



Million Veteran Program:

A Partnership with Veterans

General MVP Q&As

Overview

The Department of Veterans Affairs (VA) Million Veteran Program (MVP) is a national, voluntary research initiative of VA's Office of Research and Development (ORD) to better understand the effects that genes have on health and illness, with the ultimate objective of improving Veterans' health care. The goal is to make the opportunity to participate in MVP available to as many Veterans as possible. MVP expects to enroll one million Veterans nationwide over the next five to seven years. **Participation in MVP is entirely voluntary and will not in any way affect Veterans' access to health care or benefits.** MVP has extensive safeguards in-place to ensure information security and patient confidentiality are top priorities. MVP is a research program that will allow current Veterans to help transform health care, not only for themselves, but for future generations of Veterans.

Purpose

Q1: What is the purpose of the Million Veteran Program?

A1: The purpose of MVP is to learn more about how genes affect health, and to thereby improve health care for Veterans and all Americans. MVP will establish one of the largest databases of genetic, military exposure, lifestyle, and health information. Research findings based on MVP may lead to new ways of preventing and treating illnesses in Veterans and all Americans. Such findings may help answer questions like "Why does a treatment work well for some Veterans but not for others?"; "Why are some Veterans at a greater risk for developing an illness?"; and "How can we prevent certain illnesses in the first place?"

Q2: What are genes and how do they affect health?

A2: A gene is the basic unit of hereditary and is made up of DNA. Genes determine the color of our eyes and hair, our height, and other personal traits. Through complex interactions with our environment and various lifestyle factors, genes may also contribute to our risk for disease, including common illnesses such as heart disease, diabetes, and cancer. In fact, genes may be a critical part of why some people get diseases and others do not. Genes may also affect how we respond to certain medications. Because of small differences between our genes, some people may respond better than others to a particular treatment, or experience different

side effects. Overall, a better understanding of how genes work may help to prevent and improve treatment of, disease. An increasingly common way to gain knowledge about genes and health is to collect genetic samples and health information from large groups of people, and then to conduct comparisons to learn which genes are linked to which health traits.

Q3: How does this important research help Veterans?

A3: MVP will lead to new knowledge about which genes and genetic variants put Veterans at risk for certain diseases, and which ones affect how Veterans respond to treatment. Veterans—and in fact all Americans—stand to benefit greatly as researchers learn more about the effects of genes on health. Screening, diagnosis, and treatment for some illnesses, such as certain forms of cancer, have already been improved through knowledge about the effects of certain genes. The knowledge gained through MVP may eventually lead to better treatments and preventive measures for many diseases, including common illnesses such as heart disease, diabetes, and cancer.

Q4: Why should this research be conducted at the VA?

A4: The VA is an ideal setting for a large-scale genomic and health research initiative. The VA Office of Research and Development has developed the infrastructure to enable such a program to take place, including a national genomics laboratory, a centralized recruitment structure, and a number of oversight committees. Furthermore, access to a stable patient population and a world-class electronic medical record allows researchers to easily link Veterans' health information to their genetic samples. In addition, given that this research program is embedded within a healthcare system, translation of research findings into the clinic is feasible.

Q5: What groups oversee MVP operations?

A5: The following three groups oversee MVP operations:

- 1) VA Central Institutional Review Board (IRB):
The Central IRB's function is to protect the rights of human subjects participating in research. The IRB consists of a diverse group of individuals including ethicists, physicians, scientists, clergymen, and Veterans. The Central IRB conducts annual reviews of MVP. Changes in the protocol (including recruitment materials), consent, and HIPAA Authorization are approved by the Central IRB.
- 2) Genomic Medicine Program Advisory Committee (GMPAC):
GMPAC consists of national and international experts in the areas of medical genetics, genomic science, healthcare policy and administration, health informatics, and a representative of the Veterans Service Organizations (VSOs). The members of GMPAC come from academic institutions, private sector, government, and VSOs.
- 3) Scientific Review Committee:

Veterans' samples and data will be provided to researchers only after rigorous scientific review of the project by a committee consisting of experts from universities, the private sector, and the government—as well as approval by an IRB. The IRB review will ensure that samples and data are being used only for purposes originally consented to by participants.

Participation

Q6: Who can participate in MVP?

A6: Any Veteran who uses the VA Healthcare System and is able to provide written, informed consent is invited to participate.

Q7: What does participation involve?

A7: Participation in MVP is entirely voluntary and will not in any way affect Veterans' access to health care or benefits. Veterans who volunteer to participate will fill out surveys through the mail, complete a one-time (~20 min) study visit to provide a blood sample for genetic analysis, permit authorized MVP staff to access information in their medical record on an ongoing basis, and agree to future MVP contact.

Q8: Why is it important that so many Veterans participate in the study?

A8: A useful way to learn about the role of genes in health is to collect genetic samples and health information from many people, and then to conduct analysis to learn which genes are linked to which health traits. To obtain meaningful data from such studies, researchers must compare the genetic and health information of many thousands of people. With large amounts of data available for analysis, researchers can discover important trends and patterns and gain valuable new knowledge to guide health care.

Q9: Are there risks involved in participation?

A9: Any procedure has possible risks. Besides the risks associated with having blood drawn, there is the possibility that filling out the questionnaire may result in distress if participants find out, through their own questioning, about family health conditions they may not have been previously aware of. Family members will NOT be contacted as part of MVP.

If participants choose to have a health assessment as part of their participation in MVP, there are no risks associated with routine measurements such as height, weight, blood pressure, body composition, and grip strength. The lung function test does involve forceful and rapid breathing. Some people may experience shortness of breath or dizziness. Participants will be monitored throughout the procedure.

Data Security

Q10: What will happen to the health information and blood samples that are collected?

