

VA Boston Healthcare System
150 South Huntington Avenue
(151 MAV)
Jamaica Plain, MA 02130



DATE

PATIENT NAME
ADDRESS 1
ADDRESS 2

Dear MR/MS LAST NAME,

We want to let you know about a research study in Primary & Ambulatory Care and Women's Health at the VA Boston Healthcare System. This study is called *Integrating Pharmacogenetics in Clinical Care* (I-PICC), sponsored by the VA. The I-PICC Study may help to improve the way the VA lowers Veterans' risk of cardiovascular disease, such as heart attack and stroke. Your primary care provider is participating in this study.

Many people take medications called statins to lower their cholesterol and lower their risk of cardiovascular disease. Statins are generally very safe medications, but some patients can experience severe muscle pain or weakness as a side effect. The *SLCO1B1* test is a genetic test that can help predict whether a person will experience muscle side effects when taking a commonly prescribed statin called simvastatin (Zocor). The I-PICC Study **does not require you to take a statin medication. That decision would be up to you and your provider if he or she thinks it's appropriate for your care in the future.** The goal of the I-PICC Study is to improve the care you and other Veterans receive at the VA. We want to see whether this test will improve how providers and patients use statin medications to lower cardiovascular disease risk while decreasing medication side effects.

If you are eligible for the I-PICC Study, your primary care provider may choose to add this test to your routine bloodwork (complete blood count or hemoglobin A1c). **This study does not require a separate visit to the VA or any additional blood draw.** You will not be enrolled in this study without your provider's knowledge – he or she must decide to order the test for you to participate. If your provider orders the test, your blood sample will be sent to a certified clinical laboratory for *SLCO1B1* testing, and the result will be sent back to the VA and reported to your provider.

If the *SLCO1B1* test is ordered for you, you will be randomly assigned either to have your *SLCO1B1* result sent to your provider immediately or made available to him or her after one year. As with other lab tests, your provider will share your *SLCO1B1* result with you, and it will be in your medical record. The I-PICC Study will enroll about 400 patients. At the end of the study, the study team will look at your VA medical records to compare outcomes like medication prescriptions and lab results between the two groups of patients after one year. The study staff may contact you in the future about future research projects related to this study.

The I-PICC Study poses low risk to you. We will protect the privacy of your study data by storing them on encrypted servers accessible only to the study team. As with all of your medical information, your genetic test results will only be accessible to your medical providers and others who have a legitimate reason to access your electronic health record. As always, your provider will continue to monitor your health, including your current medical conditions, any new medical conditions you develop, and any side effects you might have from any of your medications. The VA will provide treatment for any research-related injury in accordance with applicable federal laws. The *SLCO1B1* test is not currently a part of standard care, and your participation in the I-PICC Study will not affect your healthcare or other VA benefits. The

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SLCO1B1 test does not look for genetic diseases, and it is free of charge. You will not be compensated for this study.

If you would like your provider to be able to consider ordering this test and enroll you in the I-PICC Study, please call us at 857-364-6324. It will still be up to your provider to decide whether to order the test. If you reach our voicemail, please mention you are calling about the I-PICC Study and leave your full name, telephone number and the best time for us to return your call. If we do not hear from you, the study staff may reach out to you by phone to ask if you are interested in participating.

Your participation in the I-PICC Study is voluntary, and, if you enroll in the study, you may stop participation at any time without penalty by calling the study staff at 857-364-6324. If you have any questions about the study, please call 857-364-6324.

Thank you for your consideration and for your service.

Sincerely,

Handwritten signature of Jason L. Vassy.

Jason L. Vassy, MD, MPH, SM
Principal Investigator, I-PICC Study