

Title of Study: Million Veteran Program (MVP): A Partnership with Veterans (CSPG002)

Principal Investigators: J. Michael Gaziano, MD, MPH and John Concato, MD, MPH

Local Site Investigator(s): _____

Facility: | | | | | _____

Study ID: | | | | | | | | _____

**HIPAA Authorization
Research and Development Service**

Authorization for Release of Protected Health Information for Research Purposes

You have been asked to be part of a research program called the Million Veteran Program (MVP): A Partnership with Veterans. This program is being sponsored by the Department of Veterans Affairs, Office of Research and Development. J. Michael Gaziano, MD, MPH at the VA Boston Healthcare System in Jamaica Plain and John Concato, MD, MPH at the VA Connecticut Healthcare System in West Haven are serving as the Principal Investigators. The purpose of this program is to create resources within the VA that would allow researchers to conduct genetic research studies. Most diseases and illnesses have a genetic component. Genetic research will help to determine why specific diseases affect certain people, why particular people respond to medical treatments better than others, and why some people have particular reactions to medications when others do not. The Million Veteran Program plans to obtain specimens, after obtaining informed consent, from a large population of Veterans who receive their medical care through the VA in order to study health and genetic characteristics, tie that information to the patient's clinical history, and ultimately improve the quality of healthcare for the individual.

Your individual health data will be obtained to answer future genetic research questions. It is not intended to answer a specific research question at this time.

Data collected from you will include the following:

- Protected health information (PHI) including name, phone number, address, email address, date of birth, SSN, dates of diagnosis, treatment, service, deployment, discharge
- Information from your electronic health record
- Data collected from other CSP (Cooperative Studies Program) or other VA funded studies that you are enrolled in
- Pharmacy records
- Self-reported data from surveys
- Genetic information
- Information from death records including Social Security Death Master Files, National Death Index, and State Vital Statistic Registry

Participant's Name: _____
Last First

Title of Study: Million Veteran Program (MVP): A Partnership with Veterans (CSPG002)

Principal Investigators: J. Michael Gaziano, MD, MPH and John Concato, MD, MPH

Local Site Investigator(s): _____

Facility: | | | | | _____

Study ID: | | | | | | | | _____

All your information will be labeled with a study code that does not identify you directly. Your coded information will be stored in the VA Central Research Database. The key that links your study code to your identity will be kept at a VA Genomics Coordinating Center, and a limited number of authorized staff at the VA Genomics Coordinating Center will have access to the key, which will be password-protected and encrypted so that no one can read it without an encryption key.

Some data that can identify you directly including the date of diagnosis of an illness, date when a treatment was received, or date when a test was conducted will be maintained in the VA Central Research Database. It will be updated with data from your electronic health record on an ongoing basis.

By signing this document, you authorize VHA to collect, create, and use your health information for purposes of this project, and you authorize the placement of your health information as discussed above in the VA Central Research Database.

Your data that is contained within the VA Central Research Database will be available to researchers at the VA, other Federal health agencies, and academic institutions within the United States for research projects approved by applicable VA oversight committees. Approved research projects may be conducted at the VA, other Federal health agencies, or academic institutions within the United States.

Your data will be combined with data from other people taking part in the program. We will write about the combined data we have gathered. Any talks or papers about this program will not identify you.

We may provide your PHI, in limited circumstances, to human rights and protection oversight committees. These committees include the Office of Human Research Protections, the VA Office of Research Oversight, and the VA Central Institutional Review Board. You may expect the same confidentiality from these groups as you would from program staff. If you express suicidal or homicidal intent, we will notify healthcare professionals, law enforcement officials, and family members/significant others, as appropriate, to protect you and others. We are also obliged to warn anyone you have expressed the intent to harm.

If you do not sign this form, you will not be part of the program. Your existing VA care, treatment, payment, enrollment, and/or eligibility for benefits will not be affected.

Participant's Name: _____
Last First

Title of Study: Million Veteran Program (MVP): A Partnership with Veterans (CSPG002)
 Principal Investigators: J. Michael Gaziano, MD, MPH and John Concato, MD, MPH
 Local Site Investigator(s): _____
 Facility: [] [] [] [] [] [] _____
 Study ID: [] [] [] [] [] [] [] [] [] [] _____

As it relates to the collection and use of your health information for this specific program, i.e., developing the VA Central Research Database and its periodic updates, this authorization expires upon completion of this program. This authorization has no expiration date for use of the information that will become part of the VA Central Research Database.

You can revoke this authorization at any time by notifying us in writing. To revoke your authorization, you may sign and mail the attached MVP Withdrawal Form to: Department of Veterans Affairs, VA Genomics Coordinating Center, Clinical Epidemiology Research Center (151B), 950 Campbell Avenue, Building 35A, West Haven, CT 06516.

If you revoke this authorization, you will not be able to continue to participate in the program. This decision will not affect the rights and benefits to which you are otherwise entitled.

If you revoke this authorization, researchers will continue to use information about you that has already been collected. Any information that has become part of the VA Central Research Database, prior to revocation, will not be removed or destroyed. No new information will be collected, or added to the database, after you revoke the authorization.

The VA complies with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your individually-identifiable health information could be disclosed in a way that it will no longer be protected by Federal laws.

Participant Authorization:

I have read this form and have been given the opportunity to ask questions. If I have questions later, I understand I can contact the MVP Information Center at 866-441-6075. I will be given a signed copy of this form for my records. I authorize the use of my PHI as described in this form.

_____ MM / DD / YYYY
 Participant's Signature (Today's date)

Participant's Name: _____
 Last First