A10: Veterans' information and samples will be labeled with a code. Only few authorized VA staff will have access to the link to the code. The coded samples and health information will be available to researchers within VA, other federal health agencies, and academic institutions within the U.S. for future research projects approved by appropriate VA oversight committees. Researchers who are approved access to samples and data will not receive the name, address, date of birth, or social security number of participating Veterans.

Q11: How will medical records be accessed?

A11: If consent is given to participate, MVP staff will access health information from VA medical health records as needed and add that information to the VA Central Research Database so that participants' health status and health care can be followed over time. All information will be labeled with a code that does not identify participants directly.

Q12: Will results from my blood tests be forwarded to me?

A12: Individual genetic test results will not be returned to Veterans for a number of reasons. The main purpose of research genetic testing is for scientists to gain a better understanding of how genes impact health and illness. MVP anticipates that many different types of tests will be performed on an individual's sample, as researchers test new hypotheses. Genetic testing that is used to inform healthcare must be done in laboratories that are subject to regulations by the Clinical Laboratory Improvement Amendments (CLIA). Genetic testing done by CLIA-certified laboratories has been validated and the health care provider would be able to explain the relevance of the results for that particular Veteran. However, testing for research purposes is typically not performed in CLIA-certified laboratories. Furthermore, since research is underway and the effect of the genes on health is still under investigation, there would be no way to interpret the implications of the results for a given Veteran.

However, MVP may combine individual research results to draw general conclusions about how genes affect health. MVP does envision being able, at a later date, to do genetic testing that will be able to provide meaningful information for individual Veterans regarding their health.

Confidentiality

Q13: How will confidentiality and privacy be protected?

A13: The security and confidentiality of Veterans' data are MVP's top priorities. Researchers will use stringent security measures, including sophisticated computer controls and building-access systems. Confidentiality will be protected

through a variety of methods. DNA samples and health information will be labeled and stored with a code in a central research database. Veterans' samples and

information will not be labeled with name, address, date of birth, or social security numbers. Only a few authorized VA staff will have access to the key linking the code to participants' personal information. It is necessary to keep the key to the code to connect participants with their information and samples in order to track medical records, contact participants again, or destroy the samples if a participant withdraws.

Researchers who are approved access to samples and data will not receive name, address, date of birth, or social security number of participating Veterans. In addition, Veterans' privacy will be further protected by a Certificate of Confidentiality.

Q14: What is a Certificate of Confidentiality?

A14: To further protect privacy, MVP has received a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, researchers associated with the program can avoid being forced to disclose information that may identify participants, even by a court subpoena or in any civil, criminal, administrative, legislative, or other proceeding at the federal, state, or local level.

Researchers can rely on this Certificate to deny requests for information that would identify participants, except in the following situation: In the unlikely event of an audit by NIH, personnel with MVP would potentially have to reveal a name, but only to NIH's authorized representatives. The Certificate does not prevent participants or their family members from voluntarily releasing information. The Certificate also does not prevent VA from taking steps, including reporting to authorities, to prevent serious harm to participants or others. The Certificate of Confidentiality is not an endorsement of this research by the Department of Health and Human Services or the NIH.

Q15: Will any other organization have access to the results of research conducted through MVP?

A15: Samples and health information will be available to researchers at VA, other federal health agencies, and academic institutions within the U.S. for future research projects approved by appropriate VA oversight committees. Researchers will be granted access to coded samples and data for only those research studies that meet all ethical, scientific, and regulatory criteria for approval by VA and other overseeing agencies and institutions. Researchers who are approved access to samples and data will not receive the name, address, date of birth, or social security number of participating Veterans.

Q16: What is the Genetic Information Nondisclosure Act (GINA)?

A16: The Genetic Information Nondisclosure Act (GINA) is a federal law that makes it illegal for health insurance companies, group health plans, and most employers to discriminate based on genetic information. This law will protect participants in the

following ways:

- Health insurance companies and group health plans may not request genetic information obtained from this research.
- Health insurance companies and group health plans may not use genetic information obtained from this research when making decisions regarding eligibility or premiums.
- Employers with 15 or more employees may not use genetic information obtained from this research when making decisions to hire, promote, or fire a person or when setting the terms of employment.
- This federal law does not protect against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Data Storage

Q17: How long will the researchers keep the DNA/blood samples in the bio-data storage facility?

A17: Upon receipt, the blood samples will be processed to obtain DNA and other materials that will be stored indefinitely until they are used up for research studies or they are no longer of scientific value. If a Veteran decides to withdraw from MVP and notifies the VA as instructed during the consenting process, the DNA and other samples will be destroyed so that they cannot be used in any further research.

Q18: How will the survey completed by participants be stored?

A18: The information will be stored in a secure central research database without name, address, date of birth, and social security numbers. Rather, the information will be labeled with a code. Only few authorized VA staff will have access to the key to the code

All data in the database is subject to federal privacy guidelines. The data will not be released to third parties, even by court order, because the information will be covered by a Certificate of Confidentiality from NIH.

Q19: How long will the data from the surveys and medical records be stored?

A19: The data gathered from MVP will be stored indefinitely and will be used for future medical research.

Q20: How are the VA researchers who will handle this data being vetted by VA?

A20: VA researchers go through an extensive recruitment process before being hired. Each researcher undergoes an exhaustive criminal background investigation conducted by the federal government. Researchers are fingerprinted, and other data (such as college degrees earned) must be confirmed before the researcher is

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hired. Additionally, researchers undergo annual ethics training. They confer regularly with the VA's National Center for Ethics in Health Care.

Contact Information

Q21: Whom do I contact for general information about MVP?

A21: For more information about MVP, visit <http://www.research.va.gov/MVP>, or call **857-364-5759** (please note: this number is for non-Veterans only).

