What if I do not want to take part in a research study?

- If you decide to take part in a study, you do so as a VOLUNTEER. This means YOU decide.
- If anyone asks you to take part in a research study, you have the right to say "no."
- Your decision will not affect your VA health care or benefits.
- You need to weigh both the potential risks 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.

Who will answer my questions?

If you have any questions, concerns, or complaints about VA research, or if you would like to talk to someone about the VA Research program, please contact:

The VA Office of Research & Development’s Center On Advice and Compliance Help (COACH) offers free educational materials to help assure that Veterans receive adequate information when they consider participating in VA research. You can order additional copies of this brochure and other brochures, a video on VHS tape or DVD-ROM, and posters at:

www.research.va.gov/programs/pride/resources/order.cfm

What questions should I ask before volunteering?

If you are asked to participate in a research study, you might want to ask the questions on this tear out to help you decide whether or not you want to take part in the study.

Tear this page out and take it with you to remind yourself of some of the questions to ask.

- What is the purpose of the study?
- How will my information be kept private? (If this information will not be kept private, you should not participate.)
- Will I have to take part in a study if I am enrolled at a VA Medical Center?
- Will I be paid for my time and expenses?
- Will the study affect the care or treatment received in the VA health care system?
- Will I be asked to take any new treatments or medications?
- What are the potential risks and benefits of the study?
- What are my chances of getting better from the study?
- If the study is making me worse, can I get out of it? Will I be reimbursed for any harms that resulted from the study?
- What will happen to the results of the study?
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Here are some things you need to know

The Department of Veterans Affairs (VA) ranks as one of the nation’s leaders in health research. Thousands of studies are conducted at VA medical centers, outpatient clinics, and nursing homes each year. This research has significantly contributed to advancements in health care for Veterans and other Americans from every walk of life.

For example, VA researchers have:

• Used microelectronics and microchips (very small electronic components), as well as robotics, to create artificial limbs (prostheses) that look, feel, and work more like natural arms and legs.
• Developed the nicotine patch to help people stop smoking.
• Invented the cardiac pacemaker.
• Performed the first successful liver transplant.
• Played a major role in the development of the CAT (or CT) scan.
• Helped to develop new drugs and treatments for diseases such as HIV/AIDS, diabetes, Alzheimer’s, and osteoporosis.

These important health care advances are only possible because Veterans volunteered to take part in research projects.

What is a research study?
A research study is an organized way of learning more about a problem or answering a question.
A research study may be done to:

• Understand health needs, concerns, or feelings people have about an illness or their general health.
• Test if a product, such as a drug or piece of equipment, is safe and effective.
• Determine the best way to treat or prevent an illness.
• Find out what health care practices work best.

Like your medical record, the information in your research record will be kept confidential.

Are there benefits to being in a research study?

There may or may not be a direct benefit to your health or health condition if you take part in a research study. No one can predict the exact outcome of a research study or how it might affect you. The study may not help you personally, but your participation may provide information that will improve the lives of others in the future.

What is informed consent?

Informed consent is the process of learning important facts about the research study before you decide whether or not to volunteer. If you agree to volunteer, it should be based on a clear understanding of what will take place in the study and how it might affect you.

Informed consent begins when the research staff explains the study to you. These facts include details about the study, tests or procedures you may receive, the benefits and risks that could result, and your rights as a research volunteer.

Once your questions have been answered and you fully understand the facts about the research study, you will be asked to sign an “informed consent form.” You should take your time when you read the informed consent form. If you have any questions, ask the research staff to explain. It may be helpful to talk with family members, friends, or your health care providers before you make a decision.

What questions should I ask before volunteering?

If you are asked to participate in a research project, you might want to ask the following questions to help you decide whether or not you want to take part in the study.

• 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, how will it affect my daily life?
• Will I have to make extra trips to the VA?
• Could my condition get worse during the study? What happens if it does?
• Will I be charged anything or paid anything to be in this study?
• Who will be in charge of my care? Can I continue seeing my own doctor?
• Who will be told I am taking part in this study? What information will they receive?
• 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 the study if I change my mind?
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