LIB,JD Gouge, Thomas H., M.D. Hoffman, David, R.Ph., Ph.D. Martz, Merrill, Ph.D. Maxwell, Barbara L., B.A. Mitzeliotis, Claudia, R.N. Palmer, Edna Pearl, B.A. Rubinstein, Mort, M.D. Schrader, Richard C. Sharkey, Charles C., R.Ph. Tracy, Kathlene, Ph.D.</p>	<p>Co-Chief, General Internal Medicine Section Gastroenterologist/Manhattan Campus Primary Care Medicine/Bklyn Campus Assistant Professor Cardiology/Manhattan Campus Attorney/Consultant/Non-VA(NY) Surgery(NY) Research Pharmacy Neurology/Non-VA Member Community Representative/Non-Affiliated (Brooklyn) Psychiatric Clinical Nurse Specialist(Bk) Community Representative/Non-Affiliated (NY) Mental Health Community Representative/Non-VA (Bk) Pharmacy/Bklyn Campus Mental Health\ Manhattan Campus</p>
<p><u>Ex-Officio Non-Voting</u> Abarientos, Mama, M.D. Boutjdir, Mohamed, Ph.D. FAHA Dowers, Leslie, M.S.A. John, Stanley L., CCRC Meci, Robert E. Perez, Sharon Seaquist, Lindsay Tozzi, John</p>	<p>Research Compliance Officer ACOS/R&D/NYHHS AO/R&D/Bklyn Campus VAMC IRB Manager AO/R&D/New York Campus Executive Director, Narrows Institute Privacy Officer Information Security Officer</p>

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Ex-Officio Non-Voting Wenzel, Bethanne D. [for Perez]	

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.

h) Why should people participate in research studies?

Taking part of a research study can contribute, to society as a whole. It plays an active role in your own healthcare. You may gain access to new research treatment before, they are widely available and help others by contributing to medical research.

i) What are the possible risk level associated with taking part in a clinical trial?

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.

j) Questions or Concerns about clinical trials should always be addressed.

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

- Who is doing this study and what questions might it answer?
- Who reviewed or approved this study?
- What could happen to my health, good or bad, if I take part in this study?
- Is it possible that I will receive a placebo (inactive substance)?
- What tests or procedures will I have during the study?
- How long will this study last?
- If I decide to participate in this study, how will it affect my daily life?
- Could my conditions get worse during the study? What happens if it does?
- Who will be in charge of my care? Can I continue seeing my own doctor?
- What happens to any specimens that I give?
- What happens after the study ends?
- Will I be told the results of the study?
- How do I end my participation in this study if I change my mind?
- What other options or choices do I have if I decide not to take part in this study?
- Whom do I contact for questions and information about the study? treatment being studied?

How Can I Find Out About Clinical Trials?

One good way to find out if there are any clinical trials that might help you is to ask **your doctor**. Other sources of information available at our Institution include:

***Virtual Bulletin Board** Located in our Hospitals' lobbies and other high visibility patient waiting areas at both of our main Campuses are these very large wall mounted flat screen TVs. Included in the programming is a presentation "Volunteering in VA Research" which contains very important information that you will find most useful as a Research Participant.

***Research Participant Information Booths (RPIB).**

Effective 2009 you will be able to access more information from RPIB located in the main lobby areas at our main VA campuses. These booths will be staffed with personnel from our R & D Department who will be available for consultation. These RPIB will be conducted on a quarterly basis between the hours of 9:00am – 4:00 pm. Contact the research office at 212 951-3323 for NY campus and 718 630-3645 for Brooklyn Campus about the dates.

*** VA NYHHS Research Day**

In 2010 we will celebrates Research Day between **April 26 -30, 2009** at our New York Campus. This is another opportunity where anyone can access an abundance of information regarding current research activities being conducted at VAMC. There will be a yearly research day thereafter. Contact the research office at 212 951-3323 for NY campus and 718 630-3645 for Brooklyn Campus about the dates.

The National Cancer Institute 800-4-CANCER (800-422-6237) or <http://www.cancer.gov/clinicaltrials>.

For AIDS and HIV: the National Institute of Health 800-448-0440 or: <http://aidsinfo.nih.gov>

For general information about clinical trials: FDA's Office of Special Health Issues 301-827-4460: <http://www.fda.gov/oashi/home.html>

For other clinical trials:
<http://www.nih.gov/health/trials/index.htm>

